As filed with the Securities and Exchange Commission on February 25, 2022

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549

FORM 10-K

(MARK ONE)

☒ **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the Fiscal Year Ended December 31, 2021

OR

☐ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the transition period from _____ to _____

Commission File No. 1-6571

Merck & Co., Inc.

2000 Galloping Hill Road
Kenilworth New Jersey 07033

(908) 740-4000

New Jersey	**22-1918501**
(State or other jurisdiction of incorporation)	(I.R.S Employer Identification No.)

Securities Registered pursuant to Section 12(b) of the Act:

Title of Each Class	*Trading Symbol(s)*	*Name of Each Exchange on which Registered*
Common Stock ($0.50 par value)	MRK	New York Stock Exchange
0.500% Notes due 2024	MRK 24	New York Stock Exchange
1.875% Notes due 2026	MRK/26	New York Stock Exchange
2.500% Notes due 2034	MRK/34	New York Stock Exchange
1.375% Notes due 2036	MRK 36A	New York Stock Exchange

Number of shares of Common Stock ($0.50 par value) outstanding as of January 31, 2022: 2,527,733,606.

Aggregate market value of Common Stock ($0.50 par value) held by non-affiliates on June 30, 2021 based on closing price on June 30, 2021: $196,870,000,000.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. **Yes** ☒ **No** ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. **Yes** ☐ **No** ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. **Yes** ☒ **No** ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). **Yes** ☒ **No** ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check One):

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). **Yes** ☐ **No** ☒

Documents Incorporated by Reference:

Document	*Part of Form 10-K*
Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2022, to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this report	Part III

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PART I

Item 1. Business.

Merck & Co., Inc. (Merck or the Company) is a global health care company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies and animal health products. The Company's operations are principally managed on a products basis and include two operating segments, which are the Pharmaceutical and Animal Health segments, both of which are reportable segments.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities.

The Animal Health segment discovers, develops, manufactures and markets a wide range of veterinary pharmaceutical and vaccine products, as well as health management solutions and services, for the prevention, treatment and control of disease in all major livestock and companion animal species. The Company also offers an extensive suite of digitally connected identification, traceability and monitoring products. The Company sells its products to veterinarians, distributors and animal producers.

The Company previously had a Healthcare Services segment that provided services and solutions focused on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company divested the remaining businesses in this segment in the first quarter of 2020.

All product or service marks appearing in type form different from that of the surrounding text are trademarks or service marks owned, licensed to, promoted or distributed by Merck, its subsidiaries or affiliates, except as noted. All other trademarks or services marks are those of their respective owners.

Spin-Off of Organon & Co.

On June 2, 2021, Merck completed the spin-off (the Spin-Off) of products from its women's health, biosimilars and established brands businesses into a new, independent, publicly traded company named Organon & Co. (Organon) through a distribution of Organon's publicly traded stock to Company shareholders. The established brands included in the transaction consisted of dermatology, non-opioid pain management, respiratory, select cardiovascular products, as well as the rest of Merck's diversified brands franchise. Merck's existing research pipeline programs continue to be owned and developed within Merck as planned.

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Product Sales

Total Company sales, including sales of the Company's top pharmaceutical products, as well as sales of animal health products, were as follows:

($ in millions)	**2021**	2020	2019
Total Sales	**$ 48,704**	$ 41,518	$ 39,121
Pharmaceutical	**42,754**	36,610	34,100
Keytruda	**17,186**	14,380	11,084
Gardasil/Gardasil 9	**5,673**	3,938	3,737
Januvia/Janumet	**5,288**	5,276	5,524
ProQuad/M-M-R II/*Varivax*	**2,135**	1,878	2,275
Bridion	**1,532**	1,198	1,131
Alliance revenue - Lynparza[(1)]	**989**	725	444
Molnupiravir	**952**	—	—
Pneumovax 23	**893**	1,087	926
Simponi	**825**	838	830
RotaTeq	**807**	797	791
Isentress/Isentress HD	**769**	857	975
Alliance revenue - Lenvima[(1)]	**704**	580	404
Animal Health	**5,568**	4,703	4,393
Livestock	**3,295**	2,939	2,784
Companion Animals	**2,273**	1,764	1,609
Other Revenues[(2)]	**382**	205	628

[(1)] *Alliance revenue represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs.*

[(2)] *Other revenues are primarily comprised of third-party manufacturing sales and miscellaneous corporate revenues, including revenue hedging activities.*

Pharmaceutical

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines. Certain of the products within the Company's franchises are as follows:

Oncology

Keytruda (pembrolizumab), the Company's anti-PD-1 (programmed death receptor-1) therapy, as monotherapy for the treatment of certain patients with cervical cancer, classical Hodgkin Lymphoma (cHL), cutaneous squamous cell carcinoma (cSCC), esophageal or gastroesophageal junction (GEJ) carcinoma, head and neck squamous cell carcinoma (HNSCC), hepatocellular carcinoma (HCC), non-small-cell lung cancer (NSCLC), melanoma, Merkel cell carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer (solid tumors), including MSI-H/dMMR colorectal cancer (CRC), primary mediastinal large B-cell lymphoma (PMBCL), tumor mutational burden-high (TMB-H) cancer (solid tumors), and urothelial carcinoma, including non-muscle invasive bladder cancer. *Keytruda* is also approved for the treatment of certain patients in combination with chemotherapy for metastatic squamous and non-squamous NSCLC, in combination with chemotherapy for HNSCC, in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy for human epidermal growth factor 2 (HER2)-positive gastric or GEJ adenocarcinoma, in combination with platinum-and fluoropyrimidine-based chemotherapy for esophageal or GEJ carcinoma, in combination with chemotherapy, with or without bevacizumab, for cervical cancer, in combination with chemotherapy for triple-negative breast cancer (TNBC), in combination with axitinib for advanced renal cell carcinoma (RCC), and in combination with lenvatinib for endometrial carcinoma or RCC. *Keytruda* is also approved for certain patients with high-risk early-stage TNBC in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery. *Keytruda* is also approved as a monotherapy for the adjuvant treatment of certain patients

with RCC. In addition, the Company recognizes alliance revenue related to sales of Lynparza (olaparib), an oral poly (ADP-ribose) polymerase (PARP) inhibitor, for certain types of advanced ovarian, breast, pancreatic, and prostate cancers; and Lenvima (lenvatinib) for certain types of

thyroid cancer, hepatocellular carcinoma, in combination with everolimus for certain patients with RCC, and in combination with *Keytruda* for certain patients with endometrial carcinoma or RCC.

Vaccines

Gardasil (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant)/*Gardasil* 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), vaccines to help prevent certain diseases caused by certain types of human papillomavirus (HPV); *ProQuad* (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella; *M−M−R* II (Measles, Mumps and Rubella Virus Vaccine Live), a vaccine to help prevent measles, mumps and rubella; *Varivax* (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox (varicella); *Pneumovax* 23 (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease; *RotaTeq* (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children; and *Vaqta* (hepatitis A vaccine, inactivated) indicated for the prevention of disease caused by hepatitis A virus in persons 12 months of age and older.

Hospital Acute Care

Bridion (sugammadex) Injection, a medication for the reversal of two types of neuromuscular blocking agents used during surgery; *Prevymis* (letermovir) for the prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant; *Primaxin* (imipenem and cilastatin) for injection, an antibiotic for the treatment of certain bacterial infections; *Noxafil* (posaconazole), an antifungal agent for the prevention of certain invasive fungal infections; *Cancidas* (caspofungin acetate) for injection, an anti-fungal agent for the treatment of certain fungal infections; *Invanz* (ertapenem) for injection, an antibiotic for the treatment of certain bacterial infections; and *Zerbaxa* (ceftolozane and tazobactam) for injection, a combination antibacterial and beta-lactamase inhibitor for the treatment of certain bacterial infections.

Immunology

Simponi (golimumab), a once-monthly subcutaneous treatment for certain inflammatory diseases; and *Remicade* (infliximab), a treatment for inflammatory diseases, both of which the Company markets in Europe, Russia and Turkey.

Neuroscience

Belsomra (suvorexant), an orexin receptor antagonist indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

Virology

Molnupiravir, an investigational oral antiviral COVID-19 medicine; *Isentress/Isentress HD* (raltegravir), an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection.

Cardiovascular

Adempas (riociguat), a cardiovascular drug for the treatment of pulmonary arterial hypertension; Verquvo (vericiguat), a medicine to reduce the risk of cardiovascular death and heart failure hospitalization following a hospitalization for heart failure or need for outpatient intravenous diuretics in certain adults with symptomatic chronic heart failure and reduced ejection fraction.

Diabetes

Januvia (sitagliptin) and *Janumet* (sitagliptin/metformin HCl) for the treatment of type 2 diabetes.

Animal Health

The Animal Health segment discovers, develops, manufactures and markets a wide range of veterinary pharmaceuticals, vaccines and health management solutions and services, as well as an extensive suite of digitally connected identification, traceability and monitoring products. Principal products in this segment include:

Livestock Products

Nuflor (Florfenicol) antibiotic range for use in cattle and swine; *Bovilis*/*Vista* vaccine lines for infectious diseases in cattle; *Banamine* (Flunixin meglumine) bovine and swine anti-inflammatory; *Estrumate* (cloprostenol sodium) for the treatment of fertility disorders in cattle; *Matrix* (altrenogest) fertility management for swine; *Resflor* (florfenicol and flunixin meglumine), a combination broad-spectrum antibiotic and non-steroidal anti-inflammatory

drug for bovine respiratory disease; *Zuprevo* (Tildipirosin) for bovine respiratory disease; *Zilmax* (zilpaterol hydrochloride) and *Revalor* (trenbolone acetate and estradiol) to improve production efficiencies in beef cattle; *Safe-Guard* (fenbendazole) de-wormer for cattle; *M+Pac* (Mycoplasma Hyopneumoniae Bacterin) swine pneumonia vaccine; *Porcilis* (Lawsonia intracellularis baterin) and *Circumvent* (Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector) vaccine lines for infectious diseases in swine; *Nobilis*/*Innovax* (Live Marek's Disease Vector), vaccine lines for poultry; *Paracox* and *Coccivac* coccidiosis vaccines; *Exzolt*, a systemic treatment for poultry red mite infestations; *Slice* (Emamectin benzoate) parasiticide for sea lice in salmon; *Aquavac* (Avirulent Live Culture)/ *Norvax* vaccines against bacterial and viral disease in fish; *Compact PD* vaccine for salmon; *Aquaflor* (Florfenicol) antibiotic for farm-raised fish; and *Allflex Livestock Intelligence* solutions for animal identification, monitoring and traceability.

Companion Animal Products

Bravecto, a line of oral and topical parasitic control products, including the original *Bravecto* (fluralaner) products for dogs and cats that last up to 12 weeks; *Bravecto* (fluralaner) *One-Month*, a monthly product for dogs, and *Bravecto Plus* (fluralaner/moxidectin), a two-month product for cats; *Sentinel,* a line of oral parasitic products for dogs including *Sentinel Spectrum* (milbemycin oxime, lufenuron, and praziquantel) and *Sentinel Flavor Tabs* (milbemycin oxime, lufenuron); *Optimmune* (cyclosporine), an ophthalmic ointment; *Nobivac* vaccine lines for flexible dog and cat vaccination; *Otomax* (Gentamicin sulfate, USP; Betamethasone valerate USP; and Clotrimazole USP ointment)/*Mometamax* (Gentamicin sulfate, USP, Mometasone Furoate Monohydrate and Clotrimazole, USP, Otic Suspension)/*Posatex* (Orbifloxacin, Mometasone Furoate Monohydrate and Posaconazole, Suspension) ear ointments for acute and chronic otitis; *Caninsulin*/*Vetsulin* (porcine insulin zinc suspension) diabetes mellitus treatment for dogs and cats; *Panacur* (fenbendazole)/*Safeguard* (fenbendazole) broad-spectrum anthelmintic (de-wormer) for use in many animals; *Regumate* (altrenogest) fertility management for horses; *Prestige* vaccine line for horses; *Scalibor* (Deltamethrin)*/Exspot* for protecting against bites from fleas, ticks, mosquitoes and sandflies; and *Sure Petcare* products for companion animal identification and well-being, including the microchip and pet recovery system *Home Again*.

For a further discussion of sales of the Company's products, see Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" below.

2021 Product Approvals and Authorizations

Set forth below is a summary of significant product approvals and authorizations received by the Company in 2021.

Product	Date
Keytruda	January 2021
	March 2021
	March 2021
	May 2021
	June 2021

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Keytruda	June 2021
	July 2021
	July 2021
	July 2021
	August 2021
	August 2021
	August 2021
	August 2021
	September 2021
	October 2021
	October 2021

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Keytruda	November 2021
	November 2021
	December 2021
	December 2021
Lynparza[1]	June 2021
molnupiravir[2]	December 2021
	December 2021
Vaxneuvance	July 2021
	December 2021

[1] *Being jointly developed and commercialized in a worldwide collaboration with AstraZeneca.*

[2] *Being jointly developed and commercialized in a worldwide collaboration with Ridgeback Biopharmaceuticals LP. Molnupiravir has not been approved by the FDA but has been authorized for emergency use.*

[3] *Being jointly developed and commercialized in a worldwide collaboration with Bayer AG.*

Competition and the Health Care Environment

Competition

The markets in which the Company conducts its business and the pharmaceutical industry in general are highly competitive and highly regulated. The Company's competitors include other worldwide research-based pharmaceutical companies, smaller research companies with more limited therapeutic focus, generic drug manufacturers, and animal health care companies. The Company's operations may be adversely affected by generic and biosimilar competition as the Company's products mature, as well as technological advances of competitors, industry consolidation, patents granted to competitors, competitive combination products, new products of competitors, the generic availability of competitors' branded products, and new information from clinical trials of marketed products or post-marketing surveillance. In addition, patent rights are increasingly being challenged by competitors, and the outcome can be highly uncertain. An adverse result in a patent dispute can preclude commercialization of products or negatively affect sales of existing products and could result in the payment of royalties or in the recognition of an impairment charge with respect to intangible assets associated with certain products.

Pharmaceutical competition involves a rigorous search for technological innovations and the ability to market these innovations effectively. With its long-standing emphasis on research and development, the Company is well-positioned to compete in the search for technological innovations. The Company is active in acquiring and marketing products through external alliances, such as licensing arrangements and collaborations and has been refining its sales and marketing efforts to address changing industry conditions. However, the introduction of new products and processes by competitors may result in price reductions and product displacements, even for products protected by patents. For example, the number of compounds available to treat a particular disease typically increases over time and can result in slowed sales growth or reduced sales for the Company's products in that therapeutic category.

The highly competitive animal health business is affected by several factors including regulatory and legislative issues, scientific and technological advances, product innovation, the quality and price of the Company's products as well as competitors' products, effective promotional efforts and the frequent introduction of generic products by competitors.

Health Care Environment and Government Regulation

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access. Changes to the U.S. health care system as part of health care reform enacted in prior years, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, have contributed to pricing pressure. In several international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. In addition, the Company's revenue performance in 2021 was negatively affected by other cost-reduction measures taken by governments and other third parties to lower health care costs. In the U.S., the Biden Administration and Congress continue to discuss legislation designed to control health care costs, including the cost of drugs. The Company anticipates all of these actions and additional actions in the future will continue to negatively affect revenue performance.

United States

The Company faces increasing pricing pressure from managed care organizations, government agencies and programs that could negatively affect the Company's sales and profit margins, including, through (i) practices of managed care organizations, federal and state exchanges, and institutional and governmental purchasers, and (ii) federal laws and regulations related to Medicare and Medicaid, including the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and the Patient Protection and Affordable Care Act (ACA).

In the U.S., federal and state governments for many years have pursued methods to reduce the cost of drugs and vaccines for which they pay. For example, federal and state laws require the Company to pay specified rebates for medicines reimbursed by Medicaid and to provide discounts for medicines purchased by certain state and federal entities such as the Department of Defense, Veterans Affairs, Public Health Service entities and hospitals serving a disproportionate share of low income or uninsured patients.

Additionally in the U.S., consolidation and integration among health care providers is a major factor in the competitive marketplace for pharmaceutical products. Health plans and pharmacy benefit managers (PBMs) have been consolidating into fewer, larger entities, thus enhancing their purchasing strength and importance. Private third-party insurers, as well as governments, employ formularies to control costs by negotiating discounted prices in exchange for formulary inclusion. Failure to obtain timely or adequate pricing or formulary placement for Merck's products or obtaining such placement at unfavorable pricing could adversely affect revenue. In addition to formulary tier co-pay differentials, private health insurance companies and self-insured employers have been increasing the cost-sharing required from beneficiaries, particularly for branded pharmaceuticals and biotechnology products. Private health insurance companies also are increasingly imposing utilization management tools, such as clinical protocols, requiring prior authorization for a branded product or requiring the patient to first fail on one or more generic products before permitting access to a branded medicine. These same management tools are also used in treatment areas in which the payor has taken the position that multiple branded products are therapeutically comparable. As the U.S. payor market concentrates further, pharmaceutical companies may face greater pricing pressure from private third-party payors.

In order to provide information about the Company's pricing practices, the Company annually posts on its website its Pricing Transparency Report for the U.S. The report provides the Company's average annual list price, net price increases, and average discounts across the Company's U.S. portfolio dating back to 2010. In 2021, the Company's gross U.S. sales were reduced by 43.5% as a result of rebates, discounts and returns.

Legislative Changes

In 2021, Congress actively considered multiple versions of drug pricing legislation that could significantly impact branded pharmaceutical manufacturers. This legislation would implement a government negotiation plan for certain products covered by Medicare Parts B and D, institute financial penalties for price increases above inflation, and redesign the Medicare Part D program to include a cap on patients' out of pocket costs and realign the liability for costs of the benefit among manufacturers, health plans, and the government. It is unclear when or if this legislation will be passed by Congress, and it remains very uncertain as to what other proposals, if any, may be included as part of future federal legislative proposals that would directly or indirectly affect the Company.

Also in 2021, Congress passed the American Rescue Plan Act of 2021, which included a provision that eliminates the statutory cap on rebates drug manufacturers pay to Medicaid beginning in January 2024. These rebates act as a discount off the list price and eliminating the cap means that manufacturer discounts paid to Medicaid can increase. Prior to this change, manufacturers have not been required to pay more than 100% of the Average Manufacturer Price (AMP) in rebates to state Medicaid programs for Medicaid-covered drugs. As a result of this provision, beginning in 2024, it is possible that manufacturers may have to pay state Medicaid programs more in rebates than they received on sales of particular products. This change could present a risk to Merck in the future for drugs that have high Medicaid utilization and rebate exposure that is more than 100% of the AMP.

The Company also faces increasing pricing pressure in the states, which are looking to exert greater influence over the price of prescription drugs. A number of states have passed pharmaceutical price and cost transparency laws. These laws typically require manufacturers to report certain product price information or other financial data to the state. Some laws also require manufacturers to provide advance notification of price increases. The Company expects that states will continue their focus on pharmaceutical pricing and will increasingly shift to more aggressive price control tools such as Prescription Drug Affordability Boards that have the authority to conduct affordability reviews and establish upper payment limits.

Regulatory Changes

In February 2016, the Centers for Medicare & Medicaid Services (CMS) issued the Medicaid rebate final rule that implemented provisions of the ACA effective April 1, 2016. The rule provides comprehensive guidance on the calculation of AMP and Best Price, two metrics used to determine the rebates drug manufacturers are required to pay to state Medicaid programs. On December 21, 2020, CMS issued a final rule making significant changes to these requirements. Effective January 1, 2023, this final rule changes the way that manufacturers must calculate Best Price in relation to certain patient support programs, including coupons. PhRMA, a pharmaceutical industry trade group of which the Company is a member, filed a complaint challenging this rule as invalid asserting that it conflicts

with the plain language of the Medicaid drug rebate statute. Should this legal challenge fail, the impact of this and other provisions in this final rule could adversely impact the Company's business, cash flow, results of operations, financial condition and prospects.

In November 2020, the Department of Health and Human Services Office of Inspector General issued a Final Rule that would, effective January 1, 2023, eliminate the Anti-Kickback Statute safe harbor for rebates paid to Medicare Part D plans or to PBMs on behalf of such plans. While the Company cannot anticipate the effects of this change to the way it currently contracts, this new framework could significantly alter the way it does business with Part D Plan Sponsors and PBMs on behalf of such plans. This rulemaking also established, effective January 1, 2021, a new safe harbor for point of sale discounts at the pharmacy counter and a new safe harbor for certain service arrangements between pharmaceutical manufacturers and PBMs. Congress has delayed implementation of this Final Rule until January 1, 2026 and pending federal legislation would repeal it entirely.

The pharmaceutical industry also could be considered a potential source of savings via other legislative and administrative proposals that have been debated but not enacted. These types of revenue generating or cost saving proposals include additional direct price controls.

European Union

Efforts toward health care cost containment remain intense in the European Union (EU). The Company faces competitive pricing pressure resulting from generic and biosimilar drugs. In addition, a majority of countries in the EU attempt to contain drug costs by engaging in reference pricing in which authorities examine pre-determined markets for published prices of drugs. Reference pricing may either compare a product's prices in other markets (external reference pricing), or compare a product's price with those of other products in a national class (internal reference pricing). The authorities then use the price data to set new local prices for brand-name drugs, including the Company's drugs. Guidelines for examining reference pricing are usually set in local markets and can be changed pursuant to local regulations. Some EU Member States have established free-pricing systems, but regulate the pricing for drugs through profit control plans. Others seek to negotiate or set prices based on the cost-effectiveness of a product or an assessment of whether it offers a therapeutic benefit over other products in the relevant class. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In some EU Member States, cross-border imports from low-priced markets also exert competitive pressure that may reduce pricing within an EU Member State.

Additionally, EU Member States have the power to restrict the range of pharmaceutical products for which their national health insurance systems provide reimbursement. In the EU, pricing and reimbursement plans vary widely from Member State to Member State. Some EU Member States provide that drug products may be marketed only after a reimbursement price has been agreed. Some EU Member States may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to already available therapies or so-called health technology assessments (HTA), in order to obtain reimbursement or pricing approval. The HTA of pharmaceutical products is becoming an increasingly common part of the pricing and reimbursement procedures in most EU Member States. The HTA process, which is governed by the national laws of these countries, involves the assessment of the cost-effectiveness, public health impact, therapeutic impact and/or the economic and social impact of use of a given pharmaceutical product in the national health care system of the individual country in which it is conducted. Ultimately, HTA measures the added value of a new health technology compared to existing ones. The outcome of HTAs regarding specific pharmaceutical products will often influence the pricing and reimbursement status granted to these pharmaceutical products by the regulatory authorities of individual EU Member States. A negative HTA of one of the Company's products may mean that the product is not reimbursable or may force the Company to reduce its reimbursement price or offer discounts or rebates.

A negative HTA by a leading and recognized HTA body could also undermine the Company's ability to obtain reimbursement for the relevant product outside a jurisdiction. For example, EU Member States that have not yet developed HTA mechanisms may rely to some extent on the HTA performed in other countries with a developed HTA framework, to inform their pricing and reimbursement decisions. HTA procedures require additional data, reviews and administrative processes, all of which increase the complexity, timing and costs of obtaining product reimbursement and exert downward pressure on available reimbursement.

To obtain reimbursement or pricing approval in some EU Member States, the Company may be required to conduct studies that compare the cost-effectiveness of the Company's product candidates to other therapies that are considered the local standard of care. There can be no assurance that any EU Member State will allow favorable pricing, reimbursement and market access conditions for any of the Company's products, or that it will be feasible to conduct additional cost-effectiveness studies, if required.

Brexit

In 2016, the United Kingdom (UK) held a referendum in which voters approved an exit from the EU, commonly referred to as "Brexit." As a result of that referendum and subsequent negotiations, the UK left the EU on January 31, 2020. A transitional period applied from January 31, 2020 until December 31, 2020, and during this period the EU and UK operated as if the UK was an EU Member State, and the UK continued to participate in the EU Customs Union allowing for the freedom of movement for people and goods.

It was announced on December 24, 2020, that the EU and the UK agreed to a Trade and Cooperation Agreement (TCA). The TCA sets out the new arrangements for trade of goods, including medicines and vaccines, which allows goods to continue to flow between the EU and the UK. The TCA was signed on December 30, 2020, was applied provisionally as of January 1, 2021, and entered into force on May 1, 2021. As a result of the TCA, the Company believes that its operations will not be materially adversely affected by Brexit.

Japan

In Japan, the pharmaceutical industry is subject to government-mandated annual price reductions of pharmaceutical products and certain vaccines. Furthermore, the government can order re-pricings for specific products if it determines that use of such product will exceed certain thresholds defined under applicable re-pricing rules. The next government-mandated price reduction will occur in April 2022.

China

The Company's business in China has grown rapidly in the past few years, and the importance of China to the Company's overall pharmaceutical and vaccines business has increased accordingly. Continued growth of the Company's business in China is dependent upon ongoing development of a favorable environment for innovative pharmaceutical products and vaccines, sustained access for the Company's current in-line products, and the absence of trade impediments or adverse pricing controls. In recent years, the Chinese government has introduced and implemented a number of structural reforms to accelerate the shift to innovative products and reduce costs. Since 2017, there have been multiple new policies introduced by the government to improve access to new innovation, reduce the complexity of regulatory filings, and accelerate the review and approval process. This has led to a significant increase in the number of new products being approved each year. While the mechanism for drugs being added to the government's National Reimbursement Drug List (NRDL) evolves, inclusion may require a price negotiation which could impact the outlook in the market for selected brands. In 2021, drugs were added to the NRDL with an average of more than 60% price reductions. While pricing pressure has always existed in China, health care reform has increased this pressure in part due to the acceleration of generic substitution through volume based procurement (VBP). In 2019, the government implemented the VBP program through a tendering process for mature products which have generic substitutes with a Generic Quality Consistency Evaluation approval. Mature products that have entered into the last five rounds of VBP had, on average, a price reduction of more than 50%. The Company expects VBP to be a semi-annual process that will have a significant impact on mature products moving forward.

Emerging Markets

The Company's focus on emerging markets, in addition to China, has continued. Governments in many emerging markets are also focused on constraining health care costs and have enacted price controls and measures impacting intellectual property, including in exceptional cases, threats of compulsory licenses (especially for COVID-19 vaccines and drugs), that aim to put pressure on the price of innovative pharmaceuticals or result in constrained market access to innovative medicine. The Company anticipates that pricing pressures and market access challenges will continue in the future to varying degrees in the emerging markets.

Beyond pricing and market access challenges, other conditions in emerging market countries can affect the Company's efforts to continue to grow in these markets, including potential political instability, changes in trade sanctions and embargoes, significant currency fluctuation and controls, financial crises, limited or changing

availability of funding for health care, credit worthiness of health care partners, such as hospitals, due to COVID-19, and other developments that may adversely impact the business environment for the Company. Further, the Company may engage third-party agents to assist in operating in emerging market countries, which may affect its ability to realize continued growth and may also increase the Company's risk exposure.

In addressing global cost containment pressures, the Company engages in public policy advocacy with policymakers and continues to work to demonstrate that its medicines provide value to patients and to those who pay for health care. The Company advocates with government policymakers to encourage a long-term approach to sustainable health care financing that ensures access to innovative medicines and does not disproportionately target pharmaceuticals as a source of budget savings. In markets with historically low rates of health care spending, the Company encourages those governments to increase their investments and adopt market reforms in order to improve their citizens' access to appropriate health care, including medicines.

Operating conditions have become more challenging under the global pressures of competition, industry regulation and cost containment efforts. Although no one can predict the effect of these and other factors on the Company's business, the Company continually takes measures to evaluate, adapt and improve the organization and its business practices to better meet customer needs and believes that it is well-positioned to respond to the evolving health care environment and market forces.

Regulation

The pharmaceutical industry is also subject to regulation by regional, country, state and local agencies around the world focused on standards and processes for determining drug safety and effectiveness, as well as conditions for sale or reimbursement.

Of particular importance is the FDA in the U.S., which administers requirements covering the testing, approval, safety, effectiveness, manufacturing, labeling, and marketing of prescription pharmaceuticals. In some cases, the FDA requirements and practices have increased the amount of time and resources necessary to develop new products and bring them to market in the U.S. At the same time, the FDA has committed to expediting the development and review of products bearing the "breakthrough therapy" designation, which has accelerated the regulatory review process for medicines with this designation. The FDA has also undertaken efforts to bring generic competition to market more efficiently and in a more timely manner.

The EU has adopted directives and other legislation concerning the classification, approval for marketing, labeling, advertising, manufacturing, wholesale distribution, integrity of the supply chain, pharmacovigilance and safety monitoring of medicinal products for human use. These provide mandatory standards throughout the EU, which may be supplemented or implemented with additional regulations by the EU Member States. In particular, EU regulators may approve products subject to a number of post-authorization conditions. Examples of typical post-authorization commitments include additional pharmacovigilance, the conduct of clinical trials, the establishment of patient registries, physician or patient education and controlled distribution and prescribing arrangements. Non-compliance with post-authorization conditions, pharmacovigilance and other obligations can lead to regulatory action, including the variation, suspension or withdrawal of the marketing authorizations, or other enforcement or regulatory actions, including the imposition of financial penalties. The Company's policies and procedures are already consistent with the substance of these directives; consequently, it is believed that they will not have any material effect on the Company's business.

The Company believes that it will continue to be able to conduct its operations, including launching new drugs, in this regulatory environment. (See "Research and Development" below for a discussion of the regulatory approval process.)

Access to Medicines

As a global health care company, Merck's primary role is to discover and develop innovative medicines and vaccines. The Company also recognizes that, in collaboration with key stakeholders, it has a role to play in helping to ensure that its science advances health care, and its products are accessible and affordable. The Company is committed to ensuring a reliable, safe global supply of its quality medicines and vaccines, and to developing, testing and implementing innovative solutions that address barriers to access and affordability of its medicines and vaccines. The Company's approach is designed to enable it to serve the greatest number of patients today, while

meeting the needs of patients in the future. The Company's efforts in this regard are wide-ranging and include a set of principles that the Company strives to embed into its operations and business strategies to guide the Company's worldwide approach to expanding access to health care. In addition, through innovative social investments, including philanthropic programs and impact investing, Merck is also helping to strengthen health systems and build capacity, particularly in under-resourced communities. The Merck Patient Assistance Program provides medicines and adult vaccines for free to people in the U.S. who do not have prescription drug or health insurance coverage and who, without the Company's assistance, cannot afford their Merck medicines and vaccines. Merck has funded "Merck for Mothers," a long-term effort with global health partners to end preventable deaths from complications of pregnancy and childbirth. Merck has also provided funds to the Merck Foundation, an independent grantmaking organization, which has partnered with a variety of organizations dedicated to improving global health.

Privacy and Data Protection

The Company is subject to a significant number of privacy and data protection laws and regulations globally, many of which place restrictions on the Company's ability to transfer, access and use personal data across its business. The legislative and regulatory landscape for privacy and data protection continues to evolve. There has been increased attention to privacy and data protection issues in both developed and emerging markets with the potential to affect directly the Company's business, including the EU General Data Protection Regulation (GDPR), which went into effect in May 2018 and imposes penalties of up to 4% of global revenue.

The GDPR and related implementing laws in individual EU Member States govern the collection and use of personal health data and other personal data in the EU. The GDPR increased responsibility and liability in relation to personal data that the Company processes. It also imposes a number of strict obligations and restrictions on the ability to process (which includes collection, analysis and transfer of) personal data, including health data from clinical trials and adverse event reporting. The GDPR also includes requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals prior to processing their personal data or personal health data, notification of data processing obligations to the national data protection authorities, and the security and confidentiality of the personal data. Further, the GDPR prohibits the transfer of personal data to countries outside of the EU that are not considered by the EC to provide an adequate level of data protection, including to the U.S., except if the data controller meets very specific requirements. Following the Schrems II decision of the Court of Justice of the EU on July 16, 2020, there is considerable uncertainty as to the permissibility of international data transfers under the GDPR. In light of the implications of this decision, the Company may face difficulties regarding the transfer of personal data from the EU to third countries.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU Member States may result in significant monetary fines and other administrative penalties as well as civil liability claims from individuals whose personal data was processed. Data protection authorities from the different EU Member States may still implement certain variations, enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing personal data in the EU. Guidance developed at both the EU level and at the national level in individual EU Member States concerning implementation and compliance practices is often updated or otherwise revised.

There is, moreover, a growing trend towards required public disclosure of clinical trial data in the EU which adds to the complexity of obligations relating to processing health data from clinical trials. Failing to comply with these obligations could lead to government enforcement actions and significant penalties against the Company, harm to its reputation, and adversely impact its business and operating results. The uncertainty regarding the interplay between different regulatory frameworks further adds to the complexity that the Company faces with regard to data protection regulation.

On August 20, 2021, China's 13th National People's Congress passed the Personal Information Protection Law (PIPL) that aims to standardize the handling of personal information in China which became effective on November 1, 2021. The PIPL currently applies to the processing of personal information of natural persons in China, the processing of personal information outside China where the purpose is to provide products and services in China, and to analyze the activities of individuals in China. While similar to the GDPR, the PIPL contains unique requirements not found in the GDPR.

The Company has developed and implemented comprehensive plans to ensure compliance with the PIPL, with those relating to data localization and cross-border transfers yet to be completed pending forthcoming guidance from the Cyberspace Administration of China.

Additional laws and regulations enacted in the U.S. (such as the California Consumer Privacy Act), Europe, Asia, and Latin America, have increased enforcement and litigation activity in the U.S. and other developed markets, as well as increased regulatory cooperation among privacy authorities globally. The Company has adopted a comprehensive global privacy program to manage these evolving requirements and risks and to facilitate the transfer of personal information across international borders.

Distribution

The Company sells its human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers, such as health maintenance organizations, PBMs and other institutions. Human health vaccines are sold primarily to physicians, wholesalers, physician distributors and government entities. The Company's professional representatives communicate the effectiveness, safety and value of the Company's pharmaceutical and vaccine products to health care professionals in private practice, group practices, hospitals and managed care organizations. The Company sells its animal health products to veterinarians, distributors and animal producers.

Patents, Trademarks and Licenses

Patent protection is considered, in the aggregate, to be of material importance to the Company's marketing of its products in the U.S. and in most major foreign markets. Patents may cover products *per se*, pharmaceutical formulations, processes for, or intermediates useful in, the manufacture of products, or the uses of products. Protection for individual products extends for varying periods in accordance with the legal life of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent and its scope of coverage.

The Food and Drug Administration Modernization Act includes a Pediatric Exclusivity Provision that may provide an additional six months of market exclusivity in the U.S. for indications of new or currently marketed drugs if certain agreed upon pediatric studies are completed by the applicant. Current U.S. patent law provides additional patent term for periods when the patented product was under regulatory review by the FDA. The EU also provides an additional six months of pediatric market exclusivity attached to a product's Supplementary Protection Certificate (SPC). Japan provides the additional term for pediatric studies attached to market exclusivity unrelated to patent term.

Patent portfolios developed for products introduced by the Company normally provide market exclusivity. The Company has the following key patent protection in the U.S., the EU, Japan and China (including the potential for patent term extensions (PTE) and SPCs where indicated) for the following marketed products:

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Product	Year of Expiration (U.S.)	Year of Expiration (EU) [1]	Year of Expiration (Japan)[2]	Year of Expiration (China)
Januvia	2023	2022	2025-2026	2022
Janumet	2023	2022	N/A	2022
Janumet XR	2023	N/A	N/A	2022
Isentress	2024	2023[3]	2022-2026[4]	2022
Simponi	N/A[5]	2024[6]	N/A[5]	N/A[5]
Lenvima[7]	2025[3]	2026[3] (SPCs)	2026	Expired
Bridion	2026[3]	2023	2024	Expired
Bravecto	2026 (with pending PTE)	2025 (patents), 2029 (SPCs)	2029	2025
Gardasil	2028	Expired	Expired	N/A
Gardasil 9	2028	2025 (patents), 2030[3] (SPCs)	N/A	2025
Keytruda	2028	2030[3]	2032-2033	2028
Lynparza[8]	2028[3] (with pending PTE)	2024 (patents), 2029[3] (SPCs)	2028-2029	2024
Zerbaxa	2028[3]	2023 (patents), 2028[3] (SPCs)	2028 (with pending PTE)	N/A
Adempas[9]	N/A[10]	2028[3]	2027-2028	2023
Belsomra	2029[3]	N/A	2031	N/A
Prevymis	2029[3] (with pending PTE)	2024 (patents), 2029[3] (SPCs)	2029	N/A
Segluromet[11]	2031 (with pending PTE)	2029 (patents), 2034 (SPCs)	N/A[12]	2029
Steglatro[11]	2031[3] (with pending PTE)	2029 (patents), 2034[3] (SPCs)	N/A[12]	2029
Steglujan[11]	2031 (with pending PTE)	2029 (patents), 2034 (SPCs)	N/A[12]	2029
Verquvo[8]	2035 (with pending PTE)	N/A[13]	N/A[13]	N/A[13]
Vaxneuvance	2031 (with pending PTE)	No Patent	N/A	N/A
Delstrigo	2032 (with pending PTE)	2031 (patents), 2033 (SPCs)	N/A	2031
Pifeltro	2032 (with pending PTE)	2031 (patents), 2033 (SPCs)	2036	2031
Recarbrio	2033[3] (with pending PTE)	N/A	N/A	N/A
Welireg	2035 (with pending PTE)	N/A	N/A	N/A

Note: Compound patent unless otherwise noted. Certain of the products listed may be the subject of patent litigation. See Item 8. "Financial Statements and Supplementary Data," Note 11. "Contingencies and Environmental Liabilities" below.

N/A: Currently no marketing approval.

(1) The EU date represents the expiration date for the following four countries: France, Germany, Italy, and Spain (Major EU Markets). If SPC applications have been filed but have not been granted in all Major EU Markets, both the patent expiry date and the SPC expiry date are listed.

(2) The PTE system in Japan allows for a patent to be extended more than once provided the later approval is directed to a different indication from that of the previous approval. This may result in multiple PTE approvals for a given patent, each with its own expiration date.

(3) Eligible for 6 months Pediatric Exclusivity.

(4) Expiry date reflects the approved product and includes granted PTE for the 600 mg tablet in Japan.

(5) The Company has no marketing rights in the U.S., Japan or China.

(6) The distribution agreement with Janssen Pharmaceuticals, Inc. expires on October 1, 2024.

(7) Part of a global strategic oncology collaboration with Eisai Co., Ltd.

(8) *Part of a global strategic oncology collaboration with AstraZeneca.*

(9) *Being commercialized in a worldwide collaboration with Bayer AG.*

(10) *The Company has no marketing rights in the U.S.*

(11) *Being commercialized and promoted in a worldwide, except Japan, collaboration with Pfizer Inc.*

(12) *The Company has no marketing rights in Japan.*

(13) *The Company has no marketing rights in the EU, Japan or China.*

The Company has the following key U.S. patent protection for drug candidates under review in the U.S. by the FDA. Additional patent term may be provided for these pipeline candidates based on Patent Term Restoration and Pediatric Exclusivity.

Under Review in the U.S.	Currently Anticipated Year of Expiration (in the U.S.)
MK-7264 (gefapixant)	2027

The Company also has the following key U.S. patent protection for drug candidates in Phase 3 development:

Phase 3 Drug Candidate	Currently Anticipated Year of Expiration (in the U.S.)
MK-8591 (islatravir)	2026
MK-7962 (sotatercept)	2027
MK-8591A (doravirine + islatravir)	2032 (pending PTE for doravirine)
MK-1308A (quavonlimab + pembrolizumab)	2035
MK-7684A (vibostolimab + pembrolizumab)	2035
MK-4280A (favezelimab + pembrolizumab)	2035
MK-1654 (clesrovimab)	2036
MK-4482 (molnupiravir)[(1)]	2038

[(1)] *Received Emergency Use Authorization from the FDA for the treatment of high-risk adults with mild to moderate COVID-19.*

Unless otherwise noted, the patents in the above charts are compound patents. Each patent may be subject to a future patent term restoration of up to five years and six month pediatric market exclusivity, either or both of which may be available. In addition, depending on the circumstances surrounding any final regulatory approval of the compound, there may be other listed patents or patent applications pending that could have relevance to the product as finally approved; the relevance of any such application would depend upon the claims that ultimately may be granted and the nature of the final regulatory approval of the product. Also, regulatory exclusivity tied to the protection of clinical data is complementary to patent protection and, in some cases, may provide more effective or longer lasting marketing exclusivity than a compound's patent estate. In the U.S., the data protection generally runs five years from first marketing approval of a new chemical entity, extended to seven years for an orphan drug indication and 12 years from first marketing approval of a biological product.

While the expiration of a compound patent normally results in a loss of market exclusivity for the covered pharmaceutical product, commercial benefits may continue to be derived from: (i) later-expiring patents on processes and intermediates related to the most economical method of manufacture of the active ingredient of such product; (ii) patents relating to the use of such product; (iii) patents relating to novel compositions and formulations; and (iv) in the U.S. and certain other countries, market exclusivity that may be available under relevant law. The effect of product patent expiration on pharmaceutical products also depends upon many other factors such as the nature of the market and the position of the product in it, the growth of the market, the complexities and economics of the process for manufacture of the active ingredient of the product and the requirements of new drug provisions of the Federal Food, Drug and Cosmetic Act or similar laws and regulations in other countries.

Additions to market exclusivity are sought in the U.S. and other countries through all relevant laws, including laws increasing patent life. Some of the benefits of increases in patent life have been partially offset by an increase in the number of incentives for and use of generic products. Additionally, improvements in intellectual property laws are sought in the U.S. and other countries through reform of patent and other relevant laws and implementation of international treaties.

For further information with respect to the Company's patents, see Item 1A. "Risk Factors" and Item 8. "Financial Statements and Supplementary Data," Note 11. "Contingencies and Environmental Liabilities" below.

Worldwide, all of the Company's important products are sold under trademarks that are considered in the aggregate to be of material importance. Trademark protection continues in some countries as long as used; in other countries, as long as registered. Registration is for fixed terms and can be renewed indefinitely.

Royalty income in 2021 on patent and know-how licenses and other rights amounted to $286 million. Merck also incurred royalty expenses amounting to $2.4 billion in 2021 under patent and know-how licenses it holds.

Research and Development

The Company's business is characterized by the introduction of new products or new uses for existing products through a strong research and development program. At December 31, 2021, approximately 17,500 people were employed in the Company's research activities. The Company prioritizes its research and development efforts and focuses on candidates that it believes represent breakthrough science that will make a difference for patients and payers.

The Company maintains a number of long-term exploratory and fundamental research programs in biology and chemistry as well as research programs directed toward product development. The Company's research and development model is designed to increase productivity and improve the probability of success by prioritizing the Company's research and development resources on candidates the Company believes are capable of providing unambiguous, promotable advantages to patients and payers and delivering the maximum value of its approved medicines and vaccines through new indications and new formulations. Merck is pursuing emerging product opportunities independent of therapeutic area or modality (small molecule, biologics and vaccines) and is building its biologics capabilities. The Company is committed to ensuring that externally sourced programs remain an important component of its pipeline strategy, with a focus on supplementing its internal research with a licensing and external alliance strategy focused on the entire spectrum of collaborations from early research to late-stage compounds, as well as access to new technologies.

The Company's clinical pipeline includes candidates in multiple disease areas, including cancer, cardiovascular diseases, metabolic diseases, infectious diseases, neurosciences, respiratory diseases, and vaccines.

In the development of human health products, industry practice and government regulations in the U.S. and most foreign countries provide for the determination of effectiveness and safety of new chemical compounds through pre-clinical tests and controlled clinical evaluation. Before a new drug or vaccine may be marketed in the U.S., recorded data on pre-clinical and clinical experience are included in the New Drug Application (NDA) for a drug or the Biologics License Application (BLA) for a vaccine or biologic submitted to the FDA for the required approval.

Once the Company's scientists discover a new small molecule compound or biologic that they believe has promise to treat a medical condition, the Company commences pre-clinical testing with that compound. Pre-clinical testing includes laboratory testing and animal safety studies to gather data on chemistry, pharmacology, immunogenicity and toxicology. Pending acceptable pre-clinical data, the Company will initiate clinical testing in accordance with established regulatory requirements. The clinical testing begins with Phase 1 studies, which are designed to assess safety, tolerability, pharmacokinetics, and preliminary pharmacodynamic activity of the compound in humans. If favorable, additional, larger Phase 2 studies are initiated to determine the efficacy of the compound in the affected population, define appropriate dosing for the compound, as well as identify any adverse effects that could limit the compound's usefulness. In some situations, the clinical program incorporates adaptive design methodology to use accumulating data to decide how to modify aspects of the ongoing clinical study as it continues, without undermining the validity and integrity of the trial. One type of adaptive clinical trial is an adaptive Phase 2a/2b trial design, a two-stage trial design consisting of a Phase 2a proof-of-concept stage and a Phase 2b dose-optimization finding stage. If data from the Phase 2 trials are satisfactory, the Company commences large-scale Phase 3 trials to confirm the compound's efficacy and safety. Another type of adaptive clinical trial is an adaptive Phase 2/3 trial design, a study that includes an interim analysis and an adaptation that changes the trial from having features common in a Phase 2 study (e.g. multiple dose groups) to a design similar to a Phase 3 trial. An adaptive Phase 2/3 trial design reduces timelines by eliminating activities which would be required to start a separate study. Upon completion of Phase 3 trials, if satisfactory, the Company submits regulatory filings with the appropriate regulatory agencies around the world to have the product candidate approved for marketing. There can be no assurance that a compound that is the result of any particular program will obtain the regulatory approvals necessary for it to be marketed.

Vaccine development follows the same general pathway as for drugs. Pre-clinical testing focuses on the vaccine's safety and ability to elicit a protective immune response (immunogenicity). Pre-marketing vaccine clinical trials are typically done in three phases. Initial Phase 1 clinical studies are conducted in normal subjects to evaluate the safety, tolerability and immunogenicity of the vaccine candidate. Phase 2 studies are dose-ranging studies. Finally, Phase 3 trials provide the necessary data on effectiveness and safety. If successful, the Company submits regulatory filings with the appropriate regulatory agencies.

In the U.S., the FDA review process begins once a complete NDA or BLA is submitted, received and accepted for review by the agency. Within 60 days after receipt, the FDA determines if the application is sufficiently complete to permit a substantive review. The FDA also assesses, at that time, whether the application will be granted a priority review or standard review. Pursuant to the Prescription Drug User Fee Act V (PDUFA), the FDA review period target for NDAs or original BLAs is either six months, for priority review, or ten months, for a standard review, from the time the application is deemed sufficiently complete. Once the review timelines are determined, the FDA will generally act upon the application within those timelines, unless a major amendment has been submitted (either at the Company's own initiative or the FDA's request) to the pending application. If this occurs, the FDA may extend the review period to allow for review of the new information, but by no more than three months. Extensions to the review period are communicated to the Company. The FDA can act on an application either by issuing an approval letter or by issuing a Complete Response Letter (CRL) stating that the application will not be approved in its present form and describing all deficiencies that the FDA has identified. Should the Company wish to pursue an application after receiving a CRL, it can resubmit the application with information that addresses the questions or issues identified by the FDA in order to support approval. Resubmissions are subject to review period targets, which vary depending on the underlying submission type and the content of the resubmission.

The FDA has four program designations — Fast Track, Breakthrough Therapy, Accelerated Approval, and Priority Review — to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening conditions. The Fast Track designation provides pharmaceutical manufacturers with opportunities for frequent interactions with FDA reviewers during the product's development and the ability for the manufacturer to do a rolling submission of the NDA/BLA. A rolling submission allows completed portions of the application to be submitted and reviewed by the FDA on an ongoing basis. The Breakthrough Therapy designation provides manufacturers with all of the features of the Fast Track designation as well as intensive guidance on implementing an efficient development program for the product and a commitment by the FDA to involve senior managers and experienced staff in the review. The Accelerated Approval designation allows the FDA to approve a product based on an effect on a surrogate or intermediate endpoint that is reasonably likely to predict a product's clinical benefit and generally requires the manufacturer to conduct required post-approval confirmatory trials to verify the clinical benefit. The Priority Review designation means that the FDA's goal is to take action on the NDA/BLA within six months, compared to ten months under standard review. More than one of these special designations can be granted for a given application (i.e., a product designated as a Breakthrough Therapy may also be eligible for Priority Review).

Due to the COVID-19 public health crisis, the U.S. Secretary of Health and Human Services has exercised statutory authority to determine that a public health emergency exists, and declared these circumstances justify the emergency use of drugs and biological products as authorized by the FDA. While in effect, this declaration enables the FDA to issue Emergency Use Authorizations (EUAs) permitting distribution and use of specific medical products absent NDA/BLA submission or approval, including products to treat or prevent diseases or conditions caused by the SARS-CoV-2 virus, subject to the terms of any such EUAs. The FDA must make certain findings to grant an EUA, including that it is reasonable to believe based on the totality of evidence that the drug or biologic may be effective, and that known or potential benefits when used under the terms of the EUA outweigh known or potential risks. Additionally, the FDA must find that there is no adequate, approved and available alternative to the emergency use. The FDA may revise or revoke an EUA if the circumstances justifying its issuance no longer exist, the criteria for its issuance are no longer met, or other circumstances make a revision or revocation appropriate to protect the public health or safety.

The primary method the Company uses to obtain marketing authorization of pharmaceutical products in the EU is through the "centralized procedure." This procedure is compulsory for certain pharmaceutical products, in particular those using biotechnological processes, and is also available for certain new chemical compounds and products. A company seeking to market an innovative pharmaceutical product through the centralized procedure

must file a complete set of safety data and efficacy data as part of a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA). After the EMA evaluates the MAA, it provides a recommendation to the EC and the EC then approves or denies the MAA. It is also possible for new chemical products to obtain marketing authorization in the EU through a "mutual recognition procedure" in which an application is made to a single member state and, if the member state approves the pharmaceutical product under a national procedure, the applicant may submit that approval to the mutual recognition procedure of some or all other EU Member States.

Outside of the U.S. and the EU, the Company submits marketing applications to national regulatory authorities. Examples of such are the Ministry of Health, Labour and Welfare in Japan, the National Medical Products Administration in China, Health Canada, Agência Nacional de Vigilância Sanatária in Brazil, Korea Food and Drug Administration in South Korea, and the Therapeutic Goods Administration in Australia. Each country has a separate and independent review process and timeline. In many markets, approval times can be longer as the regulatory authority requires approval in a major market, such as the U.S. or the EU, and issuance of a Certificate of Pharmaceutical Product from that market before initiating their local review process.

Research and Development Update

The Company currently has several candidates under regulatory review in the U.S. and internationally or in late-stage clinical development.

MK-4482, molnupiravir, is an investigational oral antiviral medicine for the treatment of mild to moderate COVID-19 in adults who are at risk for progressing to severe disease. Merck is developing molnupiravir in collaboration with Ridgeback Biotherapeutics LP. The FDA granted Emergency Use Authorization (EUA) for molnupiravir in December 2021; as updated in February 2022, to authorize molnupiravir for the treatment of mild to moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate. The authorization is based on the Phase 3 MOVe-OUT trial. Molnupiravir is not approved for any use in the U.S. and is authorized only for the duration of the declaration that circumstances exist justifying the authorization of its emergency use under the Food, Drug and Cosmetic Act, unless the authorization is terminated or revoked sooner. Molnupiravir has also received conditional marketing authorization in the UK and Special Approval for Emergency in Japan. In November 2021, the EMA issued a positive scientific opinion for molnupiravir, which is intended to support national decision-making on the possible use of molnupiravir prior to marketing authorization. In October 2021, the EMA initiated a rolling review for molnupiravir for the treatment of COVID-19 in adults. Merck plans to work with the Committee for Medicinal Products for Human Use of the EMA to complete the rolling review process to facilitate initiating the formal review of the MAA. Applications to other regulatory bodies worldwide are underway. Molnupiravir is also being evaluated for post-exposure prophylaxis in the Phase 3 MOVe-AHEAD trial, which is evaluating the efficacy and safety of molnupiravir for the prevention of COVID-19 in adults who reside with a person with COVID-19. As previously announced, data from the MOVe-IN clinical trial indicated that molnupiravir is unlikely to demonstrate a clinical benefit in hospitalized patients, who generally had a longer duration of symptoms prior to study entry; therefore, the decision was made not to proceed to Phase 3.

MK-7264, gefapixant, is an investigational, orally administered, selective P2X3 receptor antagonist, for the treatment of refractory chronic cough or unexplained chronic cough in adults under review by the FDA. The NDA for gefapixant is based on results from the COUGH-1 and COUGH-2 clinical trials. In January 2022, the FDA issued a Complete Response Letter (CRL) regarding Merck's NDA for gefapixant. In the CRL, the FDA requested additional information related to measurement of efficacy. The CRL was not related to the safety of gefapixant. Merck is reviewing the letter and considering next steps. Gefapixant is also under review in the EU, although the review period has been extended pending the receipt of additional information from the Company.

V114 is an investigational 15-valent pneumococcal conjugate vaccine under review in Japan for use in adults. V114 was approved in the U.S. in 2021 for use in adults where it is marketed as *Vaxneuvance*. *Vaxneuvance* is also under priority review by the FDA for the prevention of invasive pneumococcal disease in children 6 weeks through 17 years of age. The FDA grants priority review to medicines and vaccines that, if approved, would provide a significant improvement in the safety or effectiveness of the treatment or prevention of a serious condition. The FDA set a PDUFA date of April 1, 2022. The supplemental BLA is supported by results from Phase 2 and Phase 3 clinical studies in pediatric populations including infants, children, and adolescents.

MK-3475, *Keytruda*, is an anti-PD-1 therapy approved for the treatment of many cancers that is in clinical development for expanded indications. These approvals were the result of a broad clinical development program that currently consists of more than 1,650 clinical trials, including more than 1,250 trials that combine *Keytruda* with other cancer treatments. These studies encompass more than 30 cancer types including: biliary, estrogen receptor positive breast cancer, cervical, colorectal, cutaneous squamous cell, endometrial, esophageal, gastric, glioblastoma, head and neck, hepatocellular, Hodgkin lymphoma, non-Hodgkin lymphoma, non-small-cell lung, small-cell lung, melanoma, mesothelioma, ovarian, prostate, renal, triple-negative breast, and urothelial, many of which are currently in Phase 3 clinical development. Further trials are being planned for other cancers.

Keytruda is under review in the EU for the adjuvant treatment of adult and pediatric (12 years and older) patients with Stage IIB or IIC melanoma following complete resection based on data from the Phase 3 KEYNOTE-716 trial.

Keytruda is under review in Japan for the adjuvant treatment of patients with RCC at intermediate-high or high risk of recurrence following nephrectomy (surgical removal of a kidney) based on data from the Phase 3 KEYNOTE-564 trial.

Keytruda is under review by the FDA for the treatment of patients with advanced endometrial cancer that is MSI-H or dMMR, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation. This submission is based on data from the KEYNOTE-158 trial. The FDA set a PDUFA date of March 28, 2022.

Keytruda is under review in the EU for the treatment of unresectable or metastatic MSI-H or dMMR colorectal, endometrial, gastric, small intestine, biliary, or pancreatic cancer in adults who have received prior therapy. The proposed indication is based on the results from the KEYNOTE-164 and KEYNOTE-158 trials.

Keytruda in combination with chemotherapy is under review in the EU and Japan for the treatment of patients with high-risk, early-stage TNBC as neoadjuvant treatment, and then as a single agent as adjuvant treatment after surgery based on data from the KEYNOTE-522 trial.

Keytruda is under review in Japan for treatment of adult patients with advanced or recurrent TMB-H solid tumors that have progressed after chemotherapy (limited to use when difficult to treat with standard of care) based on the KEYNOTE-158 trial.

Keytruda in combination with chemotherapy with or without bevacizumab is also under review in the EU and Japan for the first-line treatment of patients with persistent, recurrent or metastatic cervical cancer based on the KEYNOTE-826 trial.

In January 2021, Merck, the European Organisation for Research and Treatment of Cancer and the European Thoracic Oncology Platform announced that the Phase 3 KEYNOTE-091 trial investigating *Keytruda* met one of its dual primary endpoints of disease-free survival (DFS) for the adjuvant treatment of patients with stage IB-IIIA NSCLC following surgical resection regardless of PD-L1 expression. Based on an interim analysis review conducted by an independent Data Monitoring Committee, adjuvant treatment with *Keytruda* resulted in a statistically significant and clinically meaningful improvement in DFS compared with placebo in the all-comer population of patients with stage IB-IIIA NSCLC. At the interim analysis, there was also an improvement in DFS for patients whose tumors express PD-L1 (tumor proportion score [TPS] ≥50%) treated with *Keytruda* compared to placebo; however, this dual primary endpoint did not meet statistical significance per the pre-specified statistical plan. The trial will continue to analyze DFS in patients whose tumors express high levels of PD-L1 (TPS ≥50%) and evaluate overall survival, a key secondary endpoint. Results will be presented at an upcoming medical meeting and will be submitted to regulatory authorities.

MK-7339, Lynparza, is an oral PARP inhibitor currently approved for certain types of advanced ovarian, breast, pancreatic and prostate cancers being co-developed for multiple cancer types as part of a collaboration with AstraZeneca PLC. In November 2021, the FDA accepted for priority review a supplemental NDA for Lynparza for the adjuvant treatment of patients with *BRCA*-mutated, human epidermal growth factor receptor 2 (HER2)-negative high-risk, early-stage breast cancer who have already been treated with chemotherapy either before or after surgery based on the results from the Phase 3 OlympiA trial. The FDA set a PDUFA date during the first quarter of 2022.

This indication is also under review in the EU. Lynparza is also under review in the EU for the treatment of certain patients with metastatic castration-resistant prostate cancer based on the PROpel clinical trial.

MK-7902, Lenvima, is an oral receptor tyrosine kinase inhibitor being developed as part of a collaboration with Eisai Co., Ltd. (Eisai). Merck and Eisai are studying the *Keytruda* plus Lenvima combination through the LEAP (LEnvatinib And Pembrolizumab) clinical program that includes 17 Phase 3 studies across 14 different tumor types (biliary cancer, CRC, endometrial carcinoma, esophageal cancer, gastric cancer, glioblastoma, HCC, HNSCC, melanoma, pancreatic cancer, prostate cancer, NSCLC, SCLC and RCC).

In July 2020, Merck and Eisai announced that the FDA issued a CRL regarding Merck's and Eisai's applications seeking accelerated approval for the first-line treatment of patients with unresectable HCC based on the KEYNOTE-524/Study 116 trial. Ahead of the PDUFA action dates of Merck's and Eisai's applications, another combination therapy was approved based on a randomized, controlled trial that demonstrated improvement in overall survival versus standard-of-care treatment. Consequently, the CRL stated that Merck's and Eisai's applications do not provide evidence that *Keytruda* in combination with Lenvima represents a meaningful advantage over available therapies for the treatment of unresectable or metastatic HCC with no prior systemic therapy for advanced disease. Since the applications for KEYNOTE-524/Study 116 no longer meet the criteria for accelerated approval, both companies plan to work with the FDA to take appropriate next steps, which include conducting a well-controlled clinical trial that demonstrates substantial evidence of effectiveness and the clinical benefit of the combination. As such, LEAP-002, the Phase 3 trial evaluating the *Keytruda* plus Lenvima combination as a first-line treatment for advanced HCC, is currently underway and fully enrolled. The CRL does not impact the current approved indications for *Keytruda* or for Lenvima.

Merck and Eisai have stopped LEAP-007, the Phase 3 study evaluating the first-line treatment of Lenvima in combination with *Keytruda* in participants with metastatic squamous or non-squamous NSCLC, whose tumors are PD-L1 positive with no *EGFR* or *ALK* genomic tumor aberrations. The trial has been discontinued following the recommendation of the external Data Monitoring Committee (eDMC) which met, as scheduled, to assess safety and futility. The eDMC determined that the study had met the criteria for declaring futility and the benefit/risk profile of the combination did not support continuing the trial.

Merck and Eisai have closed LEAP-011 for further enrollment. LEAP-011 is a Phase 3 study evaluating Lenvima in combination with *Keytruda* for the first-line treatments of patients with platinum-ineligible urothelial carcinoma. Enrollment was closed following the recommendation of the eDMC, which met, as scheduled, to assess safety and futility. The eDMC determined that the benefit/risk profile of the combination did not support continuing the trial and improvements in outcomes in favor of the combination were unlikely to be as high as initially hypothesized.

The Company also has several other programs in Phase 3 clinical development.

MK-1308A is the coformulation of quavonlimab, Merck's novel investigational anti-CTLA-4 antibody, with pembrolizumab being evaluated for the treatment of RCC.

Subcutaneous MK-3475, pembrolizumab, is being evaluated for comparability with the intravenous formulation in NSCLC.

MK-4280A is the coformulation of favezelimab, Merck's novel investigational anti-LAG3 therapy, with pembrolizumab, being evaluated for the treatment of CRC.

MK-6482, *Welireg* (belzutifan), is a hypoxia-inducible factor-2α (HIF-2α) inhibitor being evaluated for a supplemental indication for the treatment of patients with RCC.

MK-7119, Tukysa, is a small molecule tyrosine kinase inhibitor, for the treatment of HER2-positive cancers in development for the treatment of breast cancer. In September 2020, Seagen granted Merck an exclusive license and entered into a co-development agreement with Merck to accelerate the global reach of Tukysa.

MK-7684A is the coformulation of vibostolimab, an anti-TIGIT therapy, with pembrolizumab being evaluated for the treatment of NSCLC.

In December 2021, Merck announced that the FDA had placed clinical holds on the investigational new drug applications for the oral and implant formulations of islatravir (MK-8591) for HIV-1 pre-exposure prophylaxis

(PrEP); the injectable formulation of islatravir for HIV-1 treatment and prophylaxis; and the oral doravirine/islatravir (MK-8591A) HIV-1 once-daily treatment regimen. The FDA's clinical hold is based on observations of decreases in total lymphocyte and CD4+ T-cell counts in some participants receiving islatravir in clinical studies. Merck previously announced it had stopped dosing in the Phase 2 IMAGINE-DR clinical trial of islatravir in combination with MK-8507 (MK-8591-013) and paused enrollment in the once-monthly Phase 3 PrEP studies, (MK-8591-022 and MK-8591-024). With the FDA's clinical hold, no new studies may be initiated. Additionally, Merck and Gilead have made the decision to stop all dosing of participants in the Phase 2 clinical study evaluating an oral-weekly combination treatment regimen of islatravir and Gilead's investigational lenacapavir in people living with HIV who are virologically suppressed on antiretroviral therapy. This decision follows the joint announcement on November 23, 2021 of a temporary hold on further enrollment and screening in the study, which commenced in October 2021. The two companies will assess whether a different dosing of islatravir in combination with lenacapavir may provide a once-weekly oral therapy option for people living with HIV. Merck and Gilead remain committed to their collaboration, which aims to develop long-acting new treatment options to address the unmet needs for people living with HIV.

MK-7962, sotatercept, is a potentially first-in-class therapy for the treatment of pulmonary arterial hypertension (PAH). Sotatercept is in clinical trials as an add-on to current standard of care for the treatment of PAH. Sotatercept was obtained in connection with Merck's acquisition of Acceleron Pharma Inc. in 2021.

MK-1654, clesrovimab, is a respiratory syncytial virus (RSV) monoclonal antibody that is being evaluated for the prevention of RSV medically attended lower respiratory tract infection in infants and certain children over 2 years of age.

In April 2021, Merck announced the discontinuation of development of MK-7110 which was being evaluated for the treatment of hospitalized patients with COVID-19. Merck obtained MK-7110 in December 2020 through its acquisition of OncoImmune, a privately held clinical-stage biopharmaceutical company. In 2021, Merck received feedback from the FDA that additional data would be needed to support a potential EUA application and therefore the Company did not expect MK-7110 would become available until the first half of 2022. Given this timeline and the technical, clinical and regulatory uncertainties, the availability of a number of medicines for patients hospitalized with COVID-19, and the need to concentrate Merck's resources on accelerating the development and manufacture of the most viable therapeutics and vaccines, Merck decided to discontinue development of MK-7110 for the treatment of COVID-19.

In September 2021, the FDA approved updated labeling for Steglatro, Steglujan and Segluromet, medicines for adults with type 2 diabetes, to include the primary efficacy and safety results from the VERTIS CV trial, which assessed the effect of Steglatro compared with placebo on cardiovascular outcomes in adult patients with type 2 diabetes and established atherosclerotic cardiovascular disease. The FDA issued a CRL concerning the Company's application for a new indication, based on additional results from the VERTIS CV trial, to reduce the risk of hospitalization for heart failure. The Company has determined not to pursue the indication.

The chart below reflects the Company's research pipeline as of February 22, 2022. Candidates shown in Phase 3 include specific products and the date such candidate entered into Phase 3 development. Candidates shown in Phase 2 include the most advanced compound with a specific mechanism or, if listed compounds have the same mechanism, they are each currently intended for commercialization in a given therapeutic area. Small molecules and biologics are given MK-number designations and vaccine candidates are given V-number designations. Except as otherwise noted, candidates in Phase 1, additional indications in the same therapeutic area (other than with respect to cancer) and additional claims, line extensions or formulations for in-line products are not shown.

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Phase 2	Phase 3 (Phase 3 entry date)	Under Review
Cancer MK-0482[2] Non-Small-Cell Lung MK-1026 (nemtabrutinib) Hematological Malignancies MK-1308 (quavonlimab)[2] Non-Small-Cell Lung MK-1308A (quavonlimab+pembrolizumab) Advanced Solid Tumors Colorectal Hepatocellular Melanoma Small-Cell-Lung MK-2140 (zilovertamab vedotin) Breast Hematological Malignancies Non-Small-Cell Lung MK-3475 *Keytruda* Advanced Solid Tumors MK-4280 (favezelimab)[2] Hematological Malignancies Non-Small-Cell Lung MK-4280A (favezelimab+pembrolizumab) Renal Cell Small-Cell Lung MK-4830[2] Non-Small-Cell Lung Renal Cell Small-Cell Lung MK-5890[2] Non-Small-Cell Lung Small-Cell Lung MK-6440 (ladiratuzumab vedotin)[1][3] Breast Esophageal Gastric Head and Neck Melanoma Non-Small-Cell Lung Prostate Small-Cell Lung MK-6482 *Welireg*[3] Biliary Colorectal Hepatocellular Pancreatic Rare cancers Von Hippel-Lindau Disease-Associated Tumors (EU) MK-7119 Tukysa[1] Advanced Solid Tumors Biliary Bladder Cervical Colorectal Endometrial Gastric Non-Small-Cell Lung MK-7339 Lynparza[1][3] Advanced Solid Tumors MK-7684 (vibostolimab)[2] Melanoma MK-7684A (vibostolimab+pembrolizumab) Biliary Breast Cervical Endometrial Esophageal Head and Neck Hematological Malignancies	**Antiviral COVID-19** MK-4482 (molnupiravir) (May 2021)[1][5] (U.S) **Cancer** MK-1308A (quavonlimab+pembrolizumab) Renal Cell (April 2021) MK-3475 *Keytruda* Biliary (September 2019) Cutaneous Squamous Cell (August 2019) (EU) Gastric (May 2015) (EU) Hepatocellular (May 2016) (EU) Mesothelioma (May 2018) Ovarian (December 2018) Prostate (May 2019) Small-Cell Lung (May 2017) MK-3475 (pembrolizumab subcutaneous) Non-Small-Cell Lung (August 2021) MK-4280A (favezelimab+pembrolizumab) Colorectal (November 2021) MK-6482 *Welireg*[3] Renal Cell (February 2020) MK-7119 Tukysa[1] Breast (October 2019) MK-7339 Lynparza[1][3] Colorectal (August 2020) Non-Small-Cell Lung (June 2019) Small-Cell Lung (December 2020) MK-7684A (vibostolimab+pembrolizumab) Non-Small-Cell Lung (April 2021) MK-7902 Lenvima[1][2] Colorectal (April 2021) Esophageal (July 2021) Gastric (December 2020) Head and Neck (February 2020) Melanoma (March 2019) Non-Small-Cell Lung (March 2019) **HIV-1 Infection** MK-8591A (doravirine+islatravir) (February 2020)[4] **HIV-1 Prevention** MK-8591 (islatravir) (February 2021)[4] **Pulmonary Arterial Hypertension** MK-7962 (sotatercept) (January 2021) **Respiratory Syncytial Virus** MK-1654 (clesrovimab) (November 2021)	**New Molecular Entities/Vaccines** **Antiviral COVID-19** MK-4482 (molnupiravir)[1] (EU) **Cough** MK-7264 (gefapixant) (U.S.)[6] (EU) **Pneumococcal Vaccine Adult** V114 (JPN) **Certain Supplemental Filings** **Cancer** MK-3475 *Keytruda* • Adjuvant Treatment of Stage IIB or IIC Melanoma (KEYNOTE-716) (EU) • Adjuvent Renal Cell Cancer (KEYNOTE-564) (JPN) • MSI-H or dMMR Endometrial Cancer (KEYNOTE-158) (U.S.) • MSI-H or dMMR Six Tumor Basket (KEYNOTE-158) (EU) • High-Risk Early-Stage Triple-Negative Breast Cancer (KEYNOTE-522) (EU) (JPN) • Tumor Mutational Burden-High (KEYNOTE-158) (JPN) • Cervical Cancer (KEYNOTE-826) (EU) (JPN) MK-7339 Lynparza[1] • *BRCA*-Mutated HER2-Negative Adjuvant Breast Cancer (OlympiA) (U.S.) (EU) • First-Line Metastatic Prostate Cancer (PROpel) (EU) MK-7902 Lenvima[1][2] • First-Line Metastatic Hepatocellular Carcinoma (KEYNOTE-524) (U.S.)[7] • Advanced Unresectable Renal Cell Carcinoma (KEYNOTE-581) (JPN)[8]

Footnotes:

[1] Being developed in a collaboration.

[2] Being developed in combination with *Keytruda*.

[3] Being developed as monotherapy and/or in combination with *Keytruda.*

[4] On FDA clinical hold.

[5] Available in the U.S. under Emergency Use Authorization.

[6] In January 2022, the FDA issued a CRL. Merck is reviewing the CRL and considering next steps.

[7] In July 2020, the FDA issued a CRL for Merck's and Eisai's applications. Merck and Eisai intend to submit additional data when available to the FDA.

[8] Approved on February 25, 2022.

Human Capital

As of December 31, 2021, the Company had approximately 68,000 employees worldwide, with approximately 27,000 employed in the U.S., including Puerto Rico, and, additionally, approximately 14,000 third-party contractors globally.[1] Approximately 67,000 of the Company's employees are full-time employees. Women and individuals from underrepresented ethnic groups comprise approximately 50% and 32% of its workforce (the Company defines workforce as its employees) in the U.S., respectively. Women comprise 46% of the members of the Board of Directors. Additionally, the Company's executive team is made up of 33% women. Approximately 23% of the Company's employees are represented by various collective bargaining groups. The Company's voluntary turnover rate was approximately 8.8% and 6.0%, respectively, in 2021 and 2020.

The Company recognizes that its employees are critical to meet the needs of its patients and customers and that its ability to excel depends on the integrity, skill, and diversity of its employees.

[1] *Third party contractors include the Company's temporary workers, independent contractors, and freelancers who are viewed as full-time equivalent employees. They exclude outsourced service providers.*

Talent Acquisition

The Company uses a comprehensive approach to ensure recruiting, retention and leadership development goals are systematically executed throughout the Company and that it hires talented leaders to achieve improved gender parity and representation across all dimensions of diversity. The Company provides training to its managers and external recruiting organizations on strategies to mitigate unconscious bias in the candidate selection and hiring process. In addition, the Company utilizes a comprehensive communications strategy, employee branding and marketing outreach, social media and strategic alliance partnerships to reach a broad pool of talent in its critical business areas. In 2021, the Company hired approximately 8,700 employees across the globe through various channels including the Company's external career site, direct passive candidate sourcing, diversity partnerships, employee referrals, universities and other external sources.

Global Diversity and Inclusion

Diversity and inclusion are fundamental to the Company's success and core to future innovation. The Company fosters a globally diverse and inclusive workforce for its employees by creating an environment of belonging, engagement, equity, and empowerment. The Company is proactive and intentional about diversity hiring and development programs to advance talent. The Company creates competitive advantages by leveraging diversity and inclusion to accelerate business performance. This includes fostering global supplier diversity, integrating diversity and inclusion into the Company's commercialization strategies and leveraging employee insights to improve performance. In addition to these efforts, the Company has ten Employee Business Resource Groups that provide opportunities for employees to take an active part in contributing to the Company's inclusive culture through their work in talent acquisition and development, business and customer insights and social and community outreach.

The Company's diversity goals include increasing representation in senior management roles[1] by 2024 of (i) women globally to 40%, up from 31% in 2020, (ii) Black/African Americans in the U.S. to 10%, up from 3% in 2020, and (iii) Hispanics/Latinos in the U.S. to 10%, up from 5% in 2020. At December 31, 2021, representation in senior management roles at the Company for (i) women globally was 36%, (ii) Black/African Americans in the U.S. was 7%, and (iii) Hispanics/Latinos in the U.S. was 6%. In addition, by 2025, the Company seeks to maintain or exceed both its current inclusion index score and its current employee engagement index score.[2]

[1] *"Senior management role" is defined as an individual holding either a Vice President or Senior Vice President title.*

[2] *The Inclusion Index is the average favorability score for employees' responses to three items in the employee pulse survey (manager supports inclusion, sense of belonging, leaders value perspective). The Employee Engagement Index is the average favorability score for employees' responses to items in the employee survey.*

Gender and Ethnicity Performance Data[(1)(2)]	**2021**	2020	2019
Women in the workforce	**50%**	50%	49%
Women in the workforce in the U.S.	**50%**	50%	50%
Women on the Board of Directors	**46%**	46%	33%
Women in executive roles[(3)]	**33%**	33%	20%
Women in management roles[(4)]	**44%**	42%	42%
Members of underrepresented ethnic groups on the Board of Directors	**23%**	23%	17%
Members of underrepresented ethnic groups in executive roles (U.S.)	**42%**	25%	40%
Members of underrepresented ethnic groups in the workforce (U.S.)	**32%**	30%	29%
Members of underrepresented ethnic groups in management roles (U.S.)	**26%**	25%	23%
New hires that were female	**53%**	50%	51%
New hires that were members of underrepresented ethnic groups (U.S.)	**46%**	40%	35%

(1) As of 12/31. As self-identified to the Company.

(2) Prior period data has not been restated to adjust for the Organon Spin-Off.

(3) "Executive role" is defined as an individual holding an Executive Vice President title.

(4) "Management role" is defined as all managers with direct reports other than executives as defined in note 3.

Compensation and Benefits

The Company provides a valuable total rewards package reflecting its commitment to attract, retain and motivate its talent, and support its employees and their families in every stage of life. The Company continuously monitors and adjusts its compensation and benefit programs to ensure they are competitive, contemporary, helpful and engaging, and that they support strategic imperatives such as diversity and inclusion, equity, flexibility, quality, security and affordability. For example, the Company added a personal health care concierge service to assist U.S. employees participating in the Company medical plan with their health care needs. Aligned with its business and in support of its cancer care strategy, the Company also improved cancer screening benefits, added resources and provided immediate access to a leading cancer center of excellence for U.S. employees. Globally, the Company implemented a minimum standard of 12 weeks of paid parental leave, which inclusively applies to all parents. In the U.S., the Company's benefits rank in the top quartile of Fortune 100 companies under the Aon 2021 Benefits Index. The Company has been included in Seramount (previously the Working Mother) 100 Best Companies ranking for 35 consecutive years and was named a Seramount top ten Best Company for Dads in 2021.

Employee Wellbeing

The Company is committed to helping its employees and their families improve their own health and wellbeing. The Company's culture of wellbeing is referred to as "*Live it*", which includes programs to support preventive health, emotional and financial wellbeing, physical fitness and nutrition. It is designed to inspire all employees to pursue, enjoy, and share healthy lifestyles. *Live it* was launched in the U.S. in 2011 and today is available in every country in which the Company has employees. In addition, many of the Company's larger sites offer onsite health clinics that provide an array of services to help its employees stay or get well, including vaccinations, cancer and biometric screenings, travel medicine and advice, diagnosis and treatment of non-occupational illnesses or injuries, health counseling and referrals. The Company's overall employee wellbeing program was recognized for excellence in health and wellbeing by receiving the most recent highest-level awards from the Business Group on Health and the American Heart Association.

COVID-19 Response

The Company recognizes that it has a unique responsibility to help in response to the COVID-19 pandemic and is committed to supporting and protecting its employees and their families, ensuring that its supply of medicines and vaccines reaches its patients, contributing its scientific expertise to the development of antiviral approaches and supporting its health care providers and the communities in which they serve. The Company continues to provide employees with easy and regular access to information, including details regarding the Company's tracking process, guidance around hygiene measures and travel and best practices for working from home. Examples of pandemic support resources and programs available to the Company's employees include pay continuation for workers who have been sick or exposed, volunteer policy adjustment to enable employees with

medical backgrounds to volunteer in SARS-CoV-2-related activities, resources to prioritize physical and mental wellness, adjustments to medical plans to cover 100% of a COVID-19-related diagnosis, testing and treatment, backup childcare and more.

Engaging Employees

The Company strives to foster employee engagement by promoting a safe, positive, diverse and inclusive work environment that provides numerous opportunities for two-way communication with employees. Some of the Company's key programs and initiatives include promoting global employee engagement surveys, ongoing pulse checks to the organization for interim feedback on specific topics, fostering professional networking and collaboration, identifying and providing opportunities for volunteering and establishing positive, cooperative business relations with designated employee representatives.

Talent Management and Development

As the Company pursues its goal of becoming the world's premier research-based biopharmaceutical company, there is a consistent focus on the importance of continuously developing its diverse and talented people. The Company's current talent management system supports company-wide performance management, leadership development, talent reviews and succession planning. Annual performance reviews help further the professional development of the Company's employees and ensure that the Company's workforce is aligned with the Company's objectives. The Company seeks to continuously build the skills and capabilities of its workforce to accelerate talent, improve performance and mitigate risk through relevant continuous learning experiences. This includes, but is not limited to, building leadership and management skills, as well as providing technical and functional training to all employees.

Environmental Matters

Environmental Sustainability

The Company strives to be a strong environmental steward, and realizes that its strategy and efforts need to continuously improve for the Company to excel in an increasingly resource-constrained world. The Company's environmental sustainability strategy has three areas of focus:

- Driving efficiency in operations;
- Designing new products to minimize environmental impact; and
- Reducing any impacts in the Company's upstream and downstream value chain.

The Company has recently adopted a set of new climate goals to address the rising expectations of its customers, investors, external stakeholders and employees regarding the environmental impact of its operations and supply chain. These goals include achieving carbon neutrality for greenhouse gas emissions across operations (Scopes 1 and 2) by 2025, reducing Scope 1 and 2 greenhouse gas emissions 46% by 2030 (from a 2019 baseline), reducing value chain (Scope 3) greenhouse gas emissions by 30% by 2030 (from a 2019 baseline), and sourcing 100% renewable energy for purchased electricity by 2025. The Company's absolute greenhouse gas reduction targets have been verified by the Science Based Target initiative. Other environmental sustainability initiatives of the Company include:

- **Global water use and stewardship.** The Company's global water strategy aims to achieve sustainable water management within its operations and its supply chain, as well as address water-related risk. Access to clean water is critical for human health, and water is a key input to the Company's manufacturing operations. The Company's sites employ a variety of technologies and techniques, such as closed-loop cooling systems and reused reverse osmosis "reject water," to reduce the Company's water footprint and improve operational performance.
- **Waste management and diversion.** The Company continuously strives to reduce the amount of operational waste it generates and to maximize the use of environmentally beneficial disposal methods such as recycling, composting and waste-to-energy.
- **Product stewardship and green and sustainable science.** The Company's product stewardship program focuses on identifying and either preventing or minimizing potential safety and environmental hazards throughout a product's life cycle. The Company is also committed to

understanding, managing and reducing the environmental impacts of its products and the materials associated with discovering and producing them. The Company's green and sustainable science program uses a "green-by-design" approach. By using more efficient and innovative processing methods and technologies, the Company is reducing the amount of energy, water and raw materials the Company uses to make the Company's products, thereby reducing the amount of waste the Company generates and lowering the Company's production costs.

- **Animal conservation.** The Company is a leading worldwide supplier of individual identification, real-time data access and advanced analytics for the animal conservation community. This enables the Company to produce actionable insights that inform recovery actions on a global scale, for species ranging from wild fish to penguins. The Company also provides wild fish conservation monitoring equipment and real-time video monitoring technology to advance fish health and welfare. Together, these technologies help to promote biodiversity and support the global need for reliable and safe sources of protein.

Management does not believe that expenditures related to these initiatives should have a material adverse effect on the Company's financial condition, results of operations, liquidity or capital resources for any year.

In December 2021, the Company completed its inaugural issuance of a $1.0 billion sustainability bond, which was part of an $8.0 billion underwritten bond offering. The Company intends to use the net proceeds from the sustainability bond offering to support projects and partnerships in the Company's priority environmental, social and governance (ESG) areas and contribute to the advancement of the United Nations Sustainable Development Goals.

Merck believes that climate change could present risks to its business. Some of the potential impacts of climate change to its business include increased operating costs due to additional regulatory requirements, physical risks to the Company's facilities, water limitations and disruptions to its supply chain. These potential risks are integrated into the Company's business planning including investment in reducing energy usage, water use and greenhouse gas emissions.

Environmental Regulation and Remediation

The Company believes that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on the Company. The Company is also remediating environmental contamination resulting from past industrial activity at certain of its sites. Expenditures for remediation and environmental liabilities were $12 million in 2021 and are estimated to be $24 million in the aggregate for the years 2022 through 2026. These amounts do not consider potential recoveries from other parties. The Company has taken an active role in identifying and accruing for these costs and, in management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $40 million and $43 million at December 31, 2021 and 2020, respectively. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed approximately $40 million in the aggregate. Management also does not believe that these expenditures should have a material adverse effect on the Company's financial condition, results of operations, liquidity or capital resources for any year.

Geographic Area Information

The Company's operations outside the U.S. are conducted primarily through subsidiaries. Sales worldwide by subsidiaries outside the U.S. as a percentage of total Company sales were 54% in 2021 and were 53% in both 2020 and 2019.

The Company's worldwide business is subject to risks of currency fluctuations, governmental actions and other governmental proceedings abroad. The Company does not regard these risks as a deterrent to further expansion of its operations abroad. However, the Company closely reviews its methods of operations and adopts strategies responsive to changing economic and political conditions.

Merck has operations in countries located in Latin America, the Middle East, Africa, Eastern Europe and Asia Pacific. Business in these developing areas, while sometimes less stable, offers important opportunities for growth over time.

Available Information

The Company's Internet website address is merck.com. The Company will make available, free of charge at the "Investors" portion of its website, its Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after such reports are electronically filed with, or furnished to, the U.S. Securities and Exchange Commission (SEC). The address of that website is sec.gov. In addition, the Company will provide without charge a copy of its Annual Report on Form 10-K, including financial statements and schedules, upon the written request of any shareholder to the Office of the Secretary, Merck & Co., Inc., 2000 Galloping Hill Road, K1-4157, Kenilworth, NJ 07033 U.S.A.

The Company's corporate governance guidelines and the charters of the Board of Directors' four standing committees are available on the Company's website at merck.com/company-overview/leadership and all such information is available in print to any shareholder who requests it from the Company.

The Company's 2020/2021 Environmental, Social & Governance (ESG) Progress Report, which provides enhanced ESG disclosures, is available on the Company's website at merck.com/company-overview/responsibility/. Information in the Company's ESG Progress Report is not incorporated by reference into this Form 10-K.

Item 1A. Risk Factors.

Summary Risk Factors

The Company is subject to a number of risks that if realized could materially adversely affect its business, results of operations, cash flow, financial condition or prospects. The following is a summary of the principal risk factors facing the Company:

- The Company is dependent on its patent rights, and if its patent rights are invalidated or circumvented, its business could be materially adversely affected.
- As the Company's products lose market exclusivity, the Company generally experiences a significant and rapid loss of sales from those products.
- Key products generate a significant amount of the Company's profits and cash flows, and any events that adversely affect the markets for its leading products could have a material adverse effect on the Company's results of operations and financial condition.
- The Company's research and development efforts may not succeed in developing commercially successful products and the Company may not be able to acquire commercially successful products in other ways; in consequence, the Company may not be able to replace sales of successful products that lose patent protection.
- The Company's success is dependent on the successful development and marketing of new products, which are subject to substantial risks.
- The Company faces continued pricing pressure with respect to its products.
- Unfavorable or uncertain economic conditions, together with cost-reduction measures being taken by certain governments, could negatively affect the Company's operating results.
- The Company faces intense competition from lower cost generic products.
- The Company faces intense competition from competitors' products.
- In 2021 and 2020, COVID-19-related disruptions had an adverse impact on the Company's business, operations and financial performance. The Company is unable to predict the full extent to which the

COVID-19 pandemic or any future pandemic, epidemic or similar public health threat will adversely impact its business, operations, financial performance, results of operations, and financial condition.

- The Company has significant global operations, which expose it to additional risks, and any adverse event could have a material adverse effect on the Company's results of operations and financial condition.
- Climate change or legal, regulatory or market measures to address climate change may negatively affect the Company's business, results of operations, cash flows and prospects.
- Environmental, social and governance (ESG) matters may impact the Company's business and reputation.
- Failure to attract and retain highly qualified personnel could affect the Company's ability to successfully develop and commercialize products.
- The Company may experience difficulties and delays in manufacturing certain of its products, including vaccines.
- The Company may not be able to realize the expected benefits of its investments in emerging markets.
- The Company is exposed to market risk from fluctuations in currency exchange rates and interest rates.
- Pharmaceutical products can develop unexpected safety or efficacy concerns.
- Reliance on third-party relationships and outsourcing arrangements could materially adversely affect the Company's business.
- Negative events in the animal health industry could have a material adverse effect on future results of operations and financial condition.
- Biologics and vaccines carry unique risks and uncertainties, which could have a material adverse effect on the Company's future results of operations and financial condition.
- The health care industry in the U.S. has been, and will continue to be, subject to increasing regulation and political action.
- The Company's products, including products in development, cannot be marketed unless the Company obtains and maintains regulatory approval.
- Developments following regulatory approval may adversely affect sales of the Company's products.
- The Company is subject to a variety of U.S. and international laws and regulations.
- The Company is subject to evolving and complex tax laws, which may result in additional liabilities that may affect results of operations and financial condition.
- Adverse outcomes in current or future legal matters could negatively affect Merck's business.
- Product liability insurance for products may be limited, cost prohibitive or unavailable.
- The Company is increasingly dependent on sophisticated software applications and computing infrastructure. In 2017, the Company experienced a network cyber-attack that led to a disruption of its worldwide operations, including manufacturing, research and sales operations. The Company could be a target of future cyber-attacks.
- Social media and mobile messaging platforms present risks and challenges.

The above list is not exhaustive, and the Company faces additional challenges and risks. Investors should carefully consider all of the information set forth in this Form 10-K, including the following risk factors, before deciding to invest in any of the Company's securities.

Risk Factors

The risks below are not the only ones the Company faces. Additional risks not currently known to the Company or that the Company presently deems immaterial may also impair its business operations. The Company's business, financial condition, results of operations, cash flow or prospects could be materially adversely affected by any of these risks. This Form 10-K also contains forward-looking statements that involve risks and uncertainties. The Company's results could materially differ from those anticipated in these forward-looking statements as a result of certain factors, including the risks it faces described below and elsewhere. See "Cautionary Factors that May Affect Future Results" below.

Risks Related to the Company's Business

The Company is dependent on its patent rights, and if its patent rights are invalidated or circumvented, its business could be materially adversely affected.

Patent protection is considered, in the aggregate, to be of material importance to the Company's marketing of human health and animal health products in the U.S. and in most major foreign markets. Patents covering products that it has introduced normally provide market exclusivity, which is important for the successful marketing and sale of its products. The Company seeks patents covering each of its products in each of the markets where it intends to sell the products and where meaningful patent protection is available.

Even if the Company succeeds in obtaining patents covering its products, third parties or government authorities may challenge or seek to invalidate or circumvent its patents and patent applications. It is important for the Company's business to successfully assert and defend the patent rights that provide market exclusivity for its products. The Company is often involved in patent disputes relating to challenges to its patents or claims by third parties of infringement against the Company. The Company asserts and defends its patents both within and outside the U.S., including by filing claims of infringement against other parties. See Item 8. "Financial Statements and Supplementary Data," Note 11. "Contingencies and Environmental Liabilities" below. In particular, manufacturers of generic pharmaceutical products from time to time file abbreviated NDAs with the FDA seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned or licensed by the Company. The Company normally responds by asserting its patent with a lawsuit alleging patent infringement. Patent litigation and other challenges to the Company's patents are costly and unpredictable and may deprive the Company of market exclusivity for a patented product or, in some cases, third-party patents may prevent the Company from marketing and selling a product in a particular geographic area.

Additionally, certain foreign governments have indicated that compulsory licenses to patents may be granted in the case of national emergencies or in other circumstances, which could diminish or eliminate sales and profits from those regions and negatively affect the Company's results of operations. Further, court decisions relating to other companies' patents, potential legislation in both the U.S. and certain foreign markets relating to patents, as well as regulatory initiatives may result in a more general weakening of intellectual property protection.

If one or more important products lose patent protection in profitable markets, sales of those products are likely to decline significantly as a result of generic versions of those products becoming available. The Company's results of operations may be adversely affected by the lost sales unless and until the Company has launched commercially successful products that replace the lost sales. In addition, if products that were measured at fair value and capitalized in connection with acquisitions experience difficulties in the market that negatively affect product cash flows, the Company may recognize material non-cash impairment charges with respect to the value of those products.

A chart listing the patent protection for certain of the Company's marketed products, and U.S. patent protection for candidates in Phase 3 clinical development is set forth above in Item 1. "Business — Patents, Trademarks and Licenses."

As the Company's products lose market exclusivity, the Company generally experiences a significant and rapid loss of sales from those products.

The Company depends upon patents to provide it with exclusive marketing rights for its products for some period of time. Loss of patent protection for one of the Company's products typically leads to a significant and

rapid loss of sales for that product as lower priced generic versions of that drug become available. In the case of products that contribute significantly to the Company's sales, the loss of market exclusivity can have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects. *Januvia* and *Janumet* will lose market exclusivity in the U.S. in January 2023. *Januvia* and *Janumet* will lose market exclusivity in the EU in September 2022 and in China in July 2022. The Company anticipates sales of *Januvia* and *Janumet* in these markets will decline substantially after the loss of exclusivity.

Key products generate a significant amount of the Company's profits and cash flows, and any events that adversely affect the markets for its leading products could have a material adverse effect on the Company's results of operations and financial condition.

The Company's ability to generate profits and operating cash flow depends largely upon the continued profitability of the Company's key products, such as *Keytruda, Gardasil/Gardasil* 9, Lynparza, *Bravecto*, and *Bridion*. In particular, in 2021, the Company's oncology portfolio, led by *Keytruda,* represented a substantial portion of the Company's revenue growth. As a result of the Company's dependence on key products, any event that adversely affects any of these products or the markets for any of these products could have a significant adverse impact on results of operations and financial condition. These events could include loss of patent protection, increased costs associated with manufacturing, generic or over-the-counter availability of the Company's product or a competitive product, the discovery of previously unknown side effects, results of post-approval trials, increased competition from the introduction of new, more effective treatments and discontinuation or removal from the market of the product for any reason. Such events could have a material adverse effect on the sales of any such products.

The Company's research and development efforts may not succeed in developing commercially successful products and the Company may not be able to acquire commercially successful products in other ways; in consequence, the Company may not be able to replace sales of successful products that lose patent protection.

In order to remain competitive, the Company, like other major pharmaceutical companies, must continue to launch new products. Expected declines in sales of products after the loss of market exclusivity mean that the Company's future success is dependent on its pipeline of new products, including new products that it may develop through collaborations and joint ventures and products that it is able to obtain through license or acquisition. To accomplish this, the Company commits substantial effort, funds and other resources to research and development, both through its own dedicated resources and through various collaborations with third parties. There is a high rate of failure inherent in the research and development process for new drugs and vaccines. As a result, there is a high risk that funds invested by the Company in research programs will not generate financial returns. This risk profile is compounded by the fact that this research has a long investment cycle. To bring a pharmaceutical compound from the discovery phase to market may take a decade or more and failure can occur at any point in the process, including later in the process after significant funds have been invested.

For a description of the research and development process, see Item 1. "Business — Research and Development" above. Each phase of testing is highly regulated and during each phase there is a substantial risk that the Company will encounter serious obstacles or will not achieve its goals. Therefore, the Company may abandon a product in which it has invested substantial amounts of time and resources. Some of the risks encountered in the research and development process include the following: pre-clinical testing of a new compound may yield disappointing results; competing products from other manufacturers may reach the market first; clinical trials of a new drug may not be successful; a new drug may not be effective or may have harmful side effects; a new drug may not be approved by the regulators for its intended use; it may not be possible to obtain a patent for a new drug; payers may refuse to cover or reimburse the new product; or sales of a new product may be disappointing.

The Company cannot state with certainty when or whether any of its products now under development will be approved or launched; whether it will be able to develop, license or otherwise acquire compounds, product candidates or products; or whether any products, once launched, will be commercially successful. The Company must maintain a continuous flow of successful new products and successful new indications for existing products sufficient both to cover its substantial research and development costs and to replace sales that are lost as profitable products lose market exclusivity or are displaced by competing products or therapies. Failure to do so in the short

term or long term would have a material adverse effect on the Company's business, results of operations, cash flow, financial condition and prospects.

The Company's success is dependent on the successful development and marketing of new products, which are subject to substantial risks.

Products that appear promising in development may fail to reach the market or fail to succeed for numerous reasons, including the following:

- findings of ineffectiveness, superior safety or efficacy of competing products, or harmful side effects in clinical or pre-clinical testing;
- failure to receive the necessary regulatory approvals, including delays in the approval of new products and new indications, or the anticipated labeling, and uncertainties about the time required to obtain regulatory approvals and the benefit/risk standards applied by regulatory agencies in determining whether to grant approvals;
- failure in certain markets to obtain reimbursement commensurate with the level of innovation and clinical benefit presented by the product;
- lack of economic feasibility due to manufacturing costs or other factors; and
- preclusion from commercialization by the proprietary rights of others.

In the future, if certain pipeline programs are cancelled or if the Company believes that their commercial prospects have been reduced, the Company may recognize material non-cash impairment charges for those programs that were measured at fair value and capitalized in connection with acquisitions or certain collaborations.

Failure to successfully develop and market new products in the short term or long term would have a material adverse effect on the Company's business, results of operations, cash flow, financial condition and prospects.

The Company faces continued pricing pressure with respect to its products.

The Company faces continued pricing pressure globally and, particularly in mature markets, from managed care organizations, government agencies and programs that could negatively affect the Company's sales and profit margins. In the U.S., these include (i) practices of managed care groups and institutional and governmental purchasers, (ii) U.S. federal laws and regulations related to Medicare and Medicaid, including the Medicare Prescription Drug Improvement and Modernization Act of 2003 and the ACA, and (iii) state activities aimed at increasing price transparency, including new laws as noted above in Item 1. "Competition and the Health Care Environment." Changes to the health care system enacted as part of health care reform in the U.S., as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, could result in further pricing pressures. In addition, in the U.S., larger customers have received higher rebates on drugs in certain highly competitive categories. The Company must also compete to be placed on formularies of managed care organizations. Exclusion of a product from a formulary can lead to reduced usage in the managed care organization.

In order to provide information about the Company's pricing practices, the Company annually posts on its website its Pricing Transparency Report for the U.S. The report provides the Company's average annual list price and net price increases across the Company's U.S. portfolio dating back to 2010. In 2021, the Company's gross U.S. sales were reduced by 43.5% as a result of rebates, discounts and returns.

Outside the U.S., numerous major markets, including the EU, Japan and China have pervasive government involvement in funding health care and, in that regard, fix the pricing and reimbursement of pharmaceutical and vaccine products. Consequently, in those markets, the Company is subject to government decision making and budgetary actions with respect to its products. In Japan, the pharmaceutical industry is subject to government-mandated annual price reductions of pharmaceutical products and certain vaccines. Furthermore, the government can order re-pricing for specific products if it determines that use of such product will exceed certain thresholds defined under applicable re-pricing rules.

The Company expects pricing pressures to continue in the future.

Unfavorable or uncertain economic conditions, together with cost-reduction measures being taken by certain governments, could negatively affect the Company's operating results.

The Company's business may be adversely affected by local and global economic conditions, including with respect to inflation, interest rates, and costs of raw materials and packaging. Uncertainty in global economic and geopolitical conditions may result in a slowdown to the global economy that could affect the Company's business by reducing the prices that drug wholesalers and retailers, hospitals, government agencies and managed health care providers may be able or willing to pay for the Company's products or by reducing the demand for the Company's products, which could in turn negatively impact the Company's sales and result in a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects.

As discussed above in "Competition and the Health Care Environment," global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. Changes to the U.S. health care system as part of health care reform, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, have contributed to pricing pressure. In several international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. In addition, the Company's revenue performance in 2021 was negatively affected by other cost-reduction measures taken by governments and other third parties to lower health care costs. The Company anticipates all of these actions, and additional actions in the future, will continue to negatively affect revenue performance.

If credit and economic conditions worsen, the resulting economic and currency impacts in the affected markets and globally could have a material adverse effect on the Company's results.

In addition, the COVID-19 pandemic has caused some disruption and volatility in the Company's global supply chain network, and the Company may experience disruptions in availability and delays in shipments of raw materials and packaging, as well as related cost inflation. Any such disruptions, delays or costs may result in the Company's inability to meet demand for the Company's products.

The Company faces intense competition from lower cost generic products.

In general, the Company faces increasing competition from lower-cost generic products. The patent rights that protect its products are of varying strengths and durations. In addition, in some countries, patent protection is significantly weaker than in the U.S. or in the EU. In the U.S. and the EU, political pressure to reduce spending on prescription drugs has led to legislation and other measures that encourage the use of generic and biosimilar products. Although it is the Company's policy to actively protect its patent rights, generic challenges to the Company's products can arise at any time, and the Company's patents may not prevent the emergence of generic competition for its products.

Loss of patent protection for a product typically is followed promptly by generic substitutes, reducing the Company's sales of that product. Availability of generic substitutes for the Company's drugs may adversely affect its results of operations and cash flow. In addition, proposals emerge from time to time in the U.S. and other countries for legislation to further encourage the early and rapid approval of generic drugs. Any such proposal that is enacted into law could worsen this substantial negative effect on the Company's sales and, potentially, its business, cash flow, results of operations, financial condition and prospects.

The Company faces intense competition from competitors' products.

The Company's products face intense competition from competitors' products. This competition may increase as new products enter the market. In such an event, the competitors' products may be safer or more effective, more convenient to use, have better insurance coverage or reimbursement levels or be more effectively marketed and sold than the Company's products. Alternatively, in the case of generic competition, including the generic availability of competitors' branded products, they may be equally safe and effective products that are sold at a substantially lower price than the Company's products. As a result, if the Company fails to maintain its competitive position, this could have a material adverse effect on its business, cash flow, results of operations, financial condition and prospects. In addition, if products that were measured at fair value and capitalized in

connection with acquisitions experience difficulties in the market that negatively impact product cash flows, the Company may recognize material non-cash impairment charges with respect to the value of those products.

In 2021 and 2020, COVID-19-related disruptions had an adverse impact on the Company's business, operations and financial performance. The Company is unable to predict the full extent to which the COVID-19 pandemic or any future pandemic, epidemic or similar public health threat will adversely impact its business, operations, financial performance, results of operations, and financial condition.

The Company's business and financial results were negatively impacted by COVID-19-related disruptions in 2021 and 2020. The continued duration and severity of the COVID-19 pandemic is uncertain, rapidly changing and difficult to predict. The degree to which COVID-19-related disruptions impact the Company's results in 2022 will depend on future developments, beyond the Company's knowledge or control, including, but not limited to, the duration of the pandemic, its severity, the success of actions taken to contain or prevent the virus or treat its impact, and how quickly and to what extent normal economic and operating conditions can resume.

In 2021, the COVID-19 pandemic impacted the Company's business in numerous ways. As expected, within the Company's human health business, which is comprised largely of physician-administered products, revenue was negatively impacted by social distancing measures and fewer well visits, which negatively affected vaccine and oncology sales in particular. The estimated negative impact of COVID-19-related disruptions to Merck's revenue for the full year 2021 was approximately $1.3 billion, attributable to the Pharmaceutical segment.

Merck believes that global health systems and patients have largely adapted to the impacts of COVID-19, however, roughly 75% of Merck's Pharmaceutical segment revenue is comprised of physician-administered products which could be adversely affected by the pandemic if its effects worsen. Despite the Company's efforts to manage the impacts of the COVID-19 pandemic, their ultimate effect will also depend on factors beyond the Company's knowledge or control, including the duration of the COVID-19 pandemic as well as governmental and third-party actions taken to contain or prevent the spread and treatment of the virus and mitigate its public health and economic effects. In addition, any future pandemic, epidemic or similar public health threat could present similar risks to the Company's business, cash flow, results of operations, financial condition and prospects.

The Company has significant global operations, which expose it to additional risks, and any adverse event could have a material adverse effect on the Company's results of operations and financial condition.

The extent of the Company's operations outside the U.S. is significant. Risks inherent in conducting a global business include:

- changes in medical reimbursement policies and programs and pricing restrictions in key markets;
- multiple regulatory requirements that could restrict the Company's ability to manufacture and sell its products in key markets;
- trade protection measures and import or export licensing requirements, including the imposition of trade sanctions or similar restrictions by the U.S. or other governments;
- foreign exchange fluctuations;
- diminished protection of intellectual property in some countries; and
- possible nationalization and expropriation.

In addition, there may be changes to the Company's business and political position if there is instability, disruption or destruction in a significant geographic region, regardless of cause, including war, terrorism, riot, civil insurrection or social unrest; and natural or man-made disasters, including famine, flood, fire, earthquake, storm or disease. In particular, in February 2022, armed conflict escalated between Russia and Ukraine. It is not possible to predict the broader consequences of this conflict, which could include sanctions, embargoes, regional instability, geopolitical shifts and adverse effects on macroeconomic conditions, currency exchange rates and financial markets.

Climate change or legal, regulatory or market measures to address climate change may negatively affect the Company's business, results of operations, cash flows and prospects.

The Company believes that climate change has the potential to negatively affect its business and results of operations, cash flows and prospects. The Company is exposed to physical risks (such as extreme weather conditions or rising sea levels), risks in transitioning to a low-carbon economy (such as additional legal or regulatory requirements, changes in technology, market risk and reputational risk) and social and human effects (such as population dislocations and harm to health and well-being) associated with climate change. These risks can be either acute (short-term) or chronic (long-term).

The adverse impacts of climate change include increased frequency and severity of natural disasters and extreme weather events such as hurricanes, tornados, wildfires (exacerbated by drought), flooding, and extreme heat. Extreme weather and sea-level rise pose physical risks to the Company's facilities as well as those of its suppliers. Such risks include losses incurred as a result of physical damage to facilities, loss or spoilage of inventory, and business interruption caused by such natural disasters and extreme weather events. Other potential physical impacts due to climate change include reduced access to high-quality water in certain regions and the loss of biodiversity, which could impact future product development. These risks could disrupt the Company's operations and its supply chain, which may result in increased costs.

New legal or regulatory requirements may be enacted to prevent, mitigate, or adapt to the implications of a changing climate and its effects on the environment. These regulations, which may differ across jurisdictions, could result in the Company being subject to new or expanded carbon pricing or taxes, increased compliance costs, restrictions on greenhouse gas emissions, investment in new technologies, increased carbon disclosure and transparency, upgrade of facilities to meet new building codes, and the redesign of utility systems, which could increase the Company's operating costs, including the cost of electricity and energy used by the Company. The Company's supply chain would likely be subject to these same transitional risks and would likely pass along any increased costs to the Company.

Environmental, social and governance (ESG) matters may impact the Company's business and reputation.

Governmental authorities, non-governmental organizations, customers, investors, external stakeholders and employees are increasingly sensitive to ESG concerns, such as diversity and inclusion, climate change, water use, recyclability or recoverability of packaging, and plastic waste. This focus on ESG concerns may lead to new requirements that could result in increased costs associated with developing, manufacturing and distributing the Company's products. The Company's ability to compete could also be affected by changing customer preferences and requirements, such as growing demand for more environmentally friendly products, packaging or supplier practices, or by failure to meet such customer expectations or demand. While the Company strives to improve its ESG performance, the Company risks negative stockholder reaction, including from proxy advisory services, as well as damage to its brand and reputation, if the Company does not act responsibly, or if the Company is perceived to not be acting responsibly in key ESG areas, including equitable access to medicines and vaccines, product quality and safety, diversity and inclusion, environmental stewardship, support for local communities, corporate governance and transparency, and addressing human capital factors in the Company's operations. If the Company does not meet the ESG expectations of its investors, customers and other stakeholders, the Company could experience reduced demand for its products, loss of customers, and other negative impacts on the Company's business and results of operations.

Failure to attract and retain highly qualified personnel could affect the Company's ability to successfully develop and commercialize products.

The Company's success is largely dependent on its continued ability to attract and retain highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical research and development, governmental regulation and commercialization. Competition for qualified personnel in the pharmaceutical industry, both in the U.S. and internationally, is intense. The Company cannot be sure that it will be able to attract and retain quality personnel or that the costs of doing so will not materially increase.

The Company may experience difficulties and delays in manufacturing certain of its products, including vaccines.

Merck has, in the past, experienced difficulties in manufacturing certain of its products, including vaccines. For example, in 2020 the Company issued a product recall for *Zerbaxa* following the identification of product sterility issues. The Company may, in the future, experience other difficulties and delays in manufacturing its products, such as (i) failure of the Company or any of its vendors or suppliers to comply with Current Good Manufacturing Practices and other applicable regulations and quality assurance guidelines that could lead to manufacturing shutdowns, product shortages and delays in product manufacturing; (ii) delays related to the construction of new facilities or the expansion of existing facilities, including those intended to support future demand for the Company's products; and (iii) other manufacturing or distribution problems including supply chain delays, shortages in raw materials, changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, changes in types of products produced, or physical limitations that could impact continuous supply. In addition, the Company could experience difficulties or delays in manufacturing its products caused by natural disasters, such as hurricanes. Manufacturing difficulties can result in product shortages, leading to lost sales and reputational harm to the Company.

The Company may not be able to realize the expected benefits of its investments in emerging markets.

The Company has been taking steps to increase its sales in emerging markets. However, there is no guarantee that the Company's efforts to expand sales in these markets will succeed. Some countries within emerging markets may be especially vulnerable to periods of global financial instability or may have very limited resources to spend on health care. In order for the Company to successfully implement its emerging markets strategy, it must attract and retain qualified personnel. The Company may also be required to increase its reliance on third-party agents within less developed markets, which may affect its ability to realize continued growth and may also increase the Company's risk exposure. In addition, many of these countries have currencies that fluctuate substantially and, if such currencies devalue and the Company cannot offset the devaluations, the Company's financial performance within such countries could be adversely affected.

The Company's business in China has grown rapidly in the past few years, and the importance of China to the Company's overall pharmaceutical and vaccines business outside the U.S. has increased accordingly. Continued growth of the Company's business in China is dependent upon ongoing development of a favorable environment for innovative pharmaceutical products and vaccines, sustained access for the Company's currently marketed products, and the absence of trade impediments or adverse pricing controls. As noted above in "Competition and the Health Care Environment," pricing pressure in China has increased as the Chinese government has been taking steps to reduce costs, including implementing health care reform that has led to the acceleration of generic substitution, where available. While the mechanism for drugs being added to the NRDL evolves, inclusion may require a price negotiation which could impact the outlook in the market for selected brands. In 2021, drugs were added to the NRDL with an average of more than 60% price reductions. While pricing pressure has always existed in China, health care reform has increased this pressure in part due to the acceleration of generic substitution through the government's VBP program. In 2019, the government implemented the VBP program through a tendering process for mature products which have generic substitutes with a Generic Quality Consistency Evaluation approval. Mature products that have entered into the last five rounds of VBP had, on average, a price reduction of more than 50%. The Company expects VBP to be a semi-annual process that will have a significant impact on mature products moving forward. In addition, the Company anticipates that the reported inquiries made by various governmental authorities involving multinational pharmaceutical companies in China may continue.

For all these reasons, sales within emerging markets carry significant risks. However, at the same time macro-economic growth of selected emerging markets is expected to outpace Europe and even the U.S., leading to significant increased health care spending in those countries and access to innovative medicines for patients. A failure to maintain the Company's presence in emerging markets could therefore have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects.

The Company is exposed to market risk from fluctuations in currency exchange rates and interest rates.

The Company operates in multiple jurisdictions and virtually all sales are denominated in currencies of the local jurisdiction. Additionally, the Company has entered and will enter into business development transactions, borrowings or other financial transactions that may give rise to currency and interest rate exposure.

Since the Company cannot, with certainty, foresee and mitigate against such adverse fluctuations, fluctuations in currency exchange rates, interest rates and inflation could negatively affect the Company's business, cash flow, results of operations, financial condition and prospects.

In order to mitigate against the adverse impact of these market fluctuations, the Company will from time to time enter into hedging agreements. While hedging agreements, such as currency options and forwards and interest rate swaps, may limit some of the exposure to exchange rate and interest rate fluctuations, such attempts to mitigate these risks may be costly and not always successful.

Certain of the Company's interest rate derivatives and investments are based on the London Interbank Offered Rate (LIBOR), and a portion of Merck's indebtedness bears interest at variable interest rates, primarily based on LIBOR. LIBOR is the subject of recent national, international and other regulatory guidance and proposals for reform, which will cause LIBOR to cease to exist entirely in the future. While the Company has begun to implement alternative reference rates as alternatives to LIBOR, the Company cannot predict the consequences and timing of any additional or unexpected developments, which could include an increase in interest expense and will also require the amendment of contracts that reference LIBOR.

Pharmaceutical products can develop unexpected safety or efficacy concerns.

Unexpected safety or efficacy concerns can arise with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals, or declining sales, as well as product liability, consumer fraud and/or other claims, including potential civil or criminal governmental actions.

Reliance on third-party relationships and outsourcing arrangements could materially adversely affect the Company's business.

The Company depends on third parties, including suppliers, alliances with other pharmaceutical and biotechnology companies, and third-party service providers, for key aspects of its business including development, manufacture and commercialization of its products and support for its information technology (IT) systems. Failure of these third parties to meet their contractual, regulatory and other obligations to the Company or the development of factors that materially disrupt the relationships between the Company and these third parties could have a material adverse effect on the Company's business.

Negative events in the animal health industry could have a material adverse effect on future results of operations and financial condition.

Future sales of key animal health products could be adversely affected by a number of risk factors including certain risks that are specific to the animal health business. For example, the outbreak of disease carried by animals, such as African Swine Fever, could lead to their widespread death and precautionary destruction as well as the reduced consumption and demand for animals, which could adversely affect the Company's results of operations. Also, the outbreak of any highly contagious diseases near the Company's main production sites could require the Company to immediately halt the manufacture of its animal health products at such sites or force the Company to incur substantial expenses in procuring raw materials or products elsewhere. Other risks specific to animal health include epidemics and pandemics, government procurement and pricing practices, weather and global agribusiness economic events. In addition, sales of *Bravecto* represent a significant portion of the Company's Animal Health segment sales. Any negative event with respect to *Bravecto* could have a material adverse effect on the Company's Animal Health sales. As the Animal Health segment of the Company's business becomes more significant, the impact of any such events on future results of operations would also become more significant.

Biologics and vaccines carry unique risks and uncertainties, which could have a material adverse effect on the Company's future results of operations and financial condition.

The successful development, testing, manufacturing and commercialization of biologics and vaccines, particularly human and animal health vaccines, is a long, complex, expensive and uncertain process. There are unique risks and uncertainties related to biologics and vaccines, including:

- There may be limited access to, and supply of, normal and diseased tissue samples, cell lines, pathogens, bacteria, viral strains and other biological materials. In addition, government regulations in multiple jurisdictions, such as the U.S. and the EU, could result in restricted access to, or transport or use of, such materials. If the Company loses access to sufficient sources of such materials, or if tighter restrictions are imposed on the use of such materials, the Company may not be able to conduct research activities as planned and may incur additional development costs.
- The development, manufacturing and marketing of biologics and vaccines are subject to regulation by the FDA, the EMA and other regulatory bodies. These regulations are often more complex and extensive than the regulations applicable to other pharmaceutical products. For example, in the U.S., a BLA, including both pre-clinical and clinical trial data and extensive data regarding the manufacturing procedures, is required for human vaccine candidates, and FDA approval is generally required for the release of each manufactured commercial human vaccine lot.
- Manufacturing biologics and vaccines, especially in large quantities, is often complex and may require the use of innovative technologies to handle living micro-organisms. Each lot of an approved biologic and vaccine must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, the Company may be required to provide pre-clinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes.
- Biologics and vaccines are frequently costly to manufacture because production ingredients are derived from living animal or plant material, and most biologics and vaccines cannot be made synthetically. In particular, keeping up with the demand for vaccines may be difficult due to the complexity of producing vaccines.
- The use of biologically derived ingredients can lead to variability in the manufacturing process and could lead to allegations of harm, including infections or allergic reactions, which allegations would be reviewed through a standard investigation process that could lead to closure of product facilities due to possible contamination. Any of these events could result in substantial costs.

Risks Relating to Government Regulation and Legal Proceedings

The health care industry in the U.S. has been, and will continue to be, subject to increasing regulation and political action.

As discussed above in "Competition and the Health Care Environment," the Company believes that the health care industry will continue to be subject to increasing regulation as well as political and legal action, as future proposals to reform the health care system are considered by the Executive branch, Congress and state legislatures.

In 2016, the Centers for Medicare & Medicaid Services (CMS) issued the Medicaid rebate final rule that implemented provisions of the ACA effective April 1, 2016. The rule provides comprehensive guidance on the calculation of Average Manufacturer Price and Best Price; two metrics utilized to determine the rebates drug manufacturers are required to pay to state Medicaid programs. On December 21, 2020, the CMS issued a final rule making significant changes to these requirements. Effective January 1, 2023, this final rule also changes the way that manufacturers must calculate Best Price, in relation to certain patient support programs, including coupons. PhRMA, a pharmaceutical industry trade group, of which the Company is a member, filed a complaint challenging this rule as invalid asserting that it conflicts with the plain language of the Medicaid drug rebate statute. Should this legal

challenge fail, the impact of this and other provisions in this final rule could adversely impact the Company's business, cash flow, results of operations, financial condition and prospects.

In 2021, Congress passed the American Rescue Plan Act of 2021, which included a provision that eliminates the statutory cap on rebates drug manufacturers pay to Medicaid beginning in January 2024. These rebates act as a discount off the list price and eliminating the cap means that manufacturer discounts paid to Medicaid can increase. Prior to this change, manufacturers have not been required to pay more than 100% of the Average Manufacturer Price (AMP) in rebates to state Medicaid programs for Medicaid-covered drugs. As a result of this provision, beginning in 2024, it is possible that manufacturers may have to pay state Medicaid programs more in rebates than they received on sales of particular products. This change could present a risk to Merck in the future for drugs that have high Medicaid utilization and rebate exposure that is more than 100% of the AMP.

In the U.S., the Biden Administration and Congress continue to discuss legislation designed to control health care costs, including the cost of drugs. The Company cannot predict what additional future changes in the health care industry in general, or the pharmaceutical industry in particular, will occur; however, any changes could have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects.

The Company's products, including products in development, cannot be marketed unless the Company obtains and maintains regulatory approval.

The Company's activities, including research, pre-clinical testing, clinical trials and the manufacturing and marketing of its products, are subject to extensive regulation by numerous federal, state and local governmental authorities in the U.S., including the FDA, and by foreign regulatory authorities, including in the EU, Japan and China. In the U.S., the FDA administers requirements covering the testing, approval, safety, effectiveness, manufacturing, labeling and marketing of prescription pharmaceuticals. In some cases, the FDA requirements have increased the amount of time and resources necessary to develop new products and bring them to market in the U.S. Regulation outside the U.S. also is primarily focused on drug safety and effectiveness and, in many cases, reduction in the cost of drugs. The FDA and foreign regulatory authorities, including in the EU, Japan and China, have substantial discretion to require additional testing, to delay or withhold registration and marketing approval and to otherwise preclude distribution and sale of a product.

Even if the Company is successful in developing new products, it will not be able to market any of those products unless and until it has obtained all required regulatory approvals in each jurisdiction where it proposes to market the new products. Once obtained, the Company must maintain approval as long as it plans to market its new products in each jurisdiction where approval is required. The Company's failure to obtain approval, significant delays in the approval process, or its failure to maintain approval in any jurisdiction will prevent it from selling the products in that jurisdiction. The Company would not be able to realize revenues for those new products in any jurisdiction where it does not have approval.

Developments following regulatory approval may adversely affect sales of the Company's products.

Even after a product reaches the market, certain developments following regulatory approval may decrease demand for the Company's products, including the following:

- results in post-approval Phase 4 trials or other studies;
- the re-review of products that are already marketed;
- the recall or loss of marketing approval of products that are already marketed;
- changing government standards or public expectations regarding safety, efficacy, quality or labeling changes;
- scrutiny of advertising and promotion; and
- the withdrawal of indications granted pursuant to accelerated approvals.

In the past, clinical trials and post-marketing surveillance of certain marketed drugs of the Company and of competitors within the industry have raised concerns that have led to recalls, withdrawals or adverse labeling of

marketed products. Clinical trials and post-marketing surveillance of certain marketed drugs also have raised concerns among some prescribers and patients relating to the safety or efficacy of pharmaceutical products in general that have negatively affected the sales of such products. In addition, increased scrutiny of the outcomes of clinical trials has led to increased volatility in market reaction. Further, these matters often attract litigation and, even where the basis for the litigation is groundless, considerable resources may be needed to respond.

In addition, following in the wake of product withdrawals and other significant safety issues, health authorities such as the FDA, the EMA, Japan's PMDA and China's NMPA have increased their focus on safety when assessing the benefit/risk balance of drugs. Some health authorities appear to have become more cautious when making decisions about approvability of new products or indications.

If previously unknown side effects are discovered or if there is an increase in negative publicity regarding known side effects of any of the Company's products, it could significantly reduce demand for the product or require the Company to take actions that could negatively affect sales, including removing the product from the market, restricting its distribution or applying for labeling changes. Further, in the current environment in which all pharmaceutical companies operate, the Company is at risk for product liability and consumer protection claims and civil and criminal governmental actions related to its products, research and/or marketing activities. In addition, dissemination of promotional materials through evolving digital channels serves to increase visibility and scrutiny in the marketplace.

The Company is subject to a variety of U.S. and international laws and regulations.

The Company is currently subject to a number of government laws and regulations and, in the future, could become subject to new government laws and regulations. The costs of compliance with such laws and regulations, or the negative results of non-compliance, could adversely affect the business, cash flow, results of operations, financial condition and prospects of the Company; these laws and regulations include (i) additional health care reform initiatives in the U.S. or in other countries, including additional mandatory discounts or fees; (ii) the U.S. Foreign Corrupt Practices Act or other anti-bribery and corruption laws; (iii) new laws, regulations and judicial or other governmental decisions affecting pricing, drug reimbursement, and access or marketing within or across jurisdictions; (iv) changes in intellectual property laws; (v) changes in accounting standards; (vi) new and increasing data privacy regulations and enforcement, particularly in the EU, the U.S., and China; (vii) legislative mandates or preferences for local manufacturing of pharmaceutical or vaccine products; (viii) emerging and new global regulatory requirements for reporting payments and other value transfers to health care professionals; (ix) environmental regulations; and (x) the potential impact of importation restrictions, embargoes, trade sanctions and legislative and/or other regulatory changes.

The Company is subject to evolving and complex tax laws, which may result in additional liabilities that may affect results of operations and financial condition.

The Company is subject to evolving and complex tax laws in the jurisdictions in which it operates. Significant judgment is required for determining the Company's tax liabilities, and the Company's tax returns are routinely examined by various tax authorities. In connection with the 2015 Organization for Economic Cooperation and Development (OECD) Base Erosion and Profit Shifting project, companies are required to disclose more information to tax authorities on operations around the world, which may lead to greater audit scrutiny of profits earned in other countries. The Company believes that its accrual for tax contingencies is adequate for all open years based on past experience, interpretations of tax law, and judgments about potential actions by tax authorities; however, due to the complexity of tax contingencies, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued. In addition, the Company may be negatively affected by changes in tax laws, or new tax laws, affecting, for example, tax rates, and/or revised tax law interpretations in domestic or foreign jurisdictions, including, among others, any potential changes to the existing U.S. tax law by the current U.S. Presidential administration and Congress, as well as any changes in tax law resulting from the implementation of the OECD's two-pillar solution to reform the international tax landscape.

The Company has taken the position, based on the opinions of tax counsel, that its distribution of Organon common stock in connection with the 2021 Spin-Off of Organon qualifies as a transaction that is tax-free for U.S. federal income tax purposes. If any facts, assumptions, representations, and undertakings from the Company and Organon regarding the past and future conduct of their respective businesses and other matters are

incorrect or not otherwise satisfied, the Spin-Off may not qualify for tax-free treatment, which could result in significant U.S. federal income tax liabilities for the Company and its shareholders.

Adverse outcomes in current or future legal matters could negatively affect Merck's business.

Current or future litigation, claims, proceedings and government investigations could preclude or delay the commercialization of Merck's products or could adversely affect Merck's business, results of operations, cash flow, prospects and financial condition. Such legal matters may include, but are not limited to: (i) intellectual property disputes; (ii) adverse decisions in litigation, including product safety and liability, consumer protection and commercial cases; (iii) anti-bribery regulations, such as the U.S. Foreign Corrupt Practices Act, including compliance with ongoing reporting obligations to the government resulting from any settlements; (iv) recalls or withdrawals of pharmaceutical products or forced closings of manufacturing plants; (v) product pricing and promotional matters; (vi) lawsuits, claims and administrative proceedings asserting, or investigations into, violations of securities, antitrust, Federal and state pricing, consumer protection, data privacy and other laws and regulations; (vii) environmental, health, safety and sustainability matters, including regulatory actions in response to climate change; and (viii) tax liabilities resulting from assessments from tax authorities. See Item 8. "Financial Statements and Supplementary Data," Note 11, "Contingencies and Environmental Liabilities" for more information on the Company's legal matters.

In 2021, Merck informed the U.S. Department of Health and Human Services, Health Resources and Services Administration (HHS) that Merck was implementing an update to its Section 340b program integrity initiative, pursuant to which Merck required all hospital covered entities to provide 340b claims data for all claims originating from contract pharmacies. For those entities that declined to submit such claims data, Merck's new initiative provided that it would no longer voluntarily honor 340b discounts or chargebacks for contract pharmacy transactions, except for a single contract pharmacy of the hospital covered entity's choice.

Also in 2021, HHS sent letters to numerous drug manufacturers stating that it had determined that those manufacturers' actions restricting contract pharmacy transactions were in violation of the 340b statute and further stating that if those manufacturers did not cease their restrictions, HHS might seek both repayment of overcharges as well as civil monetary penalties. Those manufacturers are now in litigation with the U.S. government seeking to confirm the legality of the restrictions.

Merck did not receive a similar letter from HHS. However, HHS could seek to implement administrative proceedings to recover overcharges and/or impose civil monetary penalties against Merck. If such proceedings were implemented against Merck a negative outcome could have a material adverse effect on Merck's business, results of operations, cash flow, prospects and financial condition.

Product liability insurance for products may be limited, cost prohibitive or unavailable.

As a result of a number of factors, product liability insurance has become less available while the cost of such insurance has increased significantly. The Company is subject to a substantial number of product liability claims. See Item 8. "Financial Statements and Supplementary Data," Note 11. "Contingencies and Environmental Liabilities" below for more information on the Company's current product liability litigation. With respect to product liability, the Company self-insures substantially all of its risk, as the availability of commercial insurance has become more restrictive. The Company has evaluated its risks and has determined that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and, as such, has no insurance for most product liabilities. The Company will continually assess the most efficient means to address its risk; however, there can be no guarantee that insurance coverage will be obtained or, if obtained, will be sufficient to fully cover product liabilities that may arise.

Risks Related to Technology

The Company is increasingly dependent on sophisticated software applications and computing infrastructure. In 2017, the Company experienced a network cyber-attack that led to a disruption of its worldwide operations, including manufacturing, research and sales operations. The Company could be a target of future cyber-attacks.

The Company is increasingly dependent on sophisticated software applications, complex information technology systems, computing infrastructure, and cloud service providers (collectively, IT systems) to conduct

critical operations. Certain of these systems are managed, hosted, provided or used by third parties to assist in conducting the Company's business. Disruption, degradation, or manipulation of these IT systems through intentional or accidental means by the Company's employees, third parties with authorized access or unauthorized third parties could adversely affect key business processes. Cyber-attacks against the Company's IT systems or third-party providers' IT systems, such as cloud-based systems, could result in exposure of confidential information, the modification of critical data, and/or the failure of critical operations. Misuse of any of these IT systems could result in the disclosure of sensitive personal information or the theft of trade secrets, intellectual property, or other confidential business information. The Company continues to leverage new and innovative technologies across the enterprise to improve the efficacy and efficiency of its business processes, including data acquisition; the use of which can create new risks.

In 2017, the Company experienced a network cyber-attack that led to a disruption of its worldwide operations, including manufacturing, research and sales operations, and resulting losses.

The Company has implemented a variety of measures to further enhance and modernize its systems to guard against similar attacks in the future, and also is pursuing an enterprise-wide effort to enhance the Company's resiliency against future cyber-attacks, including incidents similar to the 2017 attack. The objective of these efforts is not only to protect against future cyber-attacks, but also to improve the speed of the Company's recovery from such attacks and enable continued business operations to the greatest extent possible during any recovery period.

Although the aggregate impact of cyber-attacks and network disruptions, including the 2017 cyber-attack, on the Company's operations and financial condition has not been material to date, the Company continues to be a target of events of this nature and expects them to continue. The Company monitors its data, information technology and personnel usage of Company IT systems to reduce these risks and continues to do so on an ongoing basis for any current or potential threats. There can be no assurance that the Company's efforts to protect its data and IT systems or the efforts of third-party providers to protect their IT systems will be successful in preventing disruptions to the Company's operations, including its manufacturing, research and sales operations. Such disruptions have in the past and could in the future result in loss of revenue, or the loss of critical or sensitive information from the Company's or the Company's third-party providers' databases or IT systems and have in the past and could in the future also result in financial, legal, business or reputational harm to the Company and substantial remediation costs.

Social media and mobile messaging platforms present risks and challenges.

The inappropriate and/or unauthorized use of certain social media and mobile messaging channels could cause brand damage or information leakage or could lead to legal implications, including from the improper collection and/or dissemination of personally identifiable information. In addition, negative or inaccurate posts or comments about the Company or its products on any social networking platforms could damage the Company's reputation, brand image and goodwill. Further, the disclosure of non-public Company-sensitive information by the Company's workforce or others through external media channels could lead to information loss. Although there are internal Company Social Media and Mobile Messaging Policies that guide employees on appropriate personal and professional use of these platforms for communication about the Company, the processes in place may not completely secure and protect information. Identifying new points of entry as new communication tools expand also presents new challenges.

Cautionary Factors that May Affect Future Results

(Cautionary Statements Under the Private Securities Litigation Reform Act of 1995)

This report and other written reports and oral statements made from time to time by the Company may contain so-called "forward-looking statements," all of which are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially from those set forth in the statements. One can identify these forward-looking statements by their use of words such as "anticipates," "expects," "plans," "will," "estimates," "forecasts," "projects" and other words of similar meaning, or negative variations of any of the foregoing. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address the Company's growth strategy, financial results, product approvals, product potential, development programs, environmental or other sustainability initiatives, and include

statements related to the expected impact of the COVID-19 pandemic. One must carefully consider any such statement and should understand that many factors could cause actual results to differ materially from the Company's forward-looking statements. These factors include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. No forward-looking statement can be guaranteed and actual future results may vary materially. The Company does not assume the obligation to update any forward-looking statement. The Company cautions you not to place undue reliance on these forward-looking statements. Although it is not possible to predict or identify all such factors, they may include the following:

- Competition from generic and/or biosimilar products as the Company's products lose patent protection.
- Increased "brand" competition in therapeutic areas important to the Company's long-term business performance.
- The difficulties and uncertainties inherent in new product development. The outcome of the lengthy and complex process of new product development is inherently uncertain. A drug candidate can fail at any stage of the process and one or more late-stage product candidates could fail to receive regulatory approval. New product candidates may appear promising in development but fail to reach the market because of efficacy or safety concerns, the inability to obtain necessary regulatory approvals, the difficulty or excessive cost to manufacture and/or the infringement of patents or intellectual property rights of others. Furthermore, the sales of new products may prove to be disappointing and fail to reach anticipated levels.
- Pricing pressures, both in the U.S. and abroad, including rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and health care reform, pharmaceutical reimbursement and pricing in general.
- The impact of the global COVID-19 pandemic and any future pandemic, epidemic, or similar public health threat, on the Company's business, operations and financial performance.
- Changes in government laws and regulations, including laws governing intellectual property, and the enforcement thereof affecting the Company's business.
- Efficacy or safety concerns with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales.
- Significant changes in customer relationships or changes in the behavior and spending patterns of purchasers of health care products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing health care insurance coverage.
- Legal factors, including product liability claims, antitrust litigation and governmental investigations, including tax disputes, environmental concerns and patent disputes with branded and generic competitors, any of which could preclude commercialization of products or negatively affect the profitability of existing products.
- Cyber-attacks on the Company's or third-party providers' information technology systems, which could disrupt the Company's operations.
- Lost market opportunity resulting from delays and uncertainties in the approval process of the FDA and foreign regulatory authorities.
- Increased focus on privacy issues in countries around the world, including the U.S., the EU, and China. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect directly the Company's business, including recently enacted laws in a majority of states in the U.S. requiring security breach notification.
- Changes in tax laws including changes related to the taxation of foreign earnings.
- Changes in accounting pronouncements promulgated by standard-setting or regulatory bodies, including the Financial Accounting Standards Board and the SEC, that are adverse to the Company.

- Economic factors over which the Company has no control, including changes in inflation, interest rates and foreign currency exchange rates.

This list should not be considered an exhaustive statement of all potential risks and uncertainties. See “Risk Factors” above.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

The Company’s corporate headquarters is currently located in Kenilworth, New Jersey. The Company has previously announced that it intends to consolidate its New Jersey campuses into a single corporate headquarters location in Rahway, New Jersey by the end of 2023. The Company also maintains operational or divisional headquarters in Kenilworth, New Jersey; Madison, New Jersey and Upper Gwynedd, Pennsylvania. Principal U.S. research facilities are located in Rahway and Kenilworth, New Jersey; West Point, Pennsylvania; Boston and Cambridge, Massachusetts; South San Francisco, California; and Elkhorn, Nebraska (Animal Health). Principal research facilities outside the U.S. are located in the United Kingdom, Switzerland and China. Merck’s manufacturing operations are currently headquartered in Whitehouse Station, New Jersey. The Company also has production facilities for human health products at seven locations in the U.S. and Puerto Rico. Outside the U.S., through subsidiaries, the Company owns or has an interest in manufacturing plants or other properties in Japan, Singapore, South Africa, and other countries in Western Europe, Central and South America, and Asia. A number of properties were transferred to Organon in the Spin-Off.

Capital expenditures were $4.4 billion in 2021, $4.4 billion in 2020 and $3.4 billion in 2019. In the U.S., these amounted to $2.8 billion in 2021, $2.6 billion in 2020 and $1.9 billion in 2019. Abroad, such expenditures amounted to $1.6 billion in 2021, $1.8 billion in 2020, and $1.5 billion in 2019.

The Company and its subsidiaries own their principal facilities and manufacturing plants under titles that they consider to be satisfactory. The Company believes that its properties are in good operating condition and that its machinery and equipment have been well maintained. The Company believes that its plants for the manufacture of products are suitable for their intended purposes and have capacities and projected capacities, including previously disclosed capital expansion projects, that will be adequate for current and projected needs for existing Company products. Some capacity of the plants is being converted, with any needed modification, to the requirements of newly introduced and future products.

Item 3. Legal Proceedings.

The information called for by this Item is incorporated herein by reference to Item 8. “Financial Statements and Supplementary Data,” Note 11. “Contingencies and Environmental Liabilities”.

Item 4. Mine Safety Disclosures.

Not Applicable.

Executive Officers of the Registrant (ages as of February 1, 2022)

All officers listed below serve at the pleasure of the Board of Directors. None of these officers was elected pursuant to any arrangement or understanding between the officer and any other person(s).

Name	Age
Robert M. Davis	55
Sanat Chattopadhyay	62
Richard R. DeLuca, Jr.	59
Cristal Downing	53
Kenneth C. Frazier	67
Julie L. Gerberding	65
Rita A. Karachun	58
Michael A. Klobuchar	46
Lisa LeCointe-Cephas	40
Dean Li	59
Caroline Litchfield	53

On February 16, 2022, the Company announced that Ms. Arpa Garay will lead Human Health Global Marketing and Mr. Jannie Oosthuizen will lead U.S. Human Health. Both Ms. Garay and Mr. Oosthuizen will become Executive Officers of the Company, effective February 28, 2022.

Name	Age	Offices and Business Experience
Arpa Garay	43	President, Global Oncology and Digital (since January 2022); President, Global Pharmaceuticals, Commercial Analytics, Digital Marketing (March 2019-January 2022); Senior Vice President, U.S. Vaccines Business Unit (June 2017-March 2019); Prior to that, Managing Director MSD, Norway
Jannie Oosthuizen	54	Senior Vice President and President Merck U.S. Human Health (since January 2022); Senior Vice President and Head of Global Oncology Commercial (January 2021-December 2021); Senior Vice President and President of MSD K.K. (July 2016-December 2020)

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

The principal market for trading of the Company's Common Stock is the New York Stock Exchange (NYSE) under the symbol MRK.

As of January 31, 2022, there were approximately 99,932 shareholders of record of the Company's Common Stock.

Issuer purchases of equity securities for the three months ended December 31, 2021 were as follows:

Issuer Purchases of Equity Securities

				($ in millions)
Period	Total Number of Shares Purchased[1]	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs[1]
October 1 — October 31	246,194	$74.92	246,194	$5,047
November 1 — November 30	—	—	—	$5,047
December 1 — December 31	—	—	—	$5,047
Total	246,194	$74.92	246,194	

[1] *All shares purchased during the period were made as part of a plan approved by the Board of Directors in October 2018 to purchase up to $10 billion in Merck shares for its treasury.*

Performance Graph

The following graph assumes a $100 investment on December 31, 2016, and reinvestment of all dividends, in each of the Company's Common Stock, the S&P 500 Index, and a composite peer group of major U.S. and European-based pharmaceutical companies, which are: AbbVie Inc., Amgen Inc., AstraZeneca plc, Bristol-Myers Squibb Company, Johnson & Johnson, Eli Lilly and Company, GlaxoSmithKline plc, Novartis AG, Pfizer Inc., Roche Holding AG, and Sanofi SA.

Comparison of Five-Year Cumulative Total Return
Merck & Co., Inc., Composite Peer Group and S&P 500 Index

	End of Period Value	2021/2016 CAGR*
MERCK	$159	10%
PEER GROUP**	201	15%
S&P 500	233	18%

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	2016	2017	2018	2019	2020
MERCK	100.0	98.5	137.9	168.6	156.5
PEER GROUP	100.0	120.0	128.4	152.6	163.6
S&P 500	100.0	121.8	116.5	153.1	181.3

* *Compound Annual Growth Rate*
** *Peer group average was calculated on a market cap weighted basis as of December 31, 2016.*

This Performance Graph will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that the Company specifically incorporates it by reference. In addition, the Performance Graph will not be deemed to be "soliciting material" or to be "filed" with the SEC or subject to Regulation 14A or 14C, other than as provided in Regulation S-K, or to the liabilities of section 18 of the Securities Exchange Act of 1934, except to the extent that the Company specifically requests that such information be treated as soliciting material or specifically incorporates it by reference into a filing under the Securities Act or the Exchange Act.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Description of Merck's Business

Merck & Co., Inc. (Merck or the Company) is a global health care company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies and animal health products. The Company's operations are principally managed on a products basis and include two operating segments, which are the Pharmaceutical and Animal Health segments, both of which are reportable segments.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities.

The Animal Health segment discovers, develops, manufactures and markets a wide range of veterinary pharmaceutical and vaccine products, as well as health management solutions and services, for the prevention, treatment and control of disease in all major livestock and companion animal species. The Company also offers an extensive suite of digitally connected identification, traceability and monitoring products. The Company sells its products to veterinarians, distributors and animal producers.

The Company previously had a Healthcare Services segment that provided services and solutions focused on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company divested the remaining businesses in this segment during the first quarter of 2020.

Spin-Off of Organon & Co.

On June 2, 2021, Merck completed the spin-off of products from its women's health, biosimilars and established brands businesses into a new, independent, publicly traded company named Organon & Co. (Organon) through a distribution of Organon's publicly traded stock to Company shareholders. The distribution is expected to qualify and has been treated as tax-free to the Company and its shareholders for U.S. federal income tax purposes. The established brands included in the transaction consisted of dermatology, non-opioid pain management, respiratory, select cardiovascular products, as well as the rest of Merck's diversified brands franchise. Merck's existing research pipeline programs continue to be owned and developed within Merck as planned. The historical results of the businesses that were contributed to Organon in the spin-off have been reflected as discontinued operations in the Company's consolidated financial statements through the date of the spin-off (see Note 3 to the consolidated financial statements).

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Overview

Financial Highlights

($ in millions)	**2021**	**% Change**	**% Change Excluding Foreign Exchange**	2020	% Change	% Change Excluding Foreign Exchange	2019
Sales	**$ 48,704**	**17 %**	**16 %**	$ 41,518	6 %	8 %	$ 39,121
Net Income from Continuing Operations Attributable to Merck & Co., Inc.:							
GAAP	**$ 12,345**	*	*	$ 4,519	(21)%	(16)%	$ 5,690
Non-GAAP [(1)]	**$ 15,282**	**33 %**	**31 %**	$ 11,506	20 %	23 %	$ 9,617
Earnings per Common Share Assuming Dilution from Continuing Operations Attributable to Merck & Co., Inc. Common Shareholders:							
GAAP	**$ 4.86**	*	*	$ 1.78	(19)%	(15)%	$ 2.21
Non-GAAP [(1)]	**$ 6.02**	**33 %**	**32 %**	$ 4.53	21 %	25 %	$ 3.73

** Calculation not meaningful.*

(1) Non-GAAP net income and non-GAAP earnings per share (EPS) exclude acquisition and divestiture-related costs, restructuring costs and certain other items. For further discussion and a reconciliation of GAAP to non-GAAP net income and EPS (see "Non-GAAP Income and Non-GAAP EPS" below).

Executive Summary

During 2021, Merck delivered on its strategic priorities by executing commercially to drive strong revenue and earnings growth in the year, completing key business development transactions, accelerating its broad pipeline, and achieving notable regulatory milestones. Also, on June 2, 2021, Merck completed the spin-off of Organon. The historical results of the businesses that were contributed to Organon in the spin-off have been reflected as discontinued operations in the Company's consolidated financial statements through the date of the spin-off.

Worldwide sales were $48.7 billion in 2021, an increase of 17% compared with 2020, or 16% excluding the favorable effect of foreign exchange. The sales increase was driven primarily by growth in oncology, vaccines, hospital acute care and animal health. Additionally, revenue in 2021 reflects the benefit of sales of molnupiravir, an investigational oral antiviral COVID-19 treatment. As discussed below, COVID-19-related disruptions negatively affected sales in 2021, but to a lesser extent than in 2020, which benefited year-over-year sales growth.

Merck continues to execute scientifically compelling business development opportunities to augment its pipeline. In November 2021, Merck acquired Acceleron Pharma Inc. (Acceleron), a publicly traded biopharmaceutical company evaluating the transforming growth factor (TGF)-beta superfamily of proteins through the development of pulmonary and hematologic therapies. In April 2021, Merck acquired Pandion Therapeutics, Inc. (Pandion), a clinical-stage biotechnology company developing novel therapeutics designed to address the unmet needs of patients living with autoimmune diseases. Additionally, Merck entered into a collaboration with Gilead Sciences, Inc. (Gilead) to jointly develop and commercialize long-acting treatments in HIV.

In 2021, Merck received over 30 approvals and filed over 20 New Drug Applications (NDAs) and supplemental Biologics License Applications (BLAs) across the U.S., the EU, Japan and China. During 2021, the Company received numerous regulatory approvals within oncology. *Keytruda* received approval for additional indications in the U.S. and/or internationally as monotherapy in the therapeutic areas of breast, colorectal, cutaneous squamous cell, esophageal, melanoma and renal cell cancers, as well as in combination with chemotherapy in the therapeutic areas of breast, cervical, gastric or gastroesophageal junction cancers. *Keytruda* was also approved in combination with Lenvima both for the treatment of certain adult patients with endometrial cancer and for the treatment of renal cell cancer. Lenvima is being developed in collaboration with Eisai Co., Ltd. (Eisai). Lynparza, which is being developed in collaboration with AstraZeneca PLC (AstraZeneca), received approval in China as

monotherapy for the treatment of certain adult patients with metastatic castration resistant prostate cancer. Additionally, the U.S. Food and Drug Administration (FDA) approved *Welireg* (belzutifan), an oral hypoxia-inducible factor-2 alpha (HIF-2α) inhibitor, for the treatment of adult patients with von Hippel-Lindau (VHL)

disease who require therapy for associated renal cell carcinoma (RCC), central nervous system hemangioblastomas, or pancreatic neuroendocrine tumors, not requiring immediate surgery.

Also in 2021, as updated in February 2022, the FDA granted Emergency Use Authorization (EUA) for molnupiravir, an investigational oral antiviral COVID-19 treatment being developed in a collaboration with Ridgeback Biotherapuetics LP (Ridgeback). Molnupiravir also received conditional marketing authorization in the United Kingdom (UK) and Special Approval for Emergency in Japan. Also in 2021, the FDA and the European Commission (EC) approved *Vaxneuvance* (Pneumococcal 15-valent Conjugate Vaccine), a pneumococcal conjugate vaccine for use in adults. Additionally, Verquvo, a medicine to reduce the risk of cardiovascular death and heart failure hospitalization following a hospitalization for heart failure or need for outpatient intravenous diuretics in adults was approved in the U.S., the EU and Japan. Verquvo is being jointly developed with Bayer AG (Bayer). In January 2022, the Japan Ministry of Health, Labor and Welfare (MHLW) approved *Lyfnua* (gefapixant) for adults with refractory or unexplained chronic cough.

In addition to the recent regulatory approvals discussed above, the Company advanced its late-stage pipeline with several regulatory submissions.

Keytruda is under review in the U.S. and/or internationally for supplemental indications for the treatment of certain patients with triple negative breast, cervical, endometrial, melanoma, renal cell and tumor mutation burden-high (TMBH) cancers. Lynparza is under review for supplemental indications for the treatment of certain patients with breast and prostate cancers. Lenvima is under review in combination with *Keytruda* for a supplemental indication for the treatment of certain patients with hepatocellular carcinoma (HCC). MK-4482, molnupiravir, is under a rolling review by the European Medicines Agency (EMA); MK-7264, gefapixant, a selective, non-narcotic, orally-administered, investigational P2X3-receptor antagonist being developed for the treatment of refractory, chronic cough is under review in the U.S. and the EU; and *Vaxneuvance* (V114), a 15-valent pneumococcal conjugate vaccine, is under priority review by the FDA for the prevention of invasive pneumococcal disease in pediatric patients. V114 is also under review in Japan for use in adults.

The Company's Phase 3 oncology programs include:

- *Keytruda* in the therapeutic areas of biliary, cutaneous squamous cell, gastric, hepatocellular, mesothelioma, ovarian, prostate and small-cell lung cancers;
- Lynparza as monotherapy for colorectal cancer and in combination with *Keytruda* for non-small-cell lung and small-cell lung cancers;
- Lenvima in combination with *Keytruda* for colorectal, esophageal, gastric, head and neck, melanoma and non-small-cell lung cancers;
- *Welireg* for RCC;
- MK-1308A, the coformulation of quavonlimab, Merck's novel investigational anti-CTLA-4 antibody, and pembrolizumab for RCC;
- MK-3475, pembrolizumab subcutaneous for non-small-cell lung cancer (NSCLC);
- MK-7119, Tukysa (tucatinib), which is being developed in collaboration with Seagen Inc. (Seagen), for breast cancer;
- MK-4280A, the coformulation of favezelimab, Merck's novel investigational anti-LAG3 therapy, and pembrolizumab for colorectal cancer; and
- MK-7684A, the coformulation of vibostolimab, an anti-TIGIT therapy, and pembrolizumab for NSCLC.

Additionally, the Company has candidates in Phase 3 clinical development in several other therapeutic areas including:

- MK-7962, sotatercept, for the treatment of pulmonary arterial hypertension (PAH), which was obtained in the Acceleron acquisition;
- MK-1654, clesrovimab, for the prevention of respiratory syncytial virus;
- MK-8591, islatravir, an investigational nucleoside reverse transcriptase translocation inhibitor (NRTTI) for the prevention of HIV-1 infection (which is on clinical hold);

- MK-8591A, islatravir in combination with doravirine for the treatment of HIV-1 infection (which is on clinical hold); and
- MK-4482, molnupiravir, which is reflected in Phase 3 development in the U.S. as it remains investigational following EUA.

The Company is allocating resources to support its commercial opportunities in the near term while investing heavily in research to support future innovations and long-term growth. Research and development expenses in 2021 reflect higher clinical development spending and increased investment in discovery research and early drug development.

In November 2021, Merck's Board of Directors approved an increase to the Company's quarterly dividend, raising it to $0.69 per share from $0.65 per share on the Company's outstanding common stock. During 2021, the Company returned $7.5 billion to shareholders through dividends and share repurchases.

In December 2021, the Company completed its inaugural issuance of a $1.0 billion sustainability bond, which was part of an $8.0 billion underwritten bond offering. The Company intends to use the net proceeds from the sustainability bond offering to support projects and partnerships in the Company's priority environmental, social and governance (ESG) areas and contribute to the advancement of the United Nations Sustainable Development Goals.

COVID-19 Update

During the COVID-19 pandemic Merck has remained focused on protecting the safety of its employees, ensuring that its supply of medicines and vaccines reaches its patients, contributing its scientific expertise to the development of an antiviral therapy, supporting efforts to expand manufacturing capacity and supply of SARS-CoV-2/COVID-19 medicines and vaccines (see below), and supporting health care providers and Merck's communities. Although COVID-19-related disruptions negatively affected results in 2021 and 2020, Merck continues to experience strong global underlying demand across its business.

In 2021, Merck's sales were unfavorably affected by COVID-19-related disruptions, which resulted in an estimated negative impact to Merck's Pharmaceutical segment sales of approximately $1.3 billion. Roughly 75% of Merck's Pharmaceutical segment revenue is comprised of physician-administered products, which, despite strong underlying demand, have been affected by social distancing measures and fewer well visits. Merck's sales were favorably affected by the authorization of molnupiravir in several markets as discussed further below, which resulted in sales of $952 million in 2021. In 2020, the estimated negative impact of COVID-19-related disruptions to Merck's sales was approximately $2.1 billion, of which approximately $2.0 billion was attributable to the Pharmaceutical segment and approximately $50 million was attributable to the Animal Health segment.

In April 2021, Merck announced it was discontinuing the development of MK-7110 (formerly known as CD24Fc) for the treatment of hospitalized patients with COVID-19, which was obtained as part of Merck's acquisition of OncoImmune (see Note 4 to the consolidated financial statements). This decision resulted in charges of $207 million to *Cost of sales* in 2021. In January 2021, the Company announced the discontinuation of the development programs for its COVID-19 vaccine candidates, V590 and V591, following Merck's review of findings from Phase 1 clinical studies for the vaccines. In these studies, both V590 and V591 were generally well tolerated, but the immune responses were inferior to those seen following natural infection and those reported for other SARS-CoV-2/COVID-19 vaccines. Due to the discontinuation, the Company recorded a charge of $305 million in 2020, of which $260 million was reflected in *Cost of sales* and the remaining $45 million of costs were reflected in *Research and development* expenses.

Operating expenses reflect a minor positive effect in 2021 as investments in COVID-19-related research largely offset the favorable impact of lower spending in other areas due to the COVID-19 pandemic. Operating expenses were positively affected in 2020 by approximately $500 million primarily due to lower promotional and selling costs, as well as lower research and development expenses, net of investments in COVID-19-related antiviral and vaccine research programs. In addition, the COVID-19 pandemic has caused some disruption and volatility in the Company's global supply chain network, and the Company may in the future experience disruptions in availability and delays in shipments of raw materials and packaging, as well as related cost inflation.

In December 2021, the FDA granted EUA for molnupiravir based on positive results from the Phase 3 MOVe-OUT clinical trial. Additionally, in December 2021, Japan's MHLW granted Special Approval for

Emergency for molnupiravir. In November 2021, the UK Medicines and Healthcare products Regulatory Agency granted conditional marketing authorization for molnupiravir. In addition, in October 2021, the EMA initiated a rolling review for molnupiravir. Merck plans to work with the Committee for Medicinal Products for Human Use of the EMA to complete the rolling review process to facilitate initiating the formal review of the Marketing Authorization Application. Merck is developing molnupiravir in collaboration with Ridgeback. The companies are actively working with other regulatory agencies worldwide to submit applications for emergency use or marketing authorization. Merck has entered into advance purchase and supply agreements for molnupiravir in more than 30 markets. See Note 5 to the consolidated financial statements for additional information related to the collaboration with Ridgeback.

In March 2021, Merck announced it had entered into multiple agreements to support efforts to expand manufacturing capacity and supply of SARS-CoV-2/COVID-19 medicines and vaccines. The Biomedical Advanced Research and Development Authority (BARDA), a division of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services, is providing Merck with funding to adapt and make available a number of existing manufacturing facilities for the production of SARS-CoV-2/COVID-19 vaccines and medicines. Merck has also entered into agreements to support the manufacturing and supply of Johnson & Johnson's SARS-CoV-2/COVID-19 vaccine. Merck is using certain of its facilities in the U.S. to produce drug substance, formulate and fill vials of Johnson & Johnson's vaccine.

Pricing

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. Changes to the U.S. health care system as part of health care reform enacted in prior years, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, have contributed to pricing pressure. In several international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. In addition, the Company's revenue performance in 2021 was negatively affected by other cost-reduction measures taken by governments and other third parties to lower health care costs. In the U.S., the Biden Administration and Congress continue to discuss legislation designed to control health care costs, including the cost of drugs. The Company anticipates all of these actions and additional actions in the future will continue to negatively affect revenue performance.

Operating Results

Sales

($ in millions)	**2021**	**% Change**	**% Change Excluding Foreign Exchange**	2020	% Change	% Change Excluding Foreign Exchange	2019
United States	**$ 22,425**	**14 %**	**14 %**	$ 19,588	6 %	6 %	$ 18,420
International	**26,279**	**20 %**	**17 %**	21,930	6 %	9 %	20,701
Total	**$ 48,704**	**17 %**	**16 %**	$ 41,518	6 %	8 %	$ 39,121

Worldwide sales grew 17% in 2021 primarily due to higher sales in the oncology franchise largely driven by strong growth of *Keytruda* and increased alliance revenue from Lynparza and Lenvima, as well as higher sales in the vaccines franchise, primarily attributable to growth in *Gardasil/Gardasil* 9, *Varivax* and *ProQuad*. Also contributing to revenue growth in 2021 were higher sales in the virology franchise attributable to molnupiravir, higher sales in the hospital acute care franchise, reflecting growth in *Bridion* and *Prevymis*, as well as higher sales of animal health products. Additionally, sales in 2021 benefited from higher third-party manufacturing sales and the achievement of milestones for an out-licensed product that triggered contingent payments to Merck. As discussed above, COVID-19-related disruptions unfavorably affected sales in 2021, but to a lesser extent than in 2020, which benefited year-over-year sales growth. Sales growth in 2021 was partially offset by lower sales of *Pneumovax* 23, the suspension of sales in 2020 of hospital acute care product *Zerbaxa*, and lower sales of virology products *Isentress/Isentress HD*.

Sales in the U.S. grew 14% in 2021 primarily driven by higher sales of *Keytruda*, sales of molnupiravir, higher sales of *Bridion*, *Gardasil 9*, *Varivax* and *ProQuad*, increased alliance revenue from Lynparza and Lenvima,

as well as higher sales of animal health products. Lower sales of *Pneumovax* 23, *Januvia/Janumet* and *Zerbaxa* partially offset revenue growth in the U.S. in 2021.

International sales increased 20% in 2021 primarily due to growth in *Gardasil/Gardasil* 9, *Keytruda*, sales of molnupiravir, increased alliance revenue from Lynparza and Lenvima, as well as higher sales of *Januvia/Janumet*, *Bridion*, *Prevymis* and animal health products. International sales growth in 2021 was partially offset by lower sales of *Noxafil*, *Zerbaxa* and *Isentress/Isentress HD*. International sales represented 54% and 53% of total sales in 2021 and 2020, respectively.

Worldwide sales increased 6% in 2020 primarily due to higher sales in the oncology franchise, as well as growth in certain hospital acute care products and animal health. Growth in these areas was largely offset by the negative effects of the COVID-19 pandemic as discussed above, competitive pressure in the virology franchise and pricing pressure in the diabetes franchise.

See Note 19 to the consolidated financial statements for details on sales of the Company's products. A discussion of performance for select products in the franchises follows.

Pharmaceutical Segment

Oncology

($ in millions)	**2021**	**% Change**	**% Change Excluding Foreign Exchange**	2020	% Change	% Change Excluding Foreign Exchange	2019
Keytruda	**$ 17,186**	**20 %**	**18 %**	$ 14,380	30 %	30 %	$ 11,084
Alliance Revenue - Lynparza [(1)]	**989**	**36 %**	**35 %**	725	63 %	62 %	444
Alliance Revenue - Lenvima [(1)]	**704**	**21 %**	**20 %**	580	44 %	43 %	404
Emend	**127**	**(13)%**	**(15)%**	145	(63)%	(62)%	388

[(1)] *Alliance revenue represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs (see Note 4 to the consolidated financial statements).*

Keytruda is an anti-PD-1 (programmed death receptor-1) therapy that has been approved as monotherapy for the treatment of certain patients with cervical cancer, classical Hodgkin lymphoma (cHL), cutaneous squamous cell carcinoma (cSCC), esophageal or gastroesophageal junction (GEJ) carcinoma, head and neck squamous cell carcinoma (HNSCC), HCC, NSCLC, melanoma, Merkel cell carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer (solid tumors) including MSI-H/dMMR colorectal cancer, primary mediastinal large B-cell lymphoma, TMB-H cancer (solid tumors), and urothelial carcinoma including non-muscle invasive bladder cancer. Additionally, *Keytruda* is approved as monotherapy for the adjuvant treatment of certain patients with RCC. *Keytruda* is also approved for the treatment of certain patients in combination with chemotherapy for metastatic squamous and nonsquamous NSCLC, in combination with chemotherapy, with or without bevacizumab for cervical cancer, in combination with chemotherapy for esophageal cancer, in combination with chemotherapy for gastric cancer, in combination with chemotherapy for HNSCC, in combination with chemotherapy for triple-negative-breast cancer (TNBC), in combination with axitinib for advanced RCC, and in combination with Lenvima for both endometrial carcinoma and RCC. The *Keytruda* clinical development program includes studies across a broad range of cancer types.

Global sales of *Keytruda* grew 20% in 2021 driven by higher demand as the Company continues to launch *Keytruda* with multiple new indications globally, although the COVID-19 pandemic had a dampening effect on growing demand by negatively affecting the number of new patients starting treatment. Sales in the U.S. continue to build across the multiple approved indications, in particular for the treatment of advanced NSCLC as monotherapy, and in combination with chemotherapy for both nonsquamous and squamous metastatic NSCLC, along with continued uptake in the TNBC, RCC, HNSCC, MSI-H cancer, and esophageal cancer indications. *Keytruda* sales growth in international markets reflects continued uptake predominately for the NSCLC, HNSCC and RCC indications,

particularly in Europe. Sales growth in 2021 was partially offset by lower pricing in Europe, China and Japan. Global sales of *Keytruda* grew 30% in 2020 driven by higher demand globally, particularly in the U.S. and Europe, although the COVID-19 pandemic had an unfavorable effect on growing demand. Sales growth in 2020 was partially offset by lower pricing in Japan and Europe.

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Keytruda received numerous regulatory approvals in 2021 summarized below.

Date	Approval
January 2021	EC approval as a first-line treatment in adult patients with MSI- the KEYNOTE-177 study.
March 2021	EC approval of an expanded label as monotherapy for the treatn years and older with relapsed or refractory cHL who have failed or following at least two prior therapies when ASCT is not a trea KEYNOTE-204 and KEYNOTE-087 trials.
March 2021	FDA approval in combination with platinum- and fluoropyrimid of certain patients with locally advanced or metastatic esophage to surgical resection or definitive chemoradiation based on the K
May 2021	FDA approval in combination with trastuzumab, fluoropyrimidi chemotherapy for the first-line treatment of patients with locally human epidermal growth factor receptor 2 (HER2)-positive gast KEYNOTE-811 trial.
May 2021	EC approval of the 400 mg every six weeks (Q6W) dosing r administered in combination with other anticancer agents.
June 2021	China's National Medical Products Administration (NMPA) app patients with MSI-H or dMMR colorectal cancer that is KRAS, the KEYNOTE-177 study.
June 2021	EC approval in combination with chemotherapy for the first-line advanced unresectable or metastatic carcinoma of the esophagus in adults whose tumors express PD-L1 based on the KEYNOTE
July 2021	FDA approval as monotherapy for the treatment of patients with curable by surgery or radiation based on the KEYNOTE-629 tri
July 2021	FDA approval of *Keytruda* plus Lenvima for the treatment of pa carcinoma that is not MSI-H or dMMR who have disease progre any setting and are not candidates for curative surgery or radiati 309 trial.
July 2021	FDA approval of *Keytruda* for treatment of patients with high-ri with chemotherapy as neoadjuvant treatment and then continued after surgery based on the KEYNOTE-522 trial.
August 2021	FDA approval of *Keytruda* plus Lenvima for the first-line treatm based on the KEYNOTE-581 trial/Study 307 trial.
August 2021	Japan's Pharmaceuticals and Medical Devices Agency (PMDA) with unresectable, advanced or recurrent MSI-H colorectal canc
August 2021	Japan's PMDA approval for the treatment of patients with PD-L and HER2-negative, inoperable or recurrent breast cancer based
September 2021	China's NMPA approval in combination with chemotherapy for locally advanced, unresectable or metastatic carcinoma of the es KEYNOTE-590 trial.
October 2021	FDA approval in combination with chemotherapy, with or witho patients with persistent, recurrent or metastatic cervical cancer b
October 2021	EC approval in combination with chemotherapy for the first-line unresectable or metastatic TNBC in adults whose tumors expres chemotherapy for metastatic disease based on the KEYNOTE-3
November 2021	FDA approval for the adjuvant treatment of patients with RCC a recurrence following nephrectomy, or following nephrectomy ar the KEYNOTE-564 trial.

November 2021	EC approval of *Keytruda* plus Lenvima for the first-line treatme based on the CLEAR (Study 307)/KEYNOTE-581 trial.
November 2021	EC approval of *Keytruda* plus Lenvima for the treatment of adv in adults who have disease progression on or following prior tre therapy in any setting and who are not candidates for curative su KEYNOTE-775/Study 309 trial.
November 2021	Japan's PMDA approval in combination with chemotherapy (5-f line treatment of patients with radically unresectable, advanced combination with chemotherapy based on the KEYNOTE-590 t
December 2021	FDA approval for the adjuvant treatment of adult and pediatric (IIB or IIC melanoma following complete resection based on the indication for the adjuvant treatment of stage III melanoma follo pediatric patients (12 years and older).
December 2021	Japan's MHLW approval of *Keytruda* in combination with Lenv unresectable, advanced or recurrent endometrial carcinoma that based on the KEYNOTE-775/Study 309 trial.

In March 2021, Merck announced it was voluntarily withdrawing the U.S. indication for *Keytruda* for the treatment of patients with metastatic small-cell lung cancer with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy. The withdrawal of this indication was done in consultation with the FDA and does not affect other indications for *Keytruda*. As announced in January 2020, KEYNOTE-604, the confirmatory Phase 3 trial for this indication, met one of its dual primary endpoints of progression-free survival but did not reach statistical significance for the other primary endpoint of overall survival.

In 2022, Merck initiated the withdrawal of the U.S. accelerated approval indication for *Keytruda* for the treatment of patients with recurrent locally advanced or metastatic gastric or GEJ adenocarcinoma whose tumors express PD-L1, with disease progression on or after two or more prior lines of therapy. The decision was made in consultation with the FDA following the Oncologic Drugs Advisory Committee evaluation of this third-line gastric cancer indication for *Keytruda* as a monotherapy because it failed to meet its post-marketing requirement of demonstrating an overall survival benefit in a Phase 3 study. The withdrawal of this indication does not affect other indications for *Keytruda*.

The Company is a party to certain third-party license agreements pursuant to which the Company pays royalties on sales of *Keytruda*. Under the terms of the more significant of these agreements, Merck pays a royalty of 6.5% on worldwide sales of *Keytruda* through 2023 to one third party; this royalty will decline to 2.5% for 2024 through 2026 and will terminate thereafter. The Company pays an additional 2% royalty on worldwide sales of *Keytruda* to another third party, the termination date of which varies by country; this royalty will expire in the U.S. in 2024 and in major European markets in 2025. The royalties are included in *Cost of sales*.

Lynparza is an oral poly (ADP-ribose) polymerase (PARP) inhibitor being developed as part of a collaboration with AstraZeneca (see Note 5 to the consolidated financial statements). Lynparza is approved for the treatment of certain types of advanced ovarian, breast, pancreatic and prostate cancers. Alliance revenue related to Lynparza grew 36% in 2021 and 63% in 2020 due to continued uptake across the multiple approved indications in the U.S., Europe, Japan and China. In June 2021, Lynparza was granted conditional approval in China as monotherapy for the treatment of certain previously treated adult patients with germline or somatic *BRCA*-mutated metastatic castration-resistant prostate cancer based on the results of the PROfound trial.

Lenvima is an oral receptor tyrosine kinase inhibitor being developed as part of a collaboration with Eisai (see Note 5 to the consolidated financial statements). Lenvima is approved for the treatment of certain types of thyroid cancer, HCC, in combination with everolimus for certain patients with RCC, and in combination with *Keytruda* both for the treatment of certain patients with endometrial carcinoma and for the treatment of certain patients with RCC. Alliance revenue related to Lenvima grew 21% in 2021 and 44% in 2020 primarily due to higher demand in the U.S. and China.

Global sales of *Emend* (aprepitant), for the prevention of certain chemotherapy-induced nausea and vomiting, declined 13% in 2021 reflecting lower volumes in Europe and China. Worldwide sales of *Emend*

decreased 63% in 2020 primarily due to lower demand and pricing in the U.S. due to generic competition for *Emend* for Injection following U.S. patent expiry in September 2019. Also contributing to the *Emend* sales decline in 2020 was lower demand in Europe and Japan as a result of generic competition for the oral formulation of *Emend* following loss of market exclusivity in May 2019 and December 2019, respectively.

In June 2021, Koselugo (selumetinib) was granted conditional approval in the EU for the treatment of pediatric patients three years of age and older with neurofibromatosis type 1 who have symptomatic, inoperable plexiform neurofibromas based on positive results from the National Cancer Institute Cancer Therapy Evaluation Program-sponsored SPRINT Stratum 1 trial. Koselugo was approved by the FDA in April 2020. Koselugo is part of the same collaboration with AstraZeneca referenced above that includes Lynparza.

In August 2021, the FDA approved *Welireg*, an oral HIF-2α inhibitor, for the treatment of adult patients with VHL disease who require therapy for associated RCC, central nervous system hemangioblastomas, or pancreatic neuroendocrine tumors, not requiring immediate surgery. The approval was based on results from the open-label Study 004 trial. *Welireg* was obtained as part of Merck's 2019 acquisition of Peloton Therapeutics, Inc. (Peloton). See Note 4 to the consolidated financial statements.

Vaccines

($ in millions)	**2021**	**% Change**	**% Change Excluding Foreign Exchange**	2020	% Change	% Change Excluding Foreign Exchange	2019
Gardasil/Gardasil 9	**$ 5,673**	**44 %**	**39 %**	$ 3,938	5 %	6 %	$ 3,737
ProQuad	**773**	**14 %**	**13 %**	678	(10)%	(10)%	756
M-M-R II	**391**	**3 %**	**3 %**	378	(31)%	(31)%	549
Varivax	**971**	**18 %**	**18 %**	823	(15)%	(15)%	970
Pneumovax 23	**893**	**(18)%**	**(19)%**	1,087	17 %	18 %	926

Worldwide sales of *Gardasil/Gardasil* 9, vaccines to help prevent certain cancers and other diseases caused by certain types of human papillomavirus (HPV), grew 44% in 2021 driven primarily by strong global demand, particularly in China, as well as increased supply. Higher pricing in China and the U.S. also contributed to sales growth in 2021. Sales growth in 2021 was unfavorably affected by the replenishment in 2020 of doses borrowed from the U.S. Centers for Disease Control and Prevention (CDC) Pediatric Vaccine Stockpile, which favorably affected sales by $120 million in 2020. The timing of public sector purchases in the U.S. also partially offset sales growth in 2021. Global sales of *Gardasil/Gardasil* 9 grew 5% in 2020 primarily due to higher volumes in China and the replenishment in 2020 of doses borrowed from the CDC Pediatric Vaccine Stockpile in 2019. The replenishment resulted in the recognition of sales of $120 million in 2020, which, when combined with the reduction of sales of $120 million in 2019 due to the borrowing, resulted in a favorable impact to sales of $240 million in 2020 compared with 2019. Lower demand in the U.S. and Hong Kong, SAR, PRC attributable to the COVID-19 pandemic partially offset the increase in sales of *Gardasil/Gardasil* 9 in 2020.

The Company is a party to certain third-party license agreements pursuant to which the Company pays royalties on sales of *Gardasil/Gardasil* 9. Under the terms of the more significant of these agreements, Merck pays a 7% royalty on worldwide sales of *Gardasil/Gardasil* 9 to one third party (royalty obligations under this agreement expire in December 2023) and an additional 7% royalty on sales of *Gardasil/Gardasil* 9 in the U.S. to another third party (these royalty obligations expire in December 2028). The royalties are included in *Cost of sales*.

Global sales of *ProQuad*, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, grew 14% in 2021 due to higher sales in the U.S. reflecting higher demand driven by the ongoing COVID-19 pandemic recovery, as well as higher pricing. Worldwide sales of *ProQuad* declined 10% in 2020 driven primarily by lower demand in the U.S. resulting from fewer measles outbreaks in 2020 compared with 2019, coupled with the unfavorable impact of the COVID-19 pandemic, partially offset by higher pricing.

Worldwide sales of *M-M-R* II, a vaccine to help protect against measles, mumps and rubella, grew 3% in 2021 primarily due to higher sales in the U.S. reflecting the ongoing COVID-19 pandemic recovery inclusive of

higher public sector mix of business. Lower demand in Europe partially offset *M-M-R* II sales growth in 2021. Global sales of *M-M-R* II declined 31% in 2020 driven primarily by lower demand in the U.S. resulting from fewer

measles outbreaks in 2020 compared with 2019, coupled with the unfavorable impact of the COVID-19 pandemic. Lower demand in Brazil also contributed to the *M-M-R* II sales decline in 2020.

Global sales of *Varivax,* a vaccine to help prevent chickenpox (varicella), grew 18% in 2021 primarily reflecting the ongoing COVID-19 pandemic recovery and higher pricing in the U.S. Higher government tenders in Brazil also contributed to *Varivax* sales growth in 2021. Worldwide sales of *Varivax* declined 15% in 2020 driven primarily by lower demand in the U.S. resulting from the COVID-19 pandemic, partially offset by higher pricing. The *Varivax* sales decline in 2020 was also attributable to lower government tenders in Brazil.

Worldwide sales of *Pneumovax* 23, a vaccine to help prevent pneumococcal disease, declined 18% in 2021 primarily due to lower sales in the U.S. attributable to lower demand reflecting prioritization of COVID-19 vaccination, partially offset by higher pricing. Global sales of *Pneumovax* 23 grew 17% in 2020 primarily due to higher volumes in Europe and the U.S. attributable in part to heightened awareness of pneumococcal vaccination. Higher pricing in the U.S. also contributed to *Pneumovax* 23 sales growth in 2020.

In July 2021, the FDA approved *Vaxneuvance* for active immunization for the prevention of invasive disease caused by 15 *Streptococcus pneumoniae* serotypes in adults 18 years of age and older. In December 2021, *Vaxneuvance* was approved by the EC. These approvals were based on data from seven clinical studies assessing safety, tolerability, and immunogenicity in adults. In October 2021, the CDC's Advisory Committee on Immunization Practices (ACIP) voted to recommend vaccination either with a sequential regimen of *Vaxneuvance* followed by *Pneumovax* 23, or with a single dose of 20-valent pneumococcal conjugate vaccine both for adults 65 years and older and for adults ages 19 to 64 with certain underlying medical conditions. These recommendations subsequently were adopted by the director of the CDC and the U.S. Department of Health and Human Services and published in the CDC's *Morbidity and Mortality Weekly Report*. In September 2021, Merck announced a settlement and license agreement with Pfizer Inc. (Pfizer), resolving all worldwide patent infringement litigation related to the use of Merck's investigational and licensed pneumococcal conjugate vaccine (PCV) products, including *Vaxneuvance*. Under the terms of the agreement, Merck will make certain regulatory milestone payments to Pfizer, as well as royalty payments on the worldwide sales of its PCV products. The Company will pay royalties of 7.25% of net sales of all Merck PCV products through 2026; and 2.5% of net sales of all Merck PCV products from 2027 through 2035.

Vaxelis (Diphtheria and Tetanus Toxoids and Acellular Pertussis, Inactivated Poliovirus, Haemophilus b Conjugate and Hepatitis B Vaccine), developed as part of a U.S.-based partnership between Merck and Sanofi Pasteur, is now available in the U.S. for active immunization of children six weeks through four years of age to help prevent diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B, and invasive disease due to *Haemophilus influenzae* type b. In February 2021, the CDC's ACIP included *Vaxelis* as a combination vaccine option in the CDC's Recommended Child and Adolescent Immunization Schedule. Sales of *Vaxelis* in the U.S. are made through the U.S.-based Merck/Sanofi Pasteur partnership, the results of which are reflected in equity income from affiliates included in *Other (income) expense, net.* Supply sales to the partnership are recorded within *Sales*. *Vaxelis* is also approved in the EU where it is marketed directly by Merck and Sanofi Pasteur.

Hospital Acute Care

($ in millions)	**2021**	**% Change**	**% Change Excluding Foreign Exchange**	2020	% Change	% Change Excluding Foreign Exchange	2019
Bridion	**$ 1,532**	**28 %**	**27 %**	$ 1,198	6 %	7 %	$ 1,131
Prevymis	**370**	**32 %**	**30 %**	281	70 %	69 %	165
Noxafil	**259**	**(21)%**	**(23)%**	329	(50)%	(50)%	662
Zerbaxa	**(1)**	*	*	130	8 %	10 %	121

** Calculation not meaningful.*

Global sales of *Bridion*, for the reversal of two types of neuromuscular blocking agents used during surgery, grew 28% in 2021 due to higher demand globally, particularly in the U.S. and Europe, attributable to the COVID-19 pandemic recovery, as well as increased usage of neuromuscular blockade reversal agents and *Bridion*'s

growing share within the class. *Bridion* was also approved by the FDA in June 2021 for pediatric patients aged 2 years and older undergoing surgery. Worldwide sales of *Bridion* grew 6% in 2020 due to higher demand globally,

particularly in the U.S. However, fewer elective surgeries as a result of the COVID-19 pandemic unfavorably affected demand in 2020.

Worldwide sales of *Prevymis*, a medicine for prophylaxis (prevention) of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients of an allogenic hematopoietic stem cell transplant, grew 32% in 2021 and increased 70% in 2020 due to continued uptake since launch in several markets, particularly in Europe and the U.S.

Worldwide sales of *Noxafil*, an antifungal agent for the prevention of certain invasive fungal infections, declined 21% in 2021 primarily due to generic competition in Europe, partially offset by higher demand in China. The patent that provided market exclusivity for *Noxafil* in a number of major European markets expired in December 2019. As a result, the Company is experiencing lower demand for *Noxafil* in these markets due to generic competition and expects the decline to continue. Global sales of *Noxafil* declined 50% in 2020 due to generic competition in the U.S. and in Europe. The patent that provided U.S. market exclusivity for certain forms of *Noxafil* representing the majority of U.S. *Noxafil* sales expired in July 2019.

In December 2020, the Company temporarily suspended sales of *Zerbaxa*, a combination antibacterial and beta-lactamase inhibitor for the treatment of certain bacterial infections, and subsequently issued a product recall, following the identification of product sterility issues. As a result, the Company recorded an intangible asset impairment charge in 2020 related to *Zerbaxa* (see Note 9 to the consolidated financial statements). A phased resupply of *Zerbaxa* was initiated in the fourth quarter of 2021, which the Company expects to continue during 2022.

Immunology

($ in millions)	**2021**	**% Change**	**% Change Excluding Foreign Exchange**	2020	% Change	% Change Excluding Foreign Exchange	2019
Simponi	**$ 825**	**(2)%**	**(6)%**	$ 838	1 %	1 %	$ 830
Remicade	**299**	**(9)%**	**(12)%**	330	(20)%	(20)%	411

Sales of *Simponi*, a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), declined 2% in 2021 and were nearly flat in 2020. Sales of *Simponi* are being unfavorably affected by biosimilar competition for competing products. The Company expects this competition will continue to unfavorably affect sales of *Simponi*.

Sales of *Remicade*, a treatment for inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), declined 9% in 2021 and decreased 20% in 2020 driven by ongoing biosimilar competition in the Company's marketing territories in Europe. The Company lost market exclusivity for *Remicade* in major European markets in 2015 and no longer has market exclusivity in any of its marketing territories. The Company is experiencing pricing and volume declines in these markets as a result of biosimilar competition and expects the declines to continue.

The Company's marketing rights with respect to these products will revert to Janssen Pharmaceuticals, Inc. on October 1, 2024.

Virology

($ in millions)	**2021**	**% Change**	**% Change Excluding Foreign Exchange**	2020	% Change	% Change Excluding Foreign Exchange	2019
Molnupiravir	**$ 952**	**—**	**—**	$ —	—	—	$ —
Isentress/Isentress HD	**769**	**(10)%**	**(11)%**	857	(12)%	(11)%	975
Zepatier	**128**	**(23)%**	**(25)%**	167	(55)%	(54)%	370

Molnupiravir is an investigational oral antiviral COVID-19 medicine being developed in a collaboration with Ridgeback (see Note 5 to the consolidated financial statements). The FDA granted an EUA for molnupiravir in December 2021; as updated in February 2022, to authorize molnupiravir for the treatment of mild to moderate COVID-19 in high-risk adults for whom alternative FDA-approved or authorized treatment options are not

accessible or clinically appropriate. Also in December 2021, Japan's MHLW granted Special Approval for Emergency for molnupiravir to treat infectious disease caused by SARS-CoV-2. In November 2021, the UK's MHRA granted conditional marketing authorization for molnupiravir to treat mild to moderate COVID-19 in adults at risk of developing severe illness. Merck has entered into advance purchase and supply agreements for molnupiravir in more than 30 markets and Merck began shipping molnupiravir in the fourth quarter of 2021 to countries where it is approved or authorized. Sales of molnupiravir were $952 million in 2021 primarily consisting of sales in the U.S., the UK and Japan.

Worldwide sales of *Isentress/Isentress HD*, an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, declined 10% in 2021 and decreased 12% in 2020 primarily due to competitive pressure particularly in Europe and the U.S. The Company expects competitive pressure for *Isentress/Isentress HD* to continue.

Global sales of *Zepatier*, a treatment for adult patients with chronic hepatitis C virus genotype (GT) 1 or GT4 infection, declined 23% in 2021 primarily due to lower demand from competitive pressure in the U.S. and Europe. Worldwide sales of *Zepatier* declined 55% in 2020 driven by lower demand globally due to competition and declining patient volumes, coupled with the impact of the COVID-19 pandemic.

Cardiovascular

($ in millions)	**2021**	**% Change**	**% Change Excluding Foreign Exchange**	2020	% Change	% Change Excluding Foreign Exchange	2019
Alliance revenue - Adempas/ Verquvo [1]	**$ 342**	**22 %**	**22 %**	$ 281	38 %	38 %	$ 204
Adempas	**252**	**14 %**	**11 %**	220	3 %	2 %	215

[1] *Alliance revenue represents Merck's share of profits from sales in Bayer's marketing territories, which are product sales net of cost of sales and commercialization costs (see Note 5 to the consolidated financial statements).*

Adempas and Verquvo are part of a worldwide collaboration with Bayer to market and develop soluble guanylate cyclase (sGC) modulators (see Note 5 to the consolidated financial statements). Adempas is approved for the treatment of certain types of PAH. Verquvo was approved in the U.S. in January 2021 to reduce the risk of cardiovascular death and heart failure hospitalization following a hospitalization for heart failure or need for outpatient intravenous diuretics in adults with symptomatic chronic heart failure and reduced ejection fraction. Verquvo was also approved in Japan in June 2021 and in the EU in July 2021. These approvals were based on the results of the VICTORIA trial. Alliance revenue from the collaboration grew 22% in 2021 and rose 38% in 2020. Revenue from the collaboration also includes sales of Adempas and Verquvo in Merck's marketing territories. Sales of Adempas in Merck's marketing territories grew 14% in 2021 primarily reflecting higher demand in Europe.

Diabetes

($ in millions)	**2021**	**% Change**	**% Change Excluding Foreign Exchange**	2020	% Change	% Change Excluding Foreign Exchange	2019
Januvia/Janumet	**$ 5,288**	**— %**	**(2)%**	$ 5,276	(4)%	(4)%	$ 5,524

Worldwide combined sales of *Januvia* and *Janumet*, medicines that help lower blood sugar levels in adults with type 2 diabetes, were nearly flat in 2021 and declined 4% in 2020. Sales performance in both periods reflects continued pricing pressure and lower demand in the U.S., largely offset by higher demand in certain international markets, particularly in China. The Company expects U.S. pricing pressure to continue. *Januvia* and *Janumet* will lose market exclusivity in the U.S. in January 2023, in the EU in September 2022, and in China in July 2022. The Company anticipates sales of *Januvia* and *Janumet* in these markets will decline substantially after the loss of exclusivity. Combined sales of *Januvia* and *Janumet* in the U.S., Europe and China represented 33%, 24% and 9%, respectively, of total combined *Januvia* and *Janumet* sales in 2021.

Animal Health Segment

($ in millions)	2021	% Change	% Change Excluding Foreign Exchange	2020	% Change	% Change Excluding Foreign Exchange	2019
Livestock	$ **3,295**	**12 %**	**10 %**	$ 2,939	6 %	9 %	$ 2,784
Companion Animal	**2,273**	**29 %**	**26 %**	1,764	10 %	11 %	1,609

Sales of livestock products grew 12% in 2021 primarily due to higher demand for ruminant products, including animal health intelligence solutions for animal identification, monitoring and traceability, as well as higher demand for poultry and swine products. Sales of livestock products increased 6% in 2020 predominantly due to an additional five months of sales in 2020 related to the April 2019 acquisition of Antelliq, a leader in digital animal identification, traceability and monitoring solutions (see Note 4 to the consolidated financial statements). Sales of companion animal products grew 29% in 2021 and rose 10% in 2020 primarily due to higher demand for parasiticides, including the *Bravecto* line of products, as well as higher demand for companion animal vaccines.

Costs, Expenses and Other

($ in millions)	2021	% Change	2020	% Change	2019
Cost of sales	$ **13,626**	**— %**	$ 13,618	13 %	$ 12,016
Selling, general and administrative	**9,634**	**8 %**	8,955	(5)%	9,455
Research and development	**12,245**	**(9)%**	13,397	38 %	9,724
Restructuring costs	**661**	**15 %**	575	(8)%	626
Other (income) expense, net	**(1,341)**	**51 %**	(890)	*	129
	$ **34,825**	**(2)%**	$ 35,655	12 %	$ 31,950

** Calculation not meaningful.*

Cost of Sales

Cost of sales was $13.6 billion in both 2021 and 2020 and was $12.0 billion in 2019. Cost of sales includes the amortization of intangible assets recorded in connection with acquisitions, collaborations, and licensing arrangements, which totaled $1.6 billion in 2021, $1.8 billion in 2020 and $1.7 billion in 2019. Costs in 2021 and 2020 also include charges of $225 million and $260 million, respectively, related to the discontinuation of COVID-19 development programs (see Note 4 to the consolidated financial statements). Additionally, costs in 2020 and 2019 include intangible asset impairment charges of $1.6 billion and $705 million related to marketed products and other intangibles (see Note 9 to the consolidated financial statements). The Company may recognize additional impairment charges in the future related to intangible assets that were measured at fair value and capitalized in connection with business combinations and such charges could be material. Costs in 2020 also include inventory write-offs of $120 million related to a recall for *Zerbaxa* (see Note 9 to the consolidated financial statements). Also included in cost of sales are expenses associated with restructuring activities, which amounted to $160 million in 2021, $175 million in 2020 and $251 million in 2019, primarily reflecting accelerated depreciation and asset write-offs related to the planned sale or closure of manufacturing facilities. Separation costs associated with manufacturing-related headcount reductions have been incurred and are reflected in *Restructuring costs* as discussed below.

Gross margin was 72.0% in 2021 compared with 67.2% in 2020. The gross margin improvement in 2021 reflects lower impairments and amortization of intangible assets (noted above), as well as the favorable effects of product mix and lower inventory write-offs. Partially offsetting the gross margin improvement in 2021 were higher manufacturing costs, the impact of molnupiravir (which has a lower gross margin due to profit sharing with Ridgeback as discussed in Note 5 to the consolidated financial statements), and higher compensation and benefit costs. Gross margin was 67.2% in 2020 compared with 69.3% in 2019. The gross margin decline in 2020 reflects the unfavorable effects of higher impairments and amortization of intangible assets, pricing pressure, a charge related to

the discontinuation of COVID-19 vaccine development programs, and higher inventory write-offs related to the recall of *Zerbaxa* (noted above), partially offset by the favorable effects of product mix and lower restructuring costs.

Selling, General and Administrative

Selling, general and administrative (SG&A) expenses were $9.6 billion in 2021, an increase of 8% compared with 2020. The increase was primarily due to higher administrative costs, including compensation and benefits, higher promotional expenses in support of the Company's key growth pillars, and higher acquisition-related costs, including costs related to the acquisition of Acceleron. The COVID-19 pandemic drove lower spending in 2020 which contributed to the increase in SG&A expenses in 2021. These increases were partially offset by the favorable effects of foreign exchange and a contribution in 2020 to the Merck Foundation. SG&A expenses were $9.0 billion in 2020, a decline of 5% compared with 2019. The decline was driven primarily by lower administrative, selling and promotional costs, including lower travel and meeting expenses, due in part to the COVID-19 pandemic, and the favorable effect of foreign exchange, partially offset by a contribution to the Merck Foundation.

Research and Development

Research and development (R&D) expenses were $12.2 billion in 2021, a decline of 9% compared with 2020 primarily due to lower upfront payments related to acquisitions and collaborations. The decline was partially offset by higher clinical development spending and increased investment in discovery research and early drug development, net of the reimbursement of a portion of molnupiravir development costs through the partnership with Ridgeback. Higher compensation and benefit costs, higher in-process research and development (IPR&D) impairment charges, as well as costs related to the acquisition of Acceleron also partially offset the decline in R&D expenses in 2021. R&D expenses were $13.4 billion in 2020, an increase of 38% compared with 2019. The increase was driven largely by higher upfront payments related to acquisitions and collaborations, higher clinical development spending and increased investment in discovery research and early drug development. Higher restructuring costs also contributed to the increase in R&D expenses in 2020. The increase in R&D expenses in 2020 was partially offset by lower IPR&D impairment charges and lower costs resulting from the COVID-19 pandemic, net of spending on COVID-19-related vaccine and antiviral research programs.

R&D expenses are comprised of the costs directly incurred by Merck Research Laboratories (MRL), the Company's research and development division that focuses on human health-related activities, which were $7.1 billion in 2021, $6.5 billion in 2020 and $6.0 billion in 2019. Also included in R&D expenses are Animal Health research costs, licensing costs and costs incurred by other divisions in support of R&D activities, including depreciation, production and general and administrative, which in the aggregate were $3.0 billion in 2021, $2.6 billion in 2020 and $2.6 billion in 2019. Additionally, R&D expenses in 2021 include a $1.7 billion charge for the acquisition of Pandion. R&D expenses in 2020 include a $2.7 billion charge for the acquisition of VelosBio Inc., a $462 million charge for the acquisition of OncoImmune and charges of $826 million related to transactions with Seagen. R&D expenses in 2019 include a $993 million charge for the acquisition of Peloton. See Note 4 to the consolidated financial statements for more information on these transactions. R&D expenses also include IPR&D impairment charges of $275 million, $90 million and $172 million in 2021, 2020 and 2019, respectively (see Note 9 to the consolidated financial statements). The Company may recognize additional impairment charges in the future related to the cancellation or delay of other pipeline programs that were measured at fair value and capitalized in connection with business combinations and such charges could be material. In addition, R&D expenses in 2021 and 2020 include $28 million and $83 million, respectively, of costs associated with restructuring activities, primarily relating to accelerated depreciation. R&D expenses also include expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration recorded in connection with business combinations. The Company recorded $35 million of expenses in 2021 compared with a net reduction in expenses of $95 million and $39 million in 2020 and 2019, respectively, related to changes in these estimates.

Restructuring Costs

In 2019, Merck approved a global restructuring program (Restructuring Program) as part of a worldwide initiative focused on further optimizing the Company's manufacturing and supply network, as well as reducing its global real estate footprint. This program is a continuation of the Company's plant rationalization and builds on prior restructuring programs. The actions currently contemplated under the Restructuring Program are expected to be substantially completed by the end of 2023, with the cumulative pretax costs to be incurred by the Company to implement the program estimated to be approximately $3.5 billion. The Company expects to record charges of

approximately $400 million in 2022 related to the Restructuring Program. The Company anticipates the actions under the Restructuring Program will result in annual net cost savings of approximately $900 million by the end of 2023.

Restructuring costs, primarily representing separation and other related costs associated with these restructuring activities, were $661 million in 2021, $575 million in 2020 and $626 million in 2019. Separation costs incurred were associated with actual headcount reductions, as well as estimated expenses under existing severance programs for headcount reductions that were probable and could be reasonably estimated. Also included in restructuring costs are asset abandonment, facility shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation plan costs. For segment reporting, restructuring costs are unallocated expenses.

Additional costs associated with the Company's restructuring activities are included in *Cost of sales*, *Selling, general and administrative* expenses and *Research and development* costs. The Company recorded aggregate pretax costs of $868 million in 2021, $880 million in 2020 and $915 million in 2019 related to restructuring program activities (see Note 6 to the consolidated financial statements).

Other (Income) Expense, Net

Other (income) expense, net, was $1.3 billion of income in 2021 compared with $890 million of income in 2020 primarily due to higher income from investments in equity securities, net, largely related to higher realized and unrealized gains on certain investments including the disposition in 2021 of the Company's ownership interest in Preventice Solutions Inc. (Preventice) as a result of the acquisition of Preventice by Boston Scientific, partially offset by higher foreign exchange losses and pension settlement costs. Other (income) and expense, net, was $890 million of income in 2020 compared with $129 million of expense in 2019, primarily due to higher income from investments in equity securities, net, largely related to Moderna, Inc.

For details on the components of Other (income) expense, net, see Note 15 to the consolidated financial statements.

Segment Profits

($ in millions)	**2021**	2020	2019
Pharmaceutical segment profits	**$ 30,977**	$ 26,106	$ 23,448
Animal Health segment profits	**1,950**	1,669	1,612
Other non-reportable segment profits	**—**	1	(7)
Other	**(19,048)**	(21,913)	(17,882)
Income from Continuing Operations Before Taxes	**$ 13,879**	$ 5,863	$ 7,171

Pharmaceutical segment profits are comprised of segment sales less standard costs, as well as SG&A expenses directly incurred by the segment. Animal Health segment profits are comprised of segment sales, less all cost of sales, as well as SG&A and R&D expenses directly incurred by the segment. For internal management reporting presented to the chief operating decision maker, Merck does not allocate the remaining cost of sales not included in segment profits as described above, R&D expenses incurred by MRL, or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. Also excluded from the determination of segment profits are costs related to restructuring activities and acquisition and divestiture-related costs, including the amortization of intangible assets and amortization of purchase accounting adjustments, intangible asset impairment charges, and expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration. Additionally, segment profits do not reflect other expenses from corporate and manufacturing cost centers and other miscellaneous income or expense. These unallocated items are reflected in "Other" in the above table. Also included in "Other" are miscellaneous corporate profits (losses), as well as operating profits (losses) related to third-party manufacturing sales. Beginning in 2021, the amortization of intangible assets previously included as part of the calculation of

segment profits is now included in unallocated non-segment corporate expenses. Prior period Pharmaceutical and Animal Health segment profits have been recast to reflect this change on a comparable basis.

Pharmaceutical segment profits grew 19% in 2021 primarily due to higher sales and the favorable effect of foreign exchange, partially offset by higher administrative and promotional costs. Pharmaceutical segment profits increased 11% in 2020 driven primarily by higher sales, as well as lower selling and promotional costs. Animal Health segment profits grew 17% in 2021 reflecting higher sales, partially offset by higher promotional, selling and administrative costs. Animal Health segment profits increased 4% in 2020 driven primarily by higher sales and lower promotional and selling costs, partially offset by higher R&D costs and the unfavorable effect of foreign exchange.

Taxes on Income

The effective income tax rates from continuing operations were 11.0% in 2021, 22.9% in 2020 and 21.8% in 2019. The full year effective income tax rate reflects a favorable mix of income and expense, as well as higher foreign tax credits from ordinary business operations that the Company was able to credit in 2021. The effective income tax rate from continuing operations in 2021 also reflects the beneficial impact of the settlement of a foreign tax matter, as well as a net tax benefit of $207 million related to the settlement of certain federal income tax matters (see Note 16 to the consolidated financial statements). The effective income tax rate from continuing operations in 2021 also reflects the unfavorable effect of a charge for the acquisition of Pandion for which no tax benefit was recognized. The effective income tax rate in 2020 reflects the unfavorable impact of a charge for the acquisition of VelosBio for which no tax benefit was recognized. The effective income tax rate in 2019 reflects the favorable impact of a $106 million net tax benefit related to the settlement of certain federal income tax matters (see Note 16 to the consolidated financial statements) and the reversal of tax reserves established in connection with the 2014 divestiture of Merck's Consumer Care (MCC) business due to the lapse in the statute of limitations. In addition, the effective income tax rate in 2019 reflects the unfavorable impact of a charge for the acquisition of Peloton for which no tax benefit was recognized and charges of $117 million related to the finalization of treasury regulations for the transition tax associated with the 2017 enactment of U.S. tax legislation known as the Tax Cuts and Jobs Act (TCJA) (see Note 16 to the consolidated financial statements).

Net Income (Loss) Attributable to Noncontrolling Interests

Net income (loss) attributable to noncontrolling interests was $13 million in 2021, $4 million in 2020 and $(84) million in 2019. The loss in 2019 was driven primarily by the portion of goodwill impairment charges related to certain businesses in the Healthcare Services segment that were attributable to noncontrolling interests.

Non-GAAP Income and Non-GAAP EPS from Continuing Operations

Non-GAAP income and non-GAAP EPS are alternative views of the Company's performance that Merck is providing because management believes this information enhances investors' understanding of the Company's results as it permits investors to understand how management assesses performance. Non-GAAP income and non-GAAP EPS exclude certain items because of the nature of these items and the impact that they have on the analysis of underlying business performance and trends. The excluded items (which should not be considered non-recurring) consist of acquisition and divestiture-related costs, restructuring costs, income and losses from investments in equity securities and certain other items. These excluded items are significant components in understanding and assessing financial performance.

Non-GAAP income and non-GAAP EPS are important internal measures for the Company. Senior management receives a monthly analysis of operating results that includes non-GAAP EPS. Management uses these measures internally for planning and forecasting purposes and to measure the performance of the Company along with other metrics. In addition, senior management's annual compensation is derived in part using non-GAAP pretax income. Since non-GAAP income and non-GAAP EPS are not measures determined in accordance with GAAP, they have no standardized meaning prescribed by GAAP and, therefore, may not be comparable to the calculation of similar measures of other companies. The information on non-GAAP income and non-GAAP EPS should be considered in addition to, but not as a substitute for or superior to, net income and EPS prepared in accordance with generally accepted accounting principles in the U.S. (GAAP).

A reconciliation between GAAP financial measures and non-GAAP financial measures (from continuing operations) is as follows:

($ in millions except per share amounts)	**2021**	2020	2019
Income from continuing operations before taxes as reported under GAAP	**$ 13,879**	$ 5,863	$ 7,171
Increase (decrease) for excluded items:			
Acquisition and divestiture-related costs [1]	**2,484**	3,642	2,970
Restructuring costs	**868**	880	915
Income from investments in equity securities, net	**(1,884)**	(1,292)	(132)
Other items:			
Charge for the acquisition of Pandion	**1,704**	—	—
Charges for the discontinuation of COVID-19 development programs	**225**	305	
Charge for the acquisition of VelosBio	**(43)**	2,660	—
Charges for the formation of collaborations [2]	**—**	1,076	—
Charge for the acquisition of OncoImmune	**—**	462	—
Charge for the acquisition of Peloton	**—**	—	993
Other	**(4)**	(20)	55
Non-GAAP income from continuing operations before taxes	**17,229**	13,576	11,972
Taxes on income as reported under GAAP	**1,521**	1,340	1,565
Estimated tax benefit on excluded items [3]	**206**	793	710
Net tax benefit from the settlement of certain federal income tax matters	**207**	—	106
Adjustment to tax benefits recorded in conjunction with the 2015 Cubist Pharmaceuticals, Inc. acquisition	**—**	(67)	—
Tax benefit from the reversal of tax reserves related to the divestiture of MCC	**—**	—	86
Net tax charge related to the finalization of treasury regulations related to the enactment of the TCJA	**—**	—	(117)
Non-GAAP taxes on income from continuing operations	**1,934**	2,066	2,350
Non-GAAP net income from continuing operations	**15,295**	11,510	9,622
Less: Net income (loss) attributable to noncontrolling interests as reported under GAAP	**13**	4	(84)
Acquisition and divestiture-related costs attributable to noncontrolling interests	**—**	—	(89)
Non-GAAP net income from continuing operations attributable to noncontrolling interests	**13**	4	5
Non-GAAP net income attributable to Merck & Co., Inc.	**$ 15,282**	$ 11,506	$ 9,617
EPS assuming dilution from continuing operations as reported under GAAP	**$ 4.86**	$ 1.78	$ 2.21
EPS difference	**1.16**	2.75	1.52
Non-GAAP EPS assuming dilution from continuing operations	**$ 6.02**	$ 4.53	$ 3.73

[1] *Amount in 2020 includes a $1.6 billion intangible asset impairment charge related to* Zerbaxa*. Amount in 2019 includes a $612 million intangible asset impairment charge related to* Sivextro*. See Note 9 to the consolidated financial statements.*

[2] *Includes $826 million related to transactions with Seagen. See Note 4 to the consolidated financial statements.*

[3] *The estimated tax impact on the excluded items is determined by applying the statutory rate of the originating territory of the non-GAAP adjustments.*

Acquisition and Divestiture-Related Costs

Non-GAAP income and non-GAAP EPS exclude the impact of certain amounts recorded in connection with acquisitions and divestitures. These amounts include the amortization of intangible assets and amortization of purchase accounting adjustments to inventories, as well as intangible asset impairment charges, and expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration. Also

excluded are integration, transaction, and certain other costs associated with acquisitions and divestitures. Non-GAAP income and non-GAAP EPS also exclude amortization of intangible assets related to collaborations and licensing arrangements.

Restructuring Costs

Non-GAAP income and non-GAAP EPS exclude costs related to restructuring actions (see Note 6 to the consolidated financial statements). These amounts include employee separation costs and accelerated depreciation associated with facilities to be closed or divested. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the asset, based upon the anticipated date the site will be closed or divested or the equipment disposed of, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. Restructuring costs also include asset abandonment, facility shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation costs.

Income and Losses from Investments in Equity Securities

Non-GAAP income and non-GAAP EPS exclude realized and unrealized gains and losses from investments in equity securities either owned directly or through ownership interests in investment funds.

Certain Other Items

Non-GAAP income and non-GAAP EPS exclude certain other items. These items are adjusted for after evaluating them on an individual basis, considering their quantitative and qualitative aspects. Typically, these consist of items that are unusual in nature, significant to the results of a particular period or not indicative of future operating results. Excluded from non-GAAP income and non-GAAP EPS are charges for the acquisitions of Pandion, VelosBio, OncoImmune and Peloton, as well as charges related to collaborations, including transactions with Seagen (see Note 4 to the consolidated financial statements). Also excluded from non-GAAP income and non-GAAP EPS are charges related to the discontinuation of COVID-19 development programs (see Note 4 to the consolidated financial statements). Additionally, excluded from non-GAAP income and non-GAAP EPS are certain tax items, including net tax benefits related to the settlement of certain federal income tax matters, an adjustment to tax benefits recorded in conjunction with the 2015 acquisition of Cubist Pharmaceuticals, Inc., a tax benefit related to the reversal of tax reserves established in connection with the 2014 divestiture of MCC, and a net tax charge related to the finalization of U.S. treasury regulations related to the TCJA (see Note 16 to the consolidated financial statements).

Research and Development

Research Pipeline

The Company currently has several candidates under regulatory review in the U.S. and internationally, as well as in late-stage clinical development. A chart reflecting the Company's current research pipeline as of February 22, 2022 and related discussion is set forth in Item 1. "Business — Research and Development" above.

Acquisitions, Research Collaborations and License Agreements

Merck continues to remain focused on pursuing opportunities that have the potential to drive both near- and long-term growth. Certain recent transactions are summarized below; additional details are included in Note 4 to the consolidated financial statements. Merck actively monitors the landscape for growth opportunities that meet the Company's strategic criteria.

In March 2021, Merck and Gilead entered into an agreement to jointly develop and commercialize long-acting treatments in HIV that combine Merck's investigational NRTTI, islatravir, and Gilead's investigational capsid inhibitor, lenacapavir. The collaboration will initially focus on long-acting oral formulations and long-acting injectable formulations of these combination products, with other formulations potentially added to the collaboration as mutually agreed. There was no upfront payment made by either party upon entering into the agreement.

In April 2021, Merck acquired Pandion, a clinical-stage biotechnology company developing novel therapeutics designed to address the unmet needs of patients living with autoimmune diseases, for total consideration of $1.9 billion. Pandion is advancing a pipeline of precision immune modulators targeting critical immune control nodes.

In November 2021, Merck acquired Acceleron, a publicly traded biopharmaceutical company, for total consideration of $11.5 billion. Acceleron is evaluating the TGF-beta superfamily of proteins that is known to play a central role in the regulation of cell growth, differentiation and repair. Acceleron's lead therapeutic candidate,

sotatercept (MK-7962), has a novel mechanism of action with the potential to improve short-term and/or long-term clinical outcomes in patients with PAH. Sotatercept is in Phase 3 trials as an add-on to current standard of care for the treatment of PAH. In addition to sotatercept, Acceleron's portfolio includes Reblozyl (luspatercept), a first-in-class erythroid maturation recombinant fusion protein that is approved in the U.S., Europe, Canada and Australia for the treatment of anemia in certain rare blood disorders and is being evaluated in clinical trials for additional indications for hematology therapies. Reblozyl is being developed and commercialized through a global collaboration with Bristol Myers Squibb.

Acquired In-Process Research and Development

In connection with business combinations, the Company has recorded the fair value of in-process research projects which, at the time of acquisition, had not yet reached technological feasibility. At December 31, 2021, the balance of IPR&D was $9.3 billion (see Note 9 to the consolidated financial statements).

The IPR&D projects that remain in development are subject to the inherent risks and uncertainties in drug development and it is possible that the Company will not be able to successfully develop and complete the IPR&D programs and profitably commercialize the underlying product candidates. The time periods to receive approvals from the FDA and other regulatory agencies are subject to uncertainty. Significant delays in the approval process, or the Company's failure to obtain approval at all, would delay or prevent the Company from realizing revenues from these products. Additionally, if the IPR&D programs require additional clinical trial data than previously anticipated, or if the programs fail or are abandoned during development, then the Company will not realize the future cash flows it has estimated and recorded as IPR&D as of the acquisition date. If such circumstances were to occur, the Company's future operating results could be adversely affected and the Company may recognize impairment charges, which could be material.

In 2021, 2020, and 2019 the Company recorded IPR&D impairment charges within *Research and development* expenses of $275 million, $90 million and $172 million, respectively (see Note 9 to the consolidated financial statements).

Additional research and development will be required before any of the remaining programs reach technological feasibility. The costs to complete the research projects will depend on whether the projects are brought to their final stages of development and are ultimately submitted to the FDA or other regulatory agencies for approval.

Capital Expenditures

Capital expenditures were $4.4 billion in 2021, $4.4 billion in 2020 and $3.4 billion in 2019. Expenditures in the U.S. were $2.8 billion in 2021, $2.6 billion in 2020 and $1.9 billion in 2019. The Company plans to invest approximately $20 billion in capital projects from 2021-2025 including expanding manufacturing capacity for oncology, vaccine and animal health products.

Depreciation expense was $1.6 billion in 2021, $1.7 billion in 2020 and $1.6 billion in 2019, of which $1.1 billion in 2021, $1.2 billion in 2020 and $1.2 billion in 2019, related to locations in the U.S. Total depreciation expense in 2021, 2020 and 2019 included accelerated depreciation of $91 million, $268 million and $233 million, respectively, associated with restructuring activities (see Note 6 to the consolidated financial statements).

Analysis of Liquidity and Capital Resources

Merck's strong financial profile enables it to fund research and development, focus on external alliances, support in-line products and maximize upcoming launches while providing significant cash returns to shareholders.

Selected Data

($ in millions)	**2021**	2020	2019
Working capital	**$ 6,394**	$ 437	$ 5,263
Total debt to total liabilities and equity	**31.3 %**	34.7 %	31.2 %
Cash provided by operating activities of continuing operations to total debt	**0.4:1**	0.2:1	0.3:1

The increase in working capital in 2021 compared with 2020 is primarily related to decreased short-term debt.

Cash provided by operating activities of continuing operations was $13.1 billion in 2021 compared with $7.6 billion in 2020 and $8.9 billion in 2019. The higher cash provided by operating activities of continuing operations in 2021 reflects stronger operating performance. Cash provided by operating activities of continuing operations includes upfront and milestone payments related to collaborations of $435 million in 2021, $2.9 billion in 2020 and $805 million in 2019. Cash provided by operating activities of continuing operations continues to be the Company's source of funds to finance operating needs, with excess cash serving as the primary source of funds to finance capital expenditures, treasury stock purchases and dividends paid to shareholders.

Cash used in investing activities of continuing operations was $16.4 billion in 2021 compared with $9.2 billion in 2020. The higher use of cash in investing activities of continuing operations was primarily due to higher cash used for acquisitions, including for the acquisition of Acceleron, and lower proceeds from sales of securities and other investments, partially offset by the 2020 purchase of Seagen common stock. Cash used in investing activities of continuing operations was $9.2 billion in 2020 compared with $2.5 billion in 2019. The increase was driven primarily by lower proceeds from the sales of securities and other investments, higher use of cash for acquisitions, higher capital expenditures and the purchase of Seagen common stock, partially offset by lower purchases of securities and other investments.

Cash provided by financing activities of continuing operations was $3.1 billion in 2021 compared with a use of cash in financing activities of continuing operations of $2.8 billion in 2020. The change was primarily driven by the cash distribution received from Organon in connection with the spin-off (see Note 3 to the consolidated financial statements), higher proceeds from the issuance of debt (see below) and lower purchases of treasury stock, partially offset by a net decrease in short-term borrowings in 2021 compared with a net increase in short-term borrowings in 2020, higher payments on debt (see below) and higher dividends paid to shareholders. Cash used in financing activities of continuing operations was $2.8 billion in 2020 compared with $8.9 billion in 2019. The lower use of cash in financing activities of continuing operations was driven primarily by a net increase in short-term borrowings in 2020 compared with a net decrease in short-term borrowing in 2019, as well as lower purchases of treasury stock, partially offset by higher payments on debt (see below), lower proceeds from the issuance of debt (see below), higher dividends paid to shareholders and lower proceeds from the exercise of stock options.

In December 2021, the Company issued $8.0 billion principal amount of senior unsecured notes consisting of $1.5 billion of 1.70% notes due 2027, $1.0 billion of 1.90% notes due 2028, $2.0 billion of 2.15% notes due 2031, $2.0 billion of 2.75% notes due 2051 and $1.5 billion of 2.90% notes due 2061. Merck used the net proceeds from the offering of the 2027 notes, the 2031 notes, the 2051 notes and the 2061 notes for general corporate purposes, including the repayment of outstanding commercial paper borrowings (including commercial paper borrowings in connection with Merck's acquisition of Acceleron), and other indebtedness. Merck allocated an amount equal to the net proceeds of the offering of the notes due in 2028 to finance or refinance, in whole or in part, projects and partnerships in the Company's priority ESG areas.

In June 2020, the Company issued $4.5 billion principal amount of senior unsecured notes consisting of $1.0 billion of 0.75% notes due 2026, $1.25 billion of 1.45% notes due 2030, $1.0 billion of 2.35% notes due 2040 and $1.25 billion of 2.45% notes due 2050. Merck used the net proceeds from the offering for general corporate purposes, including the repayment of outstanding commercial paper borrowings and other indebtedness.

In March 2019, the Company issued $5.0 billion principal amount of senior unsecured notes consisting of $750 million of 2.90% notes due 2024, $1.75 billion of 3.40% notes due 2029, $1.0 billion of 3.90% notes due 2039, and $1.5 billion of 4.00% notes due 2049. The Company used the net proceeds from the offering for general corporate purposes, including the repayment of outstanding commercial paper borrowings.

In February 2022, the Company's $1.25 billion, 2.35% notes matured in accordance with their terms and were repaid. In 2021, the Company's $1.15 billion, 3.875% notes and the Company's €1.0 billion, 1.125% notes matured in accordance with their terms and were repaid. In 2020, the Company's $1.25 billion, 1.85% notes and $700 million floating-rate notes matured in accordance with their terms and were repaid.

The Company has a $6.0 billion credit facility that matures in June 2026. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

The Company expects foreseeable liquidity and capital resource requirements to be met through existing cash and cash equivalents and anticipated cash flows from operations, as well as commercial paper borrowings and long-term borrowings if needed. Merck believes that its sources of financing will be adequate to meet its future requirements. The Company's material cash requirements arising in the normal course of business primarily include:

Debt Obligations and Interest Payments – See Note 10 to the consolidated financial statements for further detail of the Company's debt obligations and the timing of expected future principal and interest payments.

Tax Liabilities – In connection with the enactment of the TCJA, the Company is required to pay a one-time transition tax, which the Company has elected to pay over a period of eight years through 2025 as permitted under the TCJA. Additionally, the Company has liabilities for unrecognized tax benefits, including interest and penalties. See Note 16 to the consolidated financial statements for further information pertaining to the transition tax and liabilities for unrecognized tax benefits.

Operating Leases – See Note 10 to consolidated financial statements for further details of the Company's lease obligations and the timing of expected future lease payments.

Contingent Milestone Payments – The Company has accrued liabilities for contingent sales-based milestone payments related to collaborations with AstraZeneca, Eisai, and Bayer where payment has been deemed probable, but remains subject to the achievement of the related sales milestone. See Note 5 to the consolidated financial statements for additional information related to these sales-based milestones.

Purchase Obligations – Purchase obligations are enforceable and legally binding obligations for purchases of goods and services including minimum inventory contracts, research and development and advertising. Purchase obligations also include future inventory purchases the Company has committed to in connection with certain divestitures. As of December 31, 2021, the Company had total purchase obligations of $5.3 billion, of which $1.6 billion is estimated to be payable in 2022.

In March 2021, the Company filed a securities registration statement with the U.S. Securities and Exchange Commission (SEC) under the automatic shelf registration process available to "well-known seasoned issuers" which is effective for three years.

Effective as of November 3, 2009, the Company executed a full and unconditional guarantee of the then existing debt of its subsidiary Merck Sharp & Dohme Corp. (MSD) and MSD executed a full and unconditional guarantee of the then existing debt of the Company (excluding commercial paper), including for payments of principal and interest. These guarantees do not extend to debt issued subsequent to that date.

The Company believes it maintains a conservative financial profile. The Company places its cash and investments in instruments that meet high credit quality standards, as specified in its investment policy guidelines. These guidelines also limit the amount of credit exposure to any one issuer. The Company does not participate in any off-balance sheet arrangements involving unconsolidated subsidiaries that provide financing or potentially expose the Company to unrecorded financial obligations.

In November 2021, Merck's Board of Directors increased the quarterly dividend, declaring a quarterly dividend of $0.69 per share on the Company's outstanding common stock that was paid in January 2022. In January 2022, the Board of Directors declared a quarterly dividend of $0.69 per share on the Company's common stock for the second quarter of 2022 payable in April 2022.

In October 2018, Merck's Board of Directors authorized purchases of up to $10 billion of Merck's common stock for its treasury. The treasury stock purchase authorization has no time limit and will be made over time in open-market transactions, block transactions, on or off an exchange, or in privately negotiated transactions. In May 2021, Merck restarted its share repurchase program, which the Company had temporarily suspended in March 2020. The Company spent $840 million to purchase 11 million shares of its common stock for its treasury during 2021 under this program. As of December 31, 2021, the Company's remaining share repurchase

authorization was $5.0 billion. The Company purchased $1.3 billion and $4.8 billion of its common stock during 2020 and 2019, respectively, under authorized share repurchase programs.

Financial Instruments Market Risk Disclosures

The Company manages the impact of foreign exchange rate movements and interest rate movements on its earnings, cash flows and fair values of assets and liabilities through operational means and through the use of various financial instruments, including derivative instruments.

A significant portion of the Company's revenues and earnings in foreign affiliates is exposed to changes in foreign exchange rates. The objectives of and accounting related to the Company's foreign currency risk management program, as well as its interest rate risk management activities are discussed below.

Foreign Currency Risk Management

The Company has established revenue hedging, balance sheet risk management, and net investment hedging programs to protect against volatility of future foreign currency cash flows and changes in fair value caused by changes in foreign exchange rates.

The objective of the revenue hedging program is to reduce the variability caused by changes in foreign exchange rates that would affect the U.S. dollar value of future cash flows derived from foreign currency denominated sales, primarily the euro, Japanese yen and Chinese renminbi. To achieve this objective, the Company will hedge a portion of its forecasted foreign currency denominated third-party and intercompany distributor entity sales (forecasted sales) that are expected to occur over its planning cycle, typically no more than two years into the future. The Company will layer in hedges over time, increasing the portion of forecasted sales hedged as it gets closer to the expected date of the forecasted sales. The portion of forecasted sales hedged is based on assessments of cost-benefit profiles that consider natural offsetting exposures, revenue and exchange rate volatilities and correlations, and the cost of hedging instruments. The Company manages its anticipated transaction exposure principally with purchased local currency put options, forward contracts, and purchased collar options.

The fair values of these derivative contracts are recorded as either assets (gain positions) or liabilities (loss positions) in the Consolidated Balance Sheet. Changes in the fair value of derivative contracts are recorded each period in either current earnings or *Other Comprehensive Income (Loss)* (*OCI)*, depending on whether the derivative is designated as part of a hedge transaction and, if so, the type of hedge transaction. For derivatives that are designated as cash flow hedges, the unrealized gains or losses on these contracts are recorded in *Accumulated Other Comprehensive Loss* (*AOCL)* and reclassified into *Sales* when the hedged anticipated revenue is recognized. For those derivatives which are not designated as cash flow hedges, but serve as economic hedges of forecasted sales, unrealized gains or losses are recorded in *Sales* each period. The cash flows from both designated and non-designated contracts are reported as operating activities in the Consolidated Statement of Cash Flows. The Company does not enter into derivatives for trading or speculative purposes.

Because Merck principally sells foreign currency in its revenue hedging program, a uniform weakening of the U.S. dollar would yield the largest overall potential loss in the market value of these hedge instruments. The market value of Merck's hedges would have declined by an estimated $648 million and $593 million at December 31, 2021 and 2020, respectively, from a uniform 10% weakening of the U.S. dollar. The market value was determined using a foreign exchange option pricing model and holding all factors except exchange rates constant. Although not predictive in nature, the Company believes that a 10% threshold reflects reasonably possible near-term changes in Merck's major foreign currency exposures relative to the U.S. dollar.

The Company manages operating activities and net asset positions at each local subsidiary in order to mitigate the effects of exchange on monetary assets and liabilities. The Company also uses a balance sheet risk management program to mitigate the exposure of net monetary assets that are denominated in a currency other than a subsidiary's functional currency from the effects of volatility in foreign exchange. In these instances, Merck principally utilizes forward exchange contracts to offset the effects of exchange on exposures denominated in developed country currencies, primarily the euro, Japanese yen, British pound, Canadian dollar and Swiss franc. For exposures in developing country currencies, including the Chinese renminbi, the Company will enter into forward contracts to offset the effects of exchange on exposures when it is deemed economical to do so based on a cost-benefit analysis that considers the magnitude of the exposure, the volatility of the exchange rate and the cost of the

hedging instrument. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

Monetary assets and liabilities denominated in a currency other than the functional currency of a given subsidiary are remeasured at spot rates in effect on the balance sheet date with the effects of changes in spot rates reported in *Other (income) expense, net*. The forward contracts are not designated as hedges and are marked to market through *Other (income) expense, net*. Accordingly, fair value changes in the forward contracts help mitigate the changes in the value of the remeasured assets and liabilities attributable to changes in foreign currency exchange rates, except to the extent of the spot-forward differences. These differences are not significant due to the short-term nature of the contracts, which typically have average maturities at inception of less than one year.

A sensitivity analysis to changes in the value of the U.S. dollar on foreign currency denominated derivatives, investments and monetary assets and liabilities indicated that if the U.S. dollar uniformly weakened by 10% against all currency exposures of the Company at December 31, 2021 and 2020, *Income from Continuing Operations Before Taxes* would have declined by approximately $125 million and $99 million in 2021 and 2020, respectively. Because the Company was in a net short (payable) position relative to its major foreign currencies after consideration of forward contracts, a uniform weakening of the U.S. dollar will yield the largest overall potential net loss in earnings due to exchange. This measurement assumes that a change in one foreign currency relative to the U.S. dollar would not affect other foreign currencies relative to the U.S. dollar. Although not predictive in nature, the Company believes that a 10% threshold reflects reasonably possible near-term changes in Merck's major foreign currency exposures relative to the U.S. dollar. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

The Company also uses forward exchange contracts to hedge a portion of its net investment in foreign operations against movements in exchange rates. The forward contracts are designated as hedges of the net investment in a foreign operation. The unrealized gains or losses on these contracts are recorded in foreign currency translation adjustment within *OCI*, and remain in *AOCL* until either the sale or complete or substantially complete liquidation of the subsidiary. The Company excludes certain portions of the change in fair value of its derivative instruments from the assessment of hedge effectiveness (excluded components). Changes in fair value of the excluded components are recognized in *OCI*. The Company recognizes in earnings the initial value of the excluded components on a straight-line basis over the life of the derivative instrument, rather than using the mark-to-market approach. The cash flows from these contracts are reported as investing activities in the Consolidated Statement of Cash Flows.

Foreign exchange risk is also managed through the use of foreign currency debt. The Company's senior unsecured euro-denominated notes have been designated as, and are effective as, economic hedges of the net investment in a foreign operation. Accordingly, foreign currency transaction gains or losses due to spot rate fluctuations on the euro-denominated debt instruments are included in foreign currency translation adjustment within *OCI*.

Interest Rate Risk Management

The Company may use interest rate swap contracts on certain investing and borrowing transactions to manage its net exposure to interest rate changes and to reduce its overall cost of borrowing. The Company does not use leveraged swaps and, in general, does not leverage any of its investment activities that would put principal capital at risk.

At December 31, 2021, the Company was a party to nine pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes as detailed in the table below.

($ in millions)	**2021**		
Debt Instrument	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
2.40% notes due 2022	$ 1,000	4	$ 1,000
2.35% notes due 2022 [(1)]	1,250	5	1,250

[(1)] *These interest rate swaps matured in February 2022.*

The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in the benchmark London Interbank Offered Rate (LIBOR) swap rate. The fair value changes in the notes attributable to changes in the LIBOR swap rate are recorded in interest expense along with the offsetting fair value changes in the swap contracts. See Note 2 to the consolidated financial statements for a discussion of the pending discontinuation of LIBOR as part of reference rate reform. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

The Company's investment portfolio includes cash equivalents and short-term investments, the market values of which are not significantly affected by changes in interest rates. The market value of the Company's medium- to long-term fixed-rate investments is modestly affected by changes in U.S. interest rates. Changes in medium- to long-term U.S. interest rates have a more significant impact on the market value of the Company's fixed-rate borrowings, which generally have longer maturities. A sensitivity analysis to measure potential changes in the market value of Merck's investments and debt from a change in interest rates indicated that a one percentage point increase in interest rates at December 31, 2021 and 2020 would have positively affected the net aggregate market value of these instruments by $3.2 billion and $2.6 billion, respectively. A one percentage point decrease at December 31, 2021 and 2020 would have negatively affected the net aggregate market value by $3.9 billion and $3.1 billion, respectively. The fair value of Merck's debt was determined using pricing models reflecting one percentage point shifts in the appropriate yield curves. The fair values of Merck's investments were determined using a combination of pricing and duration models.

Critical Accounting Estimates

The Company's consolidated financial statements are prepared in conformity with GAAP and, accordingly, include certain amounts that are based on management's best estimates and judgments. Estimates are used when accounting for amounts recorded in connection with acquisitions, including initial fair value determinations of assets and liabilities (primarily IPR&D, other intangible assets and contingent consideration), as well as subsequent fair value measurements. Additionally, estimates are used in determining such items as provisions for sales discounts and returns, depreciable and amortizable lives, recoverability of inventories, including those produced in preparation for product launches, amounts recorded for contingencies, environmental liabilities, accruals for contingent sales-based milestone payments and other reserves, pension and other postretirement benefit plan assumptions, share-based compensation assumptions, restructuring costs, impairments of long-lived assets (including intangible assets and goodwill) and investments, and taxes on income. Because of the uncertainty inherent in such estimates, actual results may differ from these estimates. Application of the following accounting policies result in accounting estimates having the potential for the most significant impact on the financial statements.

Acquisitions and Dispositions

To determine whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses, the Company makes certain judgments, which include assessment of the inputs, processes, and outputs associated with the acquired set of activities. If the Company determines that substantially all of the fair value of gross assets included in a transaction is concentrated in a single asset (or a group of similar assets), the assets would not represent a business. To be considered a business, the assets in a transaction need to include an input and a substantive process that together significantly contribute to the ability to create outputs.

In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the acquisition at their respective fair values with limited exceptions. The fair values of intangible assets are determined utilizing information available near the acquisition date based on expectations and assumptions that are deemed reasonable by management. Given the considerable judgment involved in determining fair values, the Company typically obtains assistance from third-party valuation specialists for significant items. Assets acquired and liabilities assumed in a business combination that arise from contingencies are generally recognized at fair value. If fair value cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Accordingly, the Company may be required to value assets at fair value measures that do not reflect the Company's intended use of those assets. Any excess of the purchase price (consideration transferred)

over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in the Company's consolidated financial statements after the date of the acquisition.

The judgments made in determining estimated fair values assigned to assets acquired and liabilities assumed in a business combination, as well as asset lives, can materially affect the Company's results of operations.

The fair values of identifiable intangible assets related to currently marketed products and product rights are primarily determined by using an income approach through which fair value is estimated based on each asset's discounted projected net cash flows. The Company's estimates of market participant net cash flows consider historical and projected pricing, margins and expense levels; the performance of competing products where applicable; relevant industry and therapeutic area growth drivers and factors; current and expected trends in technology and product life cycles; the time and investment that will be required to develop products and technologies; the ability to obtain marketing and regulatory approvals; the ability to manufacture and commercialize the products; the extent and timing of potential new product introductions by the Company's competitors; and the life of each asset's underlying patent and any related patent term extension, if any. The net cash flows are then probability-adjusted where appropriate to consider the uncertainties associated with the underlying assumptions, as well as the risk profile of the net cash flows utilized in the valuation. The probability-adjusted future net cash flows of each product are then discounted to present value utilizing an appropriate discount rate.

The fair values of identifiable intangible assets related to IPR&D are also determined using an income approach, through which fair value is estimated based on each asset's probability-adjusted future net cash flows, which reflect the different stages of development of each product and the associated probability of successful completion. The net cash flows are then discounted to present value using an appropriate discount rate. Amounts allocated to acquired IPR&D are capitalized and accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each IPR&D project, Merck will make a determination as to the then-useful life of the intangible asset, generally determined by the period in which the substantial majority of the cash flows are expected to be generated, and begin amortization.

Certain of the Company's business combinations involve the potential for future payment of consideration that is contingent upon the achievement of performance milestones, including product development milestones and royalty payments on future product sales. The fair value of contingent consideration liabilities is determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date, at each reporting period until the contingency is resolved, the contingent consideration liability is remeasured at current fair value with changes (either expense or income) recorded in earnings. Changes in any of the inputs may result in a significantly different fair value adjustment.

If the Company determines the transaction will not be accounted for as an acquisition of a business, the transaction will be accounted for as an asset acquisition rather than a business combination and, therefore, no goodwill will be recorded. In an asset acquisition, acquired IPR&D with no alternative future use is charged to expense and contingent consideration is not recognized at the acquisition date. In these instances, product development milestones are recognized upon achievement and sales-based milestones are recognized when the milestone is deemed probable by the Company of being achieved.

Revenue Recognition

Recognition of revenue requires evidence of a contract, probable collection of sales proceeds and completion of substantially all performance obligations. Merck acts as the principal in substantially all of its customer arrangements and therefore records revenue on a gross basis. The majority of the Company's contracts related to the Pharmaceutical and Animal Health segments have a single performance obligation - the promise to transfer goods. Shipping is considered immaterial in the context of the overall customer arrangement and damages or loss of goods in transit are rare. Therefore, shipping is not deemed a separately recognized performance obligation.

The vast majority of revenues from sales of products are recognized at a point in time when control of the goods is transferred to the customer, which the Company has determined is when title and risks and rewards of

ownership transfer to the customer and the Company is entitled to payment. For certain services in the Animal Health segment, revenue is recognized over time, generally ratably over the contract term as services are provided. These service revenues are not material.

The nature of the Company's business gives rise to several types of variable consideration including discounts and returns, which are estimated at the time of sale generally using the expected value method, although the most likely amount method is used for prompt pay discounts.

In the U.S., sales discounts are issued to customers at the point-of-sale, through an intermediary wholesaler (known as chargebacks), or in the form of rebates. Additionally, sales are generally made with a limited right of return under certain conditions. Revenues are recorded net of provisions for sales discounts and returns, which are established at the time of sale. In addition, if collection of accounts receivable is expected to be in excess of one year, sales are recorded net of time value of money discounts, which have not been material.

The U.S. provision for aggregate customer discounts covers chargebacks and rebates. Chargebacks are discounts that occur when a contracted customer purchases through an intermediary wholesaler. The contracted customer generally purchases product from the wholesaler at its contracted price plus a mark-up. The wholesaler, in turn, charges the Company back for the difference between the price initially paid by the wholesaler and the contract price paid to the wholesaler by the customer. The provision for chargebacks is based on expected sell-through levels by the Company's wholesale customers to contracted customers, as well as estimated wholesaler inventory levels. Rebates are amounts owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers after the final dispensing of the product to a benefit plan participant. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. The Company uses historical customer segment utilization mix, sales forecasts, changes to product mix and price, inventory levels in the distribution channel, government pricing calculations and prior payment history in order to estimate the expected provision. Amounts accrued for aggregate customer discounts are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal and state agencies, and other customers to the amounts accrued.

The Company continually monitors its provision for aggregate customer discounts. There were no material adjustments to estimates associated with the aggregate customer discount provision in 2021, 2020 or 2019.

Summarized information about changes in the aggregate customer discount accrual related to U.S. sales is as follows:

($ in millions)	**2021**	2020
Balance January 1	**$ 2,776**	$ 2,078
Current provision	**12,412**	11,423
Adjustments to prior years	**(110)**	(24)
Payments	**(12,234)**	(10,701)
Balance December 31	**$ 2,844**	$ 2,776

Accruals for chargebacks are reflected as a direct reduction to accounts receivable and accruals for rebates as current liabilities. The accrued balances relative to these provisions included in *Accounts receivable* and *Accrued and other current liabilities* were $207 million and $2.6 billion, respectively, at December 31, 2021 and were $208 million and $2.6 billion, respectively, at December 31, 2020.

Outside of the U.S., variable consideration in the form of discounts and rebates are a combination of commercially-driven discounts in highly competitive product classes, discounts required to gain or maintain reimbursement, or legislatively mandated rebates. In certain European countries, legislatively mandated rebates are calculated based on an estimate of the government's total unbudgeted spending and the Company's specific payback obligation. Rebates may also be required based on specific product sales thresholds. The Company applies an estimated factor against its actual invoiced sales to represent the expected level of future discount or rebate obligations associated with the sale.

The Company maintains a returns policy that allows its U.S. pharmaceutical customers to return product within a specified period prior to and subsequent to the expiration date (generally, three to six months before and 12

months after product expiration). The estimate of the provision for returns is based upon historical experience with actual returns. Additionally, the Company considers factors such as levels of inventory in the distribution channel, product dating and expiration period, whether products have been discontinued, entrance in the market of generic or other competition, changes in formularies or launch of over-the-counter products, among others. The product returns provision for U.S. pharmaceutical sales as a percentage of U.S. net pharmaceutical sales was 0.9% in 2021, 0.5% in 2020 and 1.0% in 2019. Outside of the U.S., returns are only allowed in certain countries on a limited basis.

Merck's payment terms for U.S. pharmaceutical customers are typically 36 days from receipt of invoice and for U.S. animal health customers are typically 30 days from receipt of invoice; however, certain products, including *Keytruda*, have longer payment terms, some of which are up to 90 days. Outside of the U.S., payment terms are typically 30 days to 90 days, although certain markets have longer payment terms.

Through its distribution programs with U.S. wholesalers, the Company encourages wholesalers to align purchases with underlying demand and maintain inventories below specified levels. The terms of the programs allow the wholesalers to earn fees upon providing visibility into their inventory levels, as well as by achieving certain performance parameters such as inventory management, customer service levels, reducing shortage claims and reducing product returns. Information provided through the wholesaler distribution programs includes items such as sales trends, inventory on-hand, on-order quantity and product returns.

Wholesalers generally provide only the above-mentioned data to the Company, as there is no regulatory requirement to report lot level information to manufacturers, which is the level of information needed to determine the remaining shelf life and original sale date of inventory. Given current wholesaler inventory levels, which are generally less than a month, the Company believes that collection of order lot information across all wholesale customers would have limited use in estimating sales discounts and returns.

Inventories Produced in Preparation for Product Launches

The Company capitalizes inventories produced in preparation for product launches sufficient to support estimated initial market demand. Typically, capitalization of such inventory does not begin until the related product candidates are in Phase 3 clinical trials and are considered to have a high probability of regulatory approval. The Company monitors the status of each respective product within the regulatory approval process; however, the Company generally does not disclose specific timing for regulatory approval. If the Company is aware of any specific risks or contingencies other than the normal regulatory approval process or if there are any specific issues identified during the research process relating to safety, efficacy, manufacturing, marketing or labeling, the related inventory would generally not be capitalized. Expiry dates of the inventory are affected by the stage of completion. The Company manages the levels of inventory at each stage to optimize the shelf life of the inventory in relation to anticipated market demand in order to avoid product expiry issues. For inventories that are capitalized, anticipated future sales and shelf lives support the realization of the inventory value as the inventory shelf life is sufficient to meet initial product launch requirements. Inventories produced in preparation for product launches capitalized at December 31, 2021 and 2020 were $256 million and $279 million, respectively.

Contingencies and Environmental Liabilities

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property and commercial litigation, as well as certain additional matters including governmental and environmental matters (see Note 11 to the consolidated financial statements). The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. For product liability claims, a portion of the overall accrual is actuarially determined and considers such factors as past experience, number of claims reported and estimates of claims incurred but not yet reported. Individually significant contingent losses are accrued when probable and reasonably estimable.

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense

reserves as of December 31, 2021 and 2020 of approximately $230 million and $235 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

The Company and its subsidiaries are parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund, and other federal and state equivalents. When a legitimate claim for contribution is asserted, a liability is initially accrued based upon the estimated transaction costs to manage the site. Accruals are adjusted as site investigations, feasibility studies and related cost assessments of remedial techniques are completed, and as the extent to which other potentially responsible parties who may be jointly and severally liable can be expected to contribute is determined.

The Company is also remediating environmental contamination resulting from past industrial activity at certain of its sites and takes an active role in identifying and accruing for these costs. In the past, Merck performed a worldwide survey to assess all sites for potential contamination resulting from past industrial activities. Where assessment indicated that physical investigation was warranted, such investigation was performed, providing a better evaluation of the need for remedial action. Where such need was identified, remedial action was then initiated. As definitive information became available during the course of investigations and/or remedial efforts at each site, estimates were refined and accruals were established or adjusted accordingly. These estimates and related accruals continue to be refined annually.

The Company believes that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on the Company. Expenditures for remediation and environmental liabilities were $12 million in 2021 and are estimated to be $24 million in the aggregate for the years 2022 through 2026. In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $40 million and $43 million at December 31, 2021 and 2020, respectively. These liabilities are undiscounted, do not consider potential recoveries from other parties and will be paid out over the periods of remediation for the applicable sites, which are expected to occur primarily over the next 15 years. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed approximately $40 million in the aggregate. Management also does not believe that these expenditures should result in a material adverse effect on the Company's financial condition, results of operations or liquidity for any year.

Share-Based Compensation

The Company expenses all share-based payment awards to employees, including grants of stock options, over the requisite service period based on the grant date fair value of the awards. The Company determines the fair value of certain share-based awards using the Black-Scholes option-pricing model which uses both historical and current market data to estimate the fair value. This method incorporates various assumptions such as the risk-free interest rate, expected volatility, expected dividend yield and expected life of the options. Total pretax share-based compensation expense from continuing operations was $479 million in 2021, $441 million in 2020 and $388 million in 2019. At December 31, 2021, there was $699 million of total pretax unrecognized compensation expense related to nonvested stock option, restricted stock unit and performance share unit awards which will be recognized over a weighted-average period of 1.9 years. For segment reporting, share-based compensation costs are unallocated expenses.

Pensions and Other Postretirement Benefit Plans

Net periodic benefit cost for pension plans totaled $748 million in 2021, $450 million in 2020 and $134 million in 2019. Net periodic benefit credit for other postretirement benefit plans was $83 million in 2021, $59 million in 2020 and $49 million in 2019. Pension and other postretirement benefit plan information for financial reporting purposes is calculated using actuarial assumptions including a discount rate for plan benefit obligations

and an expected rate of return on plan assets. The changes in net periodic benefit cost year over year for pension plans are attributable to settlement charges incurred by certain plans, as well as changes in the discount rate.

The Company reassesses its benefit plan assumptions on a regular basis. For both the pension and other postretirement benefit plans, the discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due. The discount rates for the Company's U.S. pension and other postretirement benefit plans ranged from 2.60% to 3.10% at December 31, 2021, compared with a range of 2.10% to 2.80% at December 31, 2020.

The expected rate of return for both the pension and other postretirement benefit plans represents the average rate of return to be earned on plan assets over the period the benefits included in the benefit obligation are to be paid. In developing the expected rate of return, the Company considers long-term compound annualized returns of historical market data, current market conditions and actual returns on the Company's plan assets. Using this reference information, the Company develops forward-looking return expectations for each asset category and a weighted-average expected long-term rate of return for a target portfolio allocated across these investment categories. The expected portfolio performance reflects the contribution of active management as appropriate. For 2022, the expected rate of return for the Company's U.S. pension and other postretirement benefit plans will be 6.70%, compared to a range of 6.50% to 6.70% in 2021.

The Company has established investment guidelines for its U.S. pension and other postretirement plans to create an asset allocation that is expected to deliver a rate of return sufficient to meet the long-term obligation of each plan, given an acceptable level of risk. The target investment portfolio of the Company's U.S. pension and other postretirement benefit plans is allocated 30% to 45% in U.S. equities, 15% to 30% in international equities, 35% to 45% in fixed-income investments, and up to 5% in cash and other investments. The portfolio's equity weighting is consistent with the long-term nature of the plans' benefit obligations. The expected annual standard deviation of returns of the target portfolio, which approximates 11%, reflects both the equity allocation and the diversification benefits among the asset classes in which the portfolio invests. For international pension plans, the targeted investment portfolio varies based on the duration of pension liabilities and local government rules and regulations. Although a significant percentage of plan assets are invested in U.S. equities, concentration risk is mitigated through the use of strategies that are diversified within management guidelines.

Actuarial assumptions are based upon management's best estimates and judgment. A reasonably possible change of plus (minus) 25 basis points in the discount rate assumption, with other assumptions held constant, would have had an estimated $85 million favorable (unfavorable) impact on the Company's net periodic benefit cost in 2021. A reasonably possible change of plus (minus) 25 basis points in the expected rate of return assumption, with other assumptions held constant, would have had an estimated $58 million favorable (unfavorable) impact on Merck's net periodic benefit cost in 2021. Required funding obligations for 2022 relating to the Company's pension and other postretirement benefit plans are not expected to be material. The preceding hypothetical changes in the discount rate and expected rate of return assumptions would not impact the Company's funding requirements.

Net loss amounts, which primarily reflect differences between expected and actual returns on plan assets as well as the effects of changes in actuarial assumptions, are recorded as a component of *AOCL*. Expected returns for pension plans are based on a calculated market-related value of assets. Net loss amounts in *AOCL* in excess of certain thresholds are amortized into net periodic benefit cost over the average remaining service life of employees.

Restructuring Costs

Restructuring costs have been recorded in connection with restructuring programs designed to streamline the Company's cost structure. As a result, the Company has made estimates and judgments regarding its future plans, including future termination benefits and other exit costs to be incurred when the restructuring actions take place. When accruing termination costs, the Company will recognize the amount within a range of costs that is the best estimate within the range. When no amount within the range is a better estimate than any other amount, the Company recognizes the minimum amount within the range. In connection with these actions, management also assesses the recoverability of long-lived assets employed in the business. In certain instances, asset lives have been shortened based on changes in the expected useful lives of the affected assets. Severance and other related costs are reflected within *Restructuring costs*. Asset-related charges are reflected within *Cost of sales*, *Selling, general and administrative* expenses and *Research and development* expenses depending upon the nature of the asset.

Impairments of Long-Lived Assets

The Company assesses changes in economic, regulatory and legal conditions and makes assumptions regarding estimated future cash flows in evaluating the value of the Company's property, plant and equipment, goodwill and other intangible assets.

The Company periodically evaluates whether current facts or circumstances indicate that the carrying values of its long-lived assets to be held and used may not be recoverable. If such circumstances are determined to exist, an estimate of the undiscounted future cash flows of these assets, or appropriate asset groupings, is compared to the carrying value to determine whether an impairment exists. If the asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows approach.

Goodwill represents the excess of the consideration transferred over the fair value of net assets of businesses acquired. Goodwill is assigned to reporting units and evaluated for impairment on at least an annual basis, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. Some of the factors considered in the assessment include general macroeconomic conditions, conditions specific to the industry and market, cost factors which could have a significant effect on earnings or cash flows, the overall financial performance of the reporting unit, and whether there have been sustained declines in the Company's share price. If the Company concludes it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a quantitative fair value test is performed. If the carrying value of a reporting unit is greater than its fair value, a goodwill impairment charge will be recorded for the difference (up to the carrying value of goodwill).

Other acquired intangible assets (excluding IPR&D) are initially recorded at fair value, assigned an estimated useful life, and amortized primarily on a straight-line basis over their estimated useful lives. When events or circumstances warrant a review, the Company will assess recoverability from future operations using pretax undiscounted cash flows derived from the lowest appropriate asset groupings. Impairments are recognized in operating results to the extent that the carrying value of the intangible asset exceeds its fair value, which is determined based on the net present value of estimated future cash flows.

IPR&D that the Company acquires in conjunction with the acquisition of a business represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. The amounts are capitalized and accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. The Company evaluates IPR&D for impairment at least annually, or more frequently if impairment indicators exist, by performing a quantitative test that compares the fair value of the IPR&D intangible asset with its carrying value. For impairment testing purposes, the Company may combine separately recorded IPR&D intangible assets into one unit of account based on the relevant facts and circumstances. Generally, the Company will combine IPR&D intangible assets for testing purposes if they operate as a single asset and are essentially inseparable. If the fair value is less than the carrying amount, an impairment loss is recognized in operating results.

The judgments made in evaluating impairment of long-lived intangibles can materially affect the Company's results of operations.

Taxes on Income

The Company's effective tax rate is based on pretax income, statutory tax rates and tax planning opportunities available in the various jurisdictions in which the Company operates. An estimated effective tax rate for a year is applied to the Company's quarterly operating results. In the event that there is a significant unusual or one-time item recognized, or expected to be recognized, in the Company's quarterly operating results, the tax attributable to that item would be separately calculated and recorded at the same time as the unusual or one-time item. The Company considers the resolution of prior year tax matters to be such items. Significant judgment is required in determining the Company's tax provision and in evaluating its tax positions. The recognition and measurement of a tax position is based on management's best judgment given the facts, circumstances and information available at the reporting date. The Company evaluates tax positions to determine whether the benefits of tax positions are more likely than not of being sustained upon audit based on the technical merits of the tax

position. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the amount of the benefit that is greater than 50% likely of being realized upon ultimate settlement in the financial statements. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit in the financial statements. If the more likely than not threshold is not met in the period for which a tax position is taken, the Company may subsequently recognize the benefit of that tax position if the tax matter is effectively settled, the statute of limitations expires, or if the more likely than not threshold is met in a subsequent period (see Note 16 to the consolidated financial statements).

Tax regulations require items to be included in the tax return at different times than the items are reflected in the financial statements. Timing differences create deferred tax assets and liabilities. Deferred tax assets generally represent items that can be used as a tax deduction or credit in the tax return in future years for which the Company has already recorded the tax benefit in the financial statements. The Company establishes valuation allowances for its deferred tax assets when the amount of expected future taxable income is not likely to support the use of the deduction or credit. Deferred tax liabilities generally represent tax expense recognized in the financial statements for which payment has been deferred or expense for which the Company has already taken a deduction on the tax return, but has not yet recognized as expense in the financial statements.

Recently Issued Accounting Standards

For a discussion of recently issued accounting standards, see Note 2 to the consolidated financial statements.

Cautionary Factors That May Affect Future Results

This report and other written reports and oral statements made from time to time by the Company may contain so-called “forward-looking statements,” all of which are based on management’s current expectations and are subject to risks and uncertainties which may cause results to differ materially from those set forth in the statements. One can identify these forward-looking statements by their use of words such as “anticipates,” “expects,” “plans,” “will,” “estimates,” “forecasts,” “projects” and other words of similar meaning, or negative variations of any of the foregoing. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address the Company’s growth strategy, financial results, product approvals, product potential, development programs, environmental or other sustainability initiatives, and include statements related to the expected impact of the COVID-19 pandemic. One must carefully consider any such statement and should understand that many factors could cause actual results to differ materially from the Company’s forward-looking statements. These factors include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. No forward-looking statement can be guaranteed and actual future results may vary materially.

The Company does not assume the obligation to update any forward-looking statement. One should carefully evaluate such statements in light of factors, including risk factors, described in the Company’s filings with the Securities and Exchange Commission, especially on this Form 10-K and Forms 10-Q and 8-K. In Item 1A. “Risk Factors” of this annual report on Form 10-K the Company discusses in more detail various important risk factors that could cause actual results to differ from expected or historic results. The Company notes these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. One should understand that it is not possible to predict or identify all such factors. Consequently, the reader should not consider any such list to be a complete statement of all potential risks or uncertainties.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

The information required by this Item is incorporated by reference to the discussion under “Financial Instruments Market Risk Disclosures” in Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

Item 8. Financial Statements and Supplementary Data.

(a) Financial Statements

The consolidated balance sheet of Merck & Co., Inc. and subsidiaries as of December 31, 2021 and 2020, and the related consolidated statements of income, of comprehensive income, of equity and of cash flows for each of the three years in the period ended December 31, 2021, the notes to consolidated financial statements, and the report dated February 25, 2022 of PricewaterhouseCoopers LLP, independent registered public accounting firm, are as follows:

Consolidated Statement of Income
Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions except per share amounts)

	2021	2020	2019
Sales	**$ 48,704**	$ 41,518	$ 39,121
Costs, Expenses and Other			
Cost of sales	**13,626**	13,618	12,016
Selling, general and administrative	**9,634**	8,955	9,455
Research and development	**12,245**	13,397	9,724
Restructuring costs	**661**	575	626
Other (income) expense, net	**(1,341)**	(890)	129
	34,825	35,655	31,950
Income from Continuing Operations Before Taxes	**13,879**	5,863	7,171
Taxes on Income from Continuing Operations	**1,521**	1,340	1,565
Net Income from Continuing Operations	**12,358**	4,523	5,606
Less: Net Income (Loss) Attributable to Noncontrolling Interests	**13**	4	(84)
Net Income from Continuing Operations Attributable to Merck & Co., Inc.	**12,345**	4,519	5,690
Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests	**704**	2,548	4,153
Net Income Attributable to Merck & Co., Inc.	**$ 13,049**	$ 7,067	$ 9,843
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders			
Income from Continuing Operations	**$ 4.88**	$ 1.79	$ 2.22
Income from Discontinued Operations	**0.28**	1.01	1.62
Net Income	**$ 5.16**	$ 2.79	$ 3.84
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders			
Income from Continuing Operations	**$ 4.86**	$ 1.78	$ 2.21
Income from Discontinued Operations	**0.28**	1.00	1.61
Net Income	**$ 5.14**	$ 2.78	$ 3.81

Consolidated Statement of Comprehensive Income
Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions)

	2021	2020	2019
Net Income Attributable to Merck & Co., Inc.	**$ 13,049**	$ 7,067	$ 9,843
Other Comprehensive Income (Loss) Net of Taxes:			
Net unrealized gain (loss) on derivatives, net of reclassifications	**410**	(297)	(135)
Net unrealized (loss) gain on investments, net of reclassifications	**—**	(18)	96
Benefit plan net gain (loss) and prior service credit (cost), net of amortization	**1,769**	(279)	(705)
Cumulative translation adjustment	**(423)**	153	96
	1,756	(441)	(648)
Comprehensive Income Attributable to Merck & Co., Inc.	**$ 14,805**	$ 6,626	$ 9,195

The accompanying notes are an integral part of these consolidated financial statements.

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Consolidated Balance Sheet
Merck & Co., Inc. and Subsidiaries
December 31
($ in millions except per share amounts)

	2021	2020
Assets		
Current Assets		
Cash and cash equivalents	**$ 8,096**	$ 8,050
Accounts receivable (net of allowance for doubtful accounts of $62 in 2021 and $67 in 2020)	**9,230**	6,803
Inventories (excludes inventories of $2,194 in 2021 and $2,070 in 2020 classified in Other assets - see Note 8)	**5,953**	5,554
Other current assets	**6,987**	4,674
Current assets of discontinued operations	**—**	2,683
Total current assets	**30,266**	27,764
Investments	**370**	785
Property, Plant and Equipment (at cost)		
Land	**326**	336
Buildings	**12,529**	11,998
Machinery, equipment and office furnishings	**16,303**	15,860
Construction in progress	**8,313**	6,968
	37,471	35,162
Less: accumulated depreciation	**18,192**	18,162
	19,279	17,000
Goodwill	**21,264**	18,882
Other Intangibles, Net	**22,933**	14,101
Other Assets	**11,582**	9,881
Noncurrent Assets of Discontinued Operations	**—**	3,175
	$ 105,694	$ 91,588
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	**$ 2,412**	$ 6,431
Trade accounts payable	**4,609**	4,327
Accrued and other current liabilities	**13,859**	12,212
Income taxes payable	**1,224**	1,597
Dividends payable	**1,768**	1,674
Current liabilities of discontinued operations	**—**	1,086
Total current liabilities	**23,872**	27,327
Long-Term Debt	**30,690**	25,360
Deferred Income Taxes	**3,441**	1,005
Other Noncurrent Liabilities	**9,434**	12,306
Noncurrent Liabilities of Discontinued Operations	**—**	186
Merck & Co., Inc. Stockholders' Equity		
Common stock, $0.50 par value Authorized - 6,500,000,000 shares Issued - 3,577,103,522 shares in 2021 and 2020	**1,788**	1,788
Other paid-in capital	**44,238**	39,588
Retained earnings	**53,696**	47,362
Accumulated other comprehensive loss	**(4,429)**	(6,634)
	95,293	82,104
Less treasury stock, at cost: 1,049,499,023 shares in 2021 and 1,046,877,695 shares in 2020	**57,109**	56,787
Total Merck & Co., Inc. stockholders' equity	**38,184**	25,317
Noncontrolling Interests	**73**	87
Total equity	**38,257**	25,404
	$ 105,694	$ 91,588

The accompanying notes are an integral part of this consolidated financial statement.

Consolidated Statement of Equity
Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions except per share amounts)

	Common Stock	Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock	Non-controlling Interests	Total
Balance January 1, 2019	$1,788	$ 38,808	$ 42,579	$ (5,545)	$ (50,929)	$ 181	$ 26,882
Net income attributable to Merck & Co., Inc.	—	—	9,843	—	—	—	9,843
Other comprehensive loss, net of taxes	—	—	—	(648)	—	—	(648)
Cash dividends declared on common stock ($2.26 per share)	—	—	(5,820)	—	—	—	(5,820)
Treasury stock shares purchased	—	1,000	—	—	(5,780)	—	(4,780)
Net loss attributable to noncontrolling interests	—	—	—	—	—	(66)	(66)
Distributions attributable to noncontrolling interests	—	—	—	—	—	(21)	(21)
Share-based compensation plans and other	—	(148)	—	—	759	—	611
Balance December 31, 2019	1,788	39,660	46,602	(6,193)	(55,950)	94	26,001
Net income attributable to Merck & Co., Inc.	—	—	7,067	—	—	—	7,067
Other comprehensive loss, net of taxes	—	—	—	(441)	—	—	(441)
Cash dividends declared on common stock ($2.48 per share)	—	—	(6,307)	—	—	—	(6,307)
Treasury stock shares purchased	—	—	—	—	(1,281)	—	(1,281)
Net income attributable to noncontrolling interests	—	—	—	—	—	15	15
Distributions attributable to noncontrolling interests	—	—	—	—	—	(22)	(22)
Share-based compensation plans and other	—	(72)	—	—	444	—	372
Balance December 31, 2020	1,788	39,588	47,362	(6,634)	(56,787)	87	25,404
Net income attributable to Merck & Co., Inc.	**—**	**—**	**13,049**	**—**	**—**	**—**	**13,049**
Other comprehensive income, net of taxes	**—**	**—**	**—**	**1,756**	**—**	**—**	**1,756**
Cash dividends declared on common stock ($2.64 per share)	**—**	**—**	**(6,715)**	**—**	**—**	**—**	**(6,715)**
Treasury stock shares purchased	**—**	**—**	**—**	**—**	**(840)**	**—**	**(840)**
Spin-off of Organon & Co.	**—**	**4,643**	**—**	**449**	**—**	**(1)**	**5,091**
Net income attributable to noncontrolling interests	**—**	**—**	**—**	**—**	**—**	**16**	**16**
Distributions attributable to noncontrolling interests	**—**	**—**	**—**	**—**	**—**	**(29)**	**(29)**
Share-based compensation plans and other	**—**	**7**	**—**	**—**	**518**	**—**	**525**
Balance December 31, 2021	**$ 1,788**	**$ 44,238**	**$ 53,696**	**$ (4,429)**	**$ (57,109)**	**$ 73**	**$ 38,257**

The accompanying notes are an integral part of this consolidated financial statement.

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Consolidated Statement of Cash Flows
Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions)

	2021	2020	2019
Cash Flows from Operating Activities of Continuing Operations			
Net income from continuing operations	**$ 12,358**	$ 4,523	$ 5,606
Adjustments to reconcile net income from continuing operations to net cash provided by operating activities of continuing operations:			
Amortization	**1,636**	1,817	1,695
Depreciation	**1,578**	1,669	1,615
Intangible asset impairment charges	**302**	1,718	1,040
Income from investments in equity securities, net	**(1,940)**	(1,338)	(170)
Charge for the acquisition of Pandion Therapeutics, Inc.	**1,556**	—	—
Charge for the acquisition of VelosBio Inc.	**—**	2,660	—
Charge for the acquisition of Peloton Therapeutics, Inc.	**—**	—	993
Deferred income taxes	**187**	(566)	(560)
Share-based compensation	**479**	441	388
Other	**805**	1,294	354
Net changes in assets and liabilities:			
Accounts receivable	**(2,033)**	(1,002)	92
Inventories	**(674)**	(895)	(473)
Trade accounts payable	**405**	684	443
Accrued and other current liabilities	**277**	(1,152)	413
Income taxes payable	**(540)**	814	(1,889)
Noncurrent liabilities	**484**	(617)	(733)
Other	**(1,758)**	(2,433)	70
Net Cash Provided by Operating Activities of Continuing Operations	**13,122**	7,617	8,884
Cash Flows from Investing Activities of Continuing Operations			
Capital expenditures	**(4,448)**	(4,429)	(3,369)
Purchase of Seagen Inc. common stock	**—**	(1,000)	—
Purchases of securities and other investments	**(1)**	(95)	(3,202)
Proceeds from sales of securities and other investments	**1,026**	2,812	8,622
Acquisition of Acceleron Pharma Inc., net of cash acquired	**(11,174)**	—	—
Acquisition of Pandion Therapeutics, Inc., net of cash acquired	**(1,554)**	—	—
Acquisition of VelosBio Inc., net of cash acquired	**—**	(2,696)	—
Acquisition of ArQule, Inc., net of cash acquired	**—**	(2,545)	—
Acquisition of Antelliq Corporation, net of cash acquired	**—**	—	(3,620)
Acquisition of Peloton Therapeutics, Inc., net of cash acquired	**—**	—	(1,040)
Other acquisitions, net of cash acquired	**(179)**	(1,365)	(294)
Other	**(91)**	125	374
Net Cash Used in Investing Activities of Continuing Operations	**(16,421)**	(9,193)	(2,529)
Cash Flows from Financing Activities of Continuing Operations			
Net change in short-term borrowings	**(3,986)**	2,549	(3,710)
Payments on debt	**(2,319)**	(1,957)	—
Proceeds from issuance of debt	**7,936**	4,419	4,958
Distribution from Organon & Co.	**9,000**	—	—
Purchases of treasury stock	**(840)**	(1,281)	(4,780)
Dividends paid to stockholders	**(6,610)**	(6,215)	(5,695)
Proceeds from exercise of stock options	**202**	89	361
Other	**(286)**	(436)	5
Net Cash Provided by (Used in) Financing Activities of Continuing Operations	**3,097**	(2,832)	(8,861)
Discontinued Operations			
Net cash provided by operating activities	**987**	2,636	4,556
Net cash used in investing activities	**(134)**	(250)	(100)
Net cash used in financing activities	**(504)**	—	—
Net Cash Flows Provided by Discontinued Operations	**349**	2,386	4,456
Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash	**(133)**	253	17
Net Increase (Decrease) in Cash, Cash Equivalents and Restricted Cash	**14**	(1,769)	1,967
Cash, Cash Equivalents and Restricted Cash at Beginning of Year (includes $103 of restricted cash at January 1, 2021 included in			

The accompanying notes are an integral part of this consolidated financial statement.

Notes to Consolidated Financial Statements
Merck & Co., Inc. and Subsidiaries
($ in millions except per share amounts)

1. Nature of Operations

Merck & Co., Inc. (Merck or the Company) is a global health care company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies and animal health products. The Company's operations are principally managed on a products basis and include two operating segments, which are the Pharmaceutical and Animal Health segments, both of which are reportable segments.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities.

The Animal Health segment discovers, develops, manufactures and markets a wide range of veterinary pharmaceutical and vaccine products, as well as health management solutions and services, for the prevention, treatment and control of disease in all major livestock and companion animal species. The Company also offers an extensive suite of digitally connected identification, traceability and monitoring products. The Company sells its products to veterinarians, distributors and animal producers.

The Company previously had a Healthcare Services segment that provided services and solutions focused on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company divested the remaining businesses in this segment during the first quarter of 2020.

Spin-Off of Organon & Co.

On June 2, 2021, Merck completed the spin-off of products from its women's health, biosimilars and established brands businesses into a new, independent, publicly traded company named Organon & Co. (Organon) through a distribution of Organon's publicly traded stock to Company shareholders. The distribution is expected to qualify and has been treated as tax-free to the Company and its shareholders for U.S. federal income tax purposes. The established brands included in the transaction consisted of dermatology, non-opioid pain management, respiratory, select cardiovascular products, as well as the rest of Merck's diversified brands franchise. Merck's existing research pipeline programs continue to be owned and developed within Merck as planned. The historical results of the businesses that were contributed to Organon in the spin-off have been reflected as discontinued operations in the Company's consolidated financial statements through the date of the spin-off (see Note 3).

2. Summary of Accounting Policies

Principles of Consolidation — The consolidated financial statements include the accounts of the Company and all of its subsidiaries in which a controlling interest is maintained. Intercompany balances and transactions are eliminated. Controlling interest is determined by majority ownership interest and the absence of substantive third-party participating rights or, in the case of variable interest entities, by majority exposure to expected losses, residual returns or both. For those consolidated subsidiaries where Merck ownership is less than 100%, the outside shareholders' interests are shown as *Noncontrolling interests* in equity. Investments in affiliates over which the Company has significant influence but not a controlling interest, such as interests in entities owned equally by the Company and a third party that are under shared control, are carried on the equity basis.

Acquisitions — In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the acquisition at their respective fair values with limited exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are generally recognized at fair value. If fair value cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized. Fair value is

defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Accordingly, the Company may be required to value assets at fair value measures that do not reflect the Company's intended use of those assets. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in the Company's consolidated financial statements after the date of the acquisition. If the Company determines the assets acquired do not meet the definition of a business under the acquisition method of accounting, the transaction will be accounted for as an acquisition of assets rather than a business combination and, therefore, no goodwill will be recorded. In an asset acquisition, acquired in-process research and development (IPR&D) with no alternative future use is charged to expense and contingent consideration is not recognized at the acquisition date.

Foreign Currency Translation — The net assets of international subsidiaries where the local currencies have been determined to be the functional currencies are translated into U.S. dollars using current exchange rates. The U.S. dollar effects that arise from translating the net assets of these subsidiaries at changing rates are recorded in the foreign currency translation account, which is included in *Accumulated other comprehensive loss* (*AOCL*) and reflected as a separate component of equity. For those subsidiaries that operate in highly inflationary economies and for those subsidiaries where the U.S. dollar has been determined to be the functional currency, non-monetary foreign currency assets and liabilities are translated using historical rates, while monetary assets and liabilities are translated at current rates, with the U.S. dollar effects of rate changes included in *Other (income) expense, net*.

Cash Equivalents — Cash equivalents are comprised of certain highly liquid investments with original maturities of less than three months.

Inventories — Inventories are valued at the lower of cost or net realizable value. The cost of a substantial majority of U.S. pharmaceutical and vaccine inventories is determined using the last-in, first-out (LIFO) method for both financial reporting and tax purposes. The cost of all other inventories is determined using the first-in, first-out (FIFO) method. Inventories consist of currently marketed products, as well as certain inventories produced in preparation for product launches that are considered to have a high probability of regulatory approval. In evaluating the recoverability of inventories produced in preparation for product launches, the Company considers the likelihood that revenue will be obtained from the future sale of the related inventory together with the status of the product within the regulatory approval process.

Investments — Investments in marketable debt securities classified as available-for-sale are reported at fair value. Fair values of the Company's investments in marketable debt securities are determined using quoted market prices in active markets for identical assets or liabilities or quoted prices for similar assets or liabilities or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Changes in fair value that are not impairment related are reported net of taxes in *Other Comprehensive Income (OCI)*. The Company considers available evidence in evaluating potential impairments of its investments in marketable debt securities, including the extent to which fair value is less than cost, whether an allowance for credit loss is required, as well as adverse factors that could affect the value of the securities. An impairment has occurred if the Company does not expect to recover the entire amortized cost basis of the marketable debt security. If the Company does not intend to sell the impaired debt security, and it is not more likely than not it will be required to sell the debt security before the recovery of its amortized cost basis, the amount of the impairment recognized in earnings, recorded in *Other (income) expense, net* is limited to the portion attributed to credit loss. The remaining portion of the impairment related to other factors is recognized in *OCI*. Realized gains and losses for debt securities are included in *Other (income) expense, net*.

Investments in publicly traded equity securities are reported at fair value determined using quoted market prices in active markets for identical assets or quoted prices for similar assets or other inputs that are observable or can be corroborated by observable market data. Changes in fair value are included in *Other (income) expense, net*. Unrealized gains and losses from investments that are directly owned are determined at the end of the reporting period. Gains and losses from ownership interests in investment funds, which are accounted for as equity method investments, are reported on a one quarter lag. Investments in equity securities without readily determinable fair values are recorded at cost, plus or minus subsequent observable price changes in orderly transactions for identical

or similar investments, minus impairments. Such adjustments are recognized in *Other (income) expense, net*. Realized gains and losses for equity securities are included in *Other (income) expense, net*.

Revenue Recognition — Recognition of revenue requires evidence of a contract, probable collection of sales proceeds and completion of substantially all performance obligations. Merck acts as the principal in substantially all of its customer arrangements and therefore records revenue on a gross basis. The majority of the Company's contracts related to the Pharmaceutical and Animal Health segments have a single performance obligation - the promise to transfer goods. Shipping is considered immaterial in the context of the overall customer arrangement and damages or loss of goods in transit are rare. Therefore, shipping is not deemed a separately recognized performance obligation.

The vast majority of revenues from sales of products are recognized at a point in time when control of the goods is transferred to the customer, which the Company has determined is when title and risks and rewards of ownership transfer to the customer and the Company is entitled to payment. The Company recognizes revenue from the sales of vaccines to the Federal government for placement into vaccine stockpiles in accordance with Securities and Exchange Commission (SEC) Interpretation*, Commission Guidance Regarding Accounting for Sales of Vaccines and BioTerror Countermeasures to the Federal Government for Placement into the Pediatric Vaccine Stockpile or the Strategic National Stockpile*. This interpretation allows companies to recognize revenue for sales of vaccines into U.S. government stockpiles even though these sales might not meet the criteria for revenue recognition under other accounting guidance. Some customers have bill-and-hold arrangements with the Company. Revenue for bill-and-hold arrangements is recognized when control transfers to the customer even though the customer does not yet have physical possession of the goods. Control transfers when the bill-and-hold arrangement has been requested by the customer, the product is identified as belonging to the customer and is ready for physical transfer, the product cannot be directed for use by anyone but the customer and, in certain circumstances, the customer has inspected and accepted the product at the Company's facility. For certain services in the Animal Health segment, revenue is recognized over time, generally ratably over the contract term as services are provided. These service revenues are not material.

The nature of the Company's business gives rise to several types of variable consideration including discounts and returns, which are estimated at the time of sale generally using the expected value method, although the most likely amount method is used for prompt pay discounts.

In the U.S., sales discounts are issued to customers at the point-of-sale, through an intermediary wholesaler (known as chargebacks), or in the form of rebates. Additionally, sales are generally made with a limited right of return under certain conditions. Revenues are recorded net of provisions for sales discounts and returns, which are established at the time of sale. In addition, if collection of accounts receivable is expected to be in excess of one year, sales are recorded net of time value of money discounts, which have not been material.

The U.S. provision for aggregate customer discounts covering chargebacks and rebates was $12.3 billion in 2021, $11.4 billion in 2020 and $9.9 billion in 2019. Chargebacks are discounts that occur when a contracted customer purchases through an intermediary wholesaler. The contracted customer generally purchases product from the wholesaler at its contracted price plus a mark-up. The wholesaler, in turn, charges the Company back for the difference between the price initially paid by the wholesaler and the contract price paid to the wholesaler by the customer. The provision for chargebacks is based on expected sell-through levels by the Company's wholesale customers to contracted customers, as well as estimated wholesaler inventory levels. Rebates are amounts owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers after the final dispensing of the product to a benefit plan participant. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. The Company uses historical customer segment utilization mix, sales forecasts, changes to product mix and price, inventory levels in the distribution channel, government pricing calculations and prior payment history in order to estimate the expected provision. Amounts accrued for aggregate customer discounts are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal and state agencies, and other customers to the amounts accrued. The accrued balances relative to the provisions for chargebacks and rebates included in *Accounts receivable* and *Accrued and other current liabilities* were $207

million and $2.6 billion, respectively, at December 31, 2021 and were $208 million and $2.6 billion, respectively, at December 31, 2020.

Outside of the U.S., variable consideration in the form of discounts and rebates are a combination of commercially-driven discounts in highly competitive product classes, discounts required to gain or maintain reimbursement, or legislatively mandated rebates. In certain European countries, legislatively mandated rebates are calculated based on an estimate of the government's total unbudgeted spending and the Company's specific payback obligation. Rebates may also be required based on specific product sales thresholds. The Company applies an estimated factor against its actual invoiced sales to represent the expected level of future discount or rebate obligations associated with the sale.

The Company maintains a returns policy that allows its U.S. pharmaceutical customers to return product within a specified period prior to and subsequent to the expiration date (generally, three to six months before and 12 months after product expiration). The estimate of the provision for returns is based upon historical experience with actual returns. Additionally, the Company considers factors such as levels of inventory in the distribution channel, product dating and expiration period, whether products have been discontinued, entrance in the market of generic or other competition, changes in formularies or launch of over-the-counter products, among others. Outside of the U.S., returns are only allowed in certain countries on a limited basis.

Merck's payment terms for U.S. pharmaceutical customers are typically 36 days from receipt of invoice and for U.S. animal health customers are typically 30 days from receipt of invoice; however, certain products, including *Keytruda*, have longer payment terms, some of which are up to 90 days. Outside of the U.S., payment terms are typically 30 days to 90 days, although certain markets have longer payment terms.

See Note 19 for disaggregated revenue disclosures.

Depreciation — Depreciation is provided over the estimated useful lives of the assets, principally using the straight-line method. For tax purposes, accelerated tax methods are used. The estimated useful lives primarily range from 25 to 45 years for *Buildings*, and from 3 to 15 years for *Machinery, equipment and office furnishings*. Depreciation expense was $1.6 billion in 2021, $1.7 billion in 2020 and $1.6 billion in 2019.

Advertising and Promotion Costs — Advertising and promotion costs are expensed as incurred. The Company recorded advertising and promotion expenses of $2.0 billion in 2021, $1.8 billion in 2020 and $1.9 billion in 2019.

Software Capitalization — The Company capitalizes certain costs incurred in connection with obtaining or developing internal-use software including external direct costs of material and services, and payroll costs for employees directly involved with the software development. These costs are included in *Property, plant and equipment*. In addition, the Company capitalizes certain costs incurred to implement a cloud computing arrangement that is considered a service agreement, which are included in *Other Assets*. Capitalized software costs are being amortized over periods ranging from 3 to 10 years, with the longer lives generally associated with enterprise-wide projects implemented over multiple years. Costs incurred during the preliminary project stage and post-implementation stage, as well as maintenance and training costs, are expensed as incurred.

Goodwill — Goodwill represents the excess of the consideration transferred over the fair value of net assets of businesses acquired. Goodwill is assigned to reporting units and evaluated for impairment on at least an annual basis, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If the Company concludes it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a quantitative fair value test is performed. If the carrying value of a reporting unit is greater than its fair value, a goodwill impairment charge will be recorded for the difference (up to the carrying value of goodwill).

Acquired Intangibles — Acquired intangibles include products and product rights, trade names and patents, licenses and other, which are initially recorded at fair value, assigned an estimated useful life, and amortized primarily on a straight-line basis over their estimated useful lives ranging from 2 to 24 years. The Company periodically evaluates whether current facts or circumstances indicate that the carrying values of its acquired intangibles may not be recoverable. If such circumstances are determined to exist, an estimate of the undiscounted

future cash flows of these assets, or appropriate asset groupings, is compared to the carrying value to determine whether an impairment exists. If the asset is determined to be impaired, the loss is measured based on the difference between the carrying value of the intangible asset and its fair value, which is determined based on the net present value of estimated future cash flows.

Acquired In-Process Research and Development — IPR&D that the Company acquires in conjunction with the acquisition of a business represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. The amounts are capitalized and are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each IPR&D project, Merck will make a determination as to the then-useful life of the intangible asset, generally determined by the period in which the substantial majority of the cash flows are expected to be generated, and begin amortization. The Company evaluates IPR&D for impairment at least annually, or more frequently if impairment indicators exist, by performing a quantitative test that compares the fair value of the IPR&D intangible asset with its carrying value. If the fair value is less than the carrying amount, an impairment loss is recognized in operating results.

Contingent Consideration — Certain of the Company's acquisitions involve the potential for future payment of consideration that is contingent upon the achievement of performance milestones, including product development milestones and royalty payments on future product sales. If the transaction is accounted for as a business combination, the fair value of contingent consideration liabilities is determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date, at each reporting period until the contingency is resolved, the contingent consideration liability is remeasured at current fair value with changes (either expense or income) recorded in earnings. Significant events that increase or decrease the probability of achieving development and regulatory milestones or that increase or decrease projected cash flows will result in corresponding increases or decreases in the fair values of the related contingent consideration obligations. If the transaction is accounted for as an acquisition of an asset rather than a business, contingent consideration is not recognized at the acquisition date. In these instances, product development milestones are recognized upon achievement and sales-based milestones are recognized when the milestone is deemed probable by the Company of being achieved.

Research and Development — Research and development is expensed as incurred. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Research and development expenses include restructuring costs and IPR&D impairment charges. In addition, research and development expenses include expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration associated with IPR&D assets. Research and development expenses also include upfront and milestone payments related to asset acquisitions and licensing transactions involving clinical development programs that have not yet received regulatory approval.

Collaborative Arrangements — Merck has entered into collaborative arrangements that provide the Company with varying rights to develop, produce and market products together with its collaborative partners. When Merck is the principal on sales transactions with third parties, the Company recognizes sales, cost of sales and selling, general and administrative expenses on a gross basis. Profit sharing amounts it pays to its collaborative partners are recorded within *Cost of sales*. When the collaborative partner is the principal on sales transactions with third parties, the Company records profit sharing amounts received from its collaborative partners as alliance revenue (within *Sales*). Alliance revenue is recorded net of cost of sales and includes an adjustment to share commercialization costs between the partners in accordance with the collaboration agreement. The adjustment is determined by comparing the commercialization costs Merck has incurred directly and reported within *Selling, general and administrative* expenses with the costs the collaborative partner has incurred. Research and development costs Merck incurs related to collaborations are recorded within *Research and development* expenses. Cost reimbursements to the collaborative partner or payments received from the collaborative partner to share these costs pursuant to the terms of the collaboration agreements are recorded as increases or decreases to *Research and development* expenses.

In addition, the terms of the collaboration agreements may require the Company to make payments based upon the achievement of certain developmental, regulatory approval or commercial milestones. Upfront and milestone payments payable by Merck to collaborative partners prior to regulatory approval are expensed as incurred and included in *Research and development* expenses. Payments due to collaborative partners upon or subsequent to regulatory approval are capitalized and amortized over the estimated useful life of the corresponding intangible asset to *Cost of sales* provided that future cash flows support the amounts capitalized. Sales-based milestones payable by Merck to collaborative partners are accrued and capitalized, subject to cumulative amortization catch-up, when probable of being achieved. The amortization catch-up is calculated either from the time of the first regulatory approval for indications that were unapproved at the time the collaboration was formed, or from time of the formation of the collaboration for approved products. The related intangible asset that is recognized is amortized to *Cost of sales* over its remaining useful life, subject to impairment testing.

Share-Based Compensation — The Company expenses all share-based payments to employees over the requisite service period based on the grant-date fair value of the awards.

Restructuring Costs — The Company records liabilities for costs associated with exit or disposal activities in the period in which the liability is incurred. In accordance with existing benefit arrangements, employee termination costs are accrued when the restructuring actions are probable and estimable. When accruing these costs, the Company will recognize the amount within a range of costs that is the best estimate within the range. When no amount within the range is a better estimate than any other amount, the Company recognizes the minimum amount within the range. Costs for one-time termination benefits in which the employee is required to render service until termination in order to receive the benefits are recognized ratably over the future service period.

Contingencies and Legal Defense Costs — The Company records accruals for contingencies and legal defense costs expected to be incurred in connection with a loss contingency when it is probable that a liability has been incurred and the amount can be reasonably estimated.

Taxes on Income — Deferred taxes are recognized for the future tax effects of temporary differences between financial and income tax reporting based on enacted tax laws and rates. The Company evaluates tax positions to determine whether the benefits of tax positions are more likely than not of being sustained upon audit based on the technical merits of the tax position. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the amount of the benefit that is greater than 50% likely of being realized upon ultimate settlement in the financial statements. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit in the financial statements. The Company recognizes interest and penalties associated with uncertain tax positions as a component of *Taxes on Income from Continuing Operations*. The Company accounts for the tax effects of the tax on global intangible low-taxed income (GILTI) of certain foreign subsidiaries in the income tax provision in the period the tax arises.

Use of Estimates — The consolidated financial statements are prepared in conformity with accounting principles generally accepted in the U.S. (GAAP) and, accordingly, include certain amounts that are based on management's best estimates and judgments. Estimates are used when accounting for amounts recorded in connection with acquisitions, including initial fair value determinations of assets and liabilities (primarily IPR&D, other intangible assets and contingent consideration), as well as subsequent fair value measurements. Additionally, estimates are used in determining such items as provisions for sales discounts and returns, depreciable and amortizable lives, recoverability of inventories, including those produced in preparation for product launches, amounts recorded for contingencies, environmental liabilities, accruals for contingent sales-based milestone payments and other reserves, pension and other postretirement benefit plan assumptions, share-based compensation assumptions, restructuring costs, impairments of long-lived assets (including intangible assets and goodwill) and investments, and taxes on income. Because of the uncertainty inherent in such estimates, actual results may differ from these estimates.

Reclassifications — Certain reclassifications have been made to prior year amounts to conform to the current year presentation.

Recently Adopted Accounting Standards — In December 2019, the Financial Accounting Standards Board (FASB) issued amended guidance on the accounting and reporting of income taxes. The guidance is intended to simplify the accounting for income taxes by removing exceptions related to certain intraperiod tax allocations and deferred tax liabilities; clarifying guidance primarily related to evaluating the step-up tax basis for goodwill in a business combination; and reflecting enacted changes in tax laws or rates in the annual effective tax rate. The Company adopted the new guidance effective January 1, 2021. There was no impact to the Company's consolidated financial statements upon adoption.

In January 2020, the FASB issued new guidance intended to clarify certain interactions between accounting standards related to equity securities, equity method investments and certain derivatives. The guidance addresses accounting for the transition into and out of the equity method of accounting and measuring certain purchased options and forward contracts to acquire investments. The Company adopted the new guidance effective January 1, 2021. There was no impact to the Company's consolidated financial statements upon adoption.

In August 2020, the FASB issued amended guidance on the accounting for convertible instruments and contracts in an entity's own equity. The guidance removes the separation model for convertible debt instruments and preferred stock, amends requirements for conversion options to be classified in equity as well as amends diluted earnings per share (EPS) calculations for certain convertible debt instruments. The amended guidance is effective for interim and annual periods in 2022. The application of the amendments in the new guidance are to be applied either on a modified retrospective or a retrospective basis. There was no impact to the Company's consolidated financial statements upon adoption on January 1, 2022.

Recently Issued Accounting Standards Not Yet Adopted — In March 2020, the FASB issued optional guidance to ease the potential burden in accounting for (or recognizing the effects of) reference rate reform on financial reporting and subsequently issued clarifying amendments. The guidance provides optional expedients and exceptions for accounting for contracts, hedging relationships, and other transactions that reference the London Interbank Offered Rate (LIBOR) or another reference rate expected to be discontinued because of reference rate reform. The optional guidance is effective upon issuance and can be applied on a prospective basis at any time between January 1, 2020 through December 31, 2022. The Company is currently evaluating the impact of adoption on its consolidated financial statements. The Company is progressing in its evaluation of LIBOR cessation exposures, including the review of debt-related contracts, leases, business development and licensing arrangements, royalty and other agreements. The Company has amended certain agreements and continues to review other agreements for potential impacts. With regard to debt-related exposures in particular, all existing interest rate swaps linked to LIBOR will mature in 2022. The Company is still evaluating the impact to its LIBOR-based debt. Based on its evaluation thus far, the Company does not anticipate a material impact to its consolidated financial statements as a result of reference rate reform.

In October 2021, the FASB issued amended guidance that requires acquiring entities to recognize and measure contract assets and liabilities in a business combination in accordance with existing revenue recognition guidance. The amended guidance is effective for interim and annual periods in 2023 and is to be applied prospectively. Early adoption is permitted on a retrospective basis to the beginning of the fiscal year of adoption. The adoption of this guidance will not have a material impact on the Company's consolidated financial statements for prior acquisitions; however, the impact in future periods will be dependent upon the contract assets and contract liabilities acquired in future business combinations.

In November 2021, the FASB issued new guidance to increase the transparency of transactions with a government that are accounted for by applying a grant or contribution accounting model by analogy. The guidance requires annual disclosures of such transactions to include the nature of the transactions and the significant terms and conditions, the accounting treatment and the impact to the company's financial statements. The guidance is effective for annual periods beginning in 2022 and is to be applied on either a prospective or retrospective basis. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

3. Spin-Off of Organon & Co.

On June 2, 2021, Merck completed the spin-off of Organon through a distribution of Organon's publicly traded stock to Company shareholders. In connection with the spin-off, each Merck shareholder received one-tenth of a share of Organon's common stock for each share of Merck common stock held by such shareholder. The

distribution is expected to qualify and has been treated as tax free to Merck and its shareholders for U.S. federal income tax purposes. Indebtedness of $9.5 billion principal amount, consisting of term loans and senior notes, was issued in 2021 in connection with the spin-off and assumed by Organon. Merck is no longer the obligor of any Organon debt or financing arrangements. Cash proceeds of $9.0 billion were distributed by Organon to Merck in connection with the spin-off.

Also in connection with the spin-off, Merck and Organon entered into a separation and distribution agreement and also entered into various other agreements to effect the spin-off and provide a framework for the relationship between Merck and Organon after the spin-off, including a transition services agreement (TSA), manufacturing and supply agreements (MSAs), trademark license agreements, intellectual property license agreements, an employee matters agreement, a tax matters agreement and certain other commercial agreements. Under the TSA, Merck will provide Organon various services and, similarly, Organon will provide Merck various services. The provision of services under the TSA generally will terminate within 25 months following the spin-off. Merck and Organon also entered into a series of interim operating agreements pursuant to which in various jurisdictions where Merck held licenses, permits and other rights in connection with marketing, import and/or distribution of Organon products prior to the separation, Merck will continue to market, import and distribute such products until such time as the relevant licenses and permits are transferred to Organon. Under such interim operating agreements and in accordance with the separation and distribution agreement, Merck will continue operations in the affected markets on behalf of Organon, with Organon receiving all of the economic benefits and burdens of such activities. Additionally, Merck and Organon entered into a number of MSAs pursuant to which Merck will (a) manufacture and supply certain active pharmaceutical ingredients for Organon, (b) toll manufacture and supply certain formulated pharmaceutical products for Organon, and (c) package and label certain finished pharmaceutical products for Organon. Similarly, Organon and Merck entered into a number of MSAs pursuant to which Organon will (a) manufacture and supply certain formulated pharmaceutical products for Merck, and (b) package and label certain finished pharmaceutical products for Merck. The terms of the MSAs range in initial duration from four years to ten years.

Amounts included in the consolidated statement of income for the above MSAs include sales of $219 million and related cost of sales of $195 million in 2021. Amounts included in the consolidated statement of income for the TSAs was immaterial in 2021. The amount due from Organon under the above agreements was $964 million at December 31, 2021 and is reflected in *Other current assets*. The amount due to Organon under these agreements was $400 million at December 31, 2021 and is included in A*ccrued and other current liabilities*.

The results of the women's health, biosimilars and established brands businesses (previously included in the Pharmaceutical segment) that were contributed to Organon in the spin-off, as well as interest expense related to the debt issuance in 2021, have been reflected as discontinued operations in the Company's consolidated statement of income as *Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests* through June 2, 2021, the date of the spin-off. Prior periods have been recast to reflect this presentation. As a result of the spin-off of Organon, Merck incurred separation costs of $556 million in 2021 and $743 million in 2020, which are also included in *Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests*. These costs primarily relate to professional fees for separation activities within finance, tax, legal and information technology functions, as well as investment banking fees. As of December 31, 2020, the assets and liabilities associated with these businesses are classified as assets and liabilities of discontinued operations in the consolidated balance sheet.

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Details of *Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests* are as follows:

Years Ended December 31	**2021**[1]	2020	2019
Sales	**$ 2,512**	$ 6,476	$ 7,719
Costs, Expenses and Other			
Cost of sales	**789**	1,867	2,096
Selling, general and administrative	**877**	1,513	1,160
Research and development	**103**	161	148
Restructuring costs	**1**	3	12
Other (income) expense, net	**(15)**	4	10
	1,755	3,548	3,426
Income from discontinued operations before taxes	**757**	2,928	4,293
Tax provision	**50**	369	122
Income from discontinued operations, net of taxes	**707**	2,559	4,171
Less: Income of discontinued operations attributable to noncontrolling interests	**3**	11	18
Income from discontinued operations, net of taxes and amounts attributable to noncontrolling interests	**$ 704**	$ 2,548	$ 4,153

[1] *Reflects amounts through the June 2, 2021 spin-off date.*

Details of assets and liabilities of discontinued operations are as follows:

December 31	2020
Cash and cash equivalents	$ 12
Accounts receivable, less allowance for doubtful accounts	1,048
Inventories	756
Other current assets	867
Current assets of discontinued operations	$ 2,683
Property, plant and equipment, net	$ 986
Goodwill	1,356
Other intangibles, net	503
Other assets	330
Noncurrent Assets of Discontinued Operations	$ 3,175
Trade accounts payable	$ 267
Accrued and other current liabilities	841
Income taxes payable	(22)
Total current liabilities of discontinued operations	$ 1,086
Deferred income taxes	$ 10
Other noncurrent liabilities	176
Noncurrent Liabilities of Discontinued Operations	$ 186

As a result of the spin-off of Organon, Merck distributed net liabilities of $5.1 billion as of June 2, 2021 consisting of debt of $9.4 billion (described above), goodwill of $1.4 billion, property, plant and equipment of $981 million, cash of $929 million, inventory of $815 million, other intangibles, net, of $519 million and other net liabilities of $328 million. The spin-off also resulted in a net decrease to *AOCL* of $449 million consisting of $421 million for the derecognition of net losses on foreign currency translation adjustments and $28 million associated

with employee benefit plans. The distribution of the net liabilities and reduction to *AOCL* resulted in a net $4.6 billion increase to *Other paid-in capital*.

Expenses for curtailments, settlements and termination benefits provided to certain employees were incurred in connection with the spin-off (see Note 14). Additionally, all outstanding Merck stock options, restricted stock units (RSUs) and performance share units (PSUs) (whether vested or unvested) were converted into adjusted Merck awards for current and former Merck employees or Organon awards for Organon employees (see Note 13).

4. Acquisitions, Research Collaborations and License Agreements

The Company continues to pursue acquisitions and the establishment of external alliances such as research collaborations and licensing agreements to complement its internal research capabilities. These arrangements often include upfront payments, as well as expense reimbursements or payments to the third party, and milestone, royalty or profit share arrangements, contingent upon the occurrence of certain future events linked to the success of the asset in development. The Company also reviews its marketed products and pipeline to examine candidates which may provide more value through out-licensing and, as part of its portfolio assessment process, may also divest certain assets. Pro forma financial information for acquired businesses is not presented if the historical financial results of the acquired entity are not significant when compared with the Company's financial results.

2021 Transactions

In November 2021, Merck acquired Acceleron Pharma Inc. (Acceleron), a publicly traded biopharmaceutical company, for total consideration of $11.5 billion. Acceleron is evaluating the transforming growth factor (TGF)-beta superfamily of proteins that is known to play a central role in the regulation of cell growth, differentiation and repair. Acceleron's lead therapeutic candidate, sotatercept (MK-7962), has a novel mechanism of action with the potential to improve short-term and/or long-term clinical outcomes in patients with pulmonary arterial hypertension (PAH). Sotatercept is in Phase 3 trials as an add-on to current standard of care for the treatment of PAH. Under a previous agreement assumed by Merck, Bristol Myers Squibb (BMS) was granted an exclusive license to develop and commercialize sotatercept outside of the pulmonary hypertension (PH) field (for which Merck would be eligible to receive contingent milestones and royalty payments), however, Merck retains the worldwide exclusive rights to develop and commercialize sotatercept in the PH field. The agreement provides for Merck to pay 22% royalties on future sales of sotatercept in the PH field to BMS.

In addition to sotatercept, Acceleron's portfolio includes *Reblozyl* (luspatercept), a first-in-class erythroid maturation recombinant fusion protein that is approved in the U.S., Europe, Canada and Australia for the treatment of anemia in certain rare blood disorders and is also being evaluated in Phase 2 and Phase 3 trials for additional indications for hematology therapies. *Reblozyl* is being developed and commercialized through a global collaboration with BMS. In connection with this ongoing collaboration, Merck receives a 20% sales royalty from BMS which could increase to a maximum of 24% based on sales levels. This royalty will be reduced by 50% upon the earlier of patent expiry or generic entry on an indication-by-indication basis in each market. Merck is eligible to receive future contingent milestone payments including up to $20 million in regulatory milestones and up to $80 million in sales-based milestones.

The transaction was accounted for as a business combination. The Company incurred $280 million of costs directly related to the acquisition of Acceleron, consisting primarily of share-based compensation payments to settle non-vested equity awards attributable to postcombination service, severance, as well as investment banking and legal fees. These costs were included in *Selling, general and administrative* expenses and *Research and development* costs in 2021.

The estimated fair value of assets acquired and liabilities assumed from Acceleron is as follows:

		November 19, 2021
Cash and cash equivalents	$	340
Investments		285
Identifiable intangible assets: [1]		
IPR&D - sotatercept		6,380
Products and product rights - *Reblozyl* (12 year useful life)		3,830
Deferred income tax liabilities, net		(1,832)
Other assets and liabilities, net		89
Total identifiable net assets		9,092
Goodwill [2]		2,422
Consideration transferred	$	11,514

[1] *The estimated fair value of the identifiable intangible assets related to sotatercept and Reblozyl were determined using an income approach, specifically the multi-period excess earnings method. The future probability-weighted net cash flows were discounted to present value utilizing a discount rate of 7.5% for sotatercept and 6.0% for* Reblozyl. *Actual cash flows are likely to be different than those assumed.*

[2] *The goodwill recognized is largely attributable to anticipated synergies expected to arise after the acquisition and was allocated to the Pharmaceutical segment. The goodwill is not deductible for tax purposes.*

In April 2021, Merck acquired Pandion Therapeutics, Inc. (Pandion), a clinical-stage biotechnology company developing novel therapeutics designed to address the unmet needs of patients living with autoimmune diseases. Pandion is advancing a pipeline of precision immune modulators targeting critical immune control nodes. Total consideration paid of $1.9 billion included $147 million of costs primarily comprised of share-based compensation payments to settle equity awards. The transaction was accounted for as an acquisition of an asset. Merck recorded net assets of $156 million (primarily cash) and *Research and development* expenses of $1.7 billion in 2021 related to the transaction. There are no future contingent payments associated with the acquisition.

In March 2021, Merck and Gilead Sciences, Inc. (Gilead) entered into an agreement to jointly develop and commercialize long-acting treatments in HIV that combine Merck's investigational nucleoside reverse transcriptase translocation inhibitor, islatravir, and Gilead's investigational capsid inhibitor, lenacapavir. The collaboration will initially focus on long-acting oral formulations and long-acting injectable formulations of these combination products, with other formulations potentially added to the collaboration as mutually agreed. There was no upfront payment made by either party upon entering into the agreement.

Under the terms of the agreement, Merck and Gilead will share operational responsibilities, as well as development, commercialization and marketing costs, and any future revenues. Global development and commercialization costs will be shared 60% Gilead and 40% Merck across the oral and injectable formulation programs. For long-acting oral products, Gilead will lead commercialization in the U.S. and Merck will lead commercialization in the EU and the rest of the world. For long-acting injectable products, Merck will lead commercialization in the U.S. and Gilead will lead commercialization in the EU and the rest of the world. Gilead and Merck will co-promote in the U.S. and certain other major markets. Merck and Gilead will share global product revenues equally until product revenues surpass certain pre-agreed per formulation revenue tiers. Upon passing $2.0 billion a year in net product sales for the oral combination, the revenue split will adjust to 65% Gilead and 35% Merck for any revenues above the threshold. Upon passing $3.5 billion a year in net product sales for the injectable combination, the revenue split will adjust to 65% Gilead and 35% Merck for any revenues above the threshold.

Beyond the potential combinations of investigational lenacapavir and investigational islatravir, Gilead will have the option to license certain of Merck's investigational oral integrase inhibitors to develop in combination with lenacapavir. Reciprocally, Merck will have the option to license certain of Gilead's investigational oral integrase inhibitors to develop in combination with islatravir. Each company may exercise its option for an investigational oral integrase inhibitor of the other company following completion of the first Phase 1 clinical trial of that integrase inhibitor. Upon exercise of an option, the companies will split development costs and revenues, unless the non-exercising company decides to opt-out.

In December 2021, the U.S. Food and Drug Administration (FDA) placed full or partial clinical holds on investigational new drug applications for certain oral, implant and injectable formulations of islatravir based on

observations of decreases in total lymphocyte and CD4+ T-cell counts in some participants receiving islatravir in clinical studies. As a result of these holds, Merck and Gilead made the decision to stop all dosing of participants in a Phase 2 clinical study evaluating islatravir and lenacapavir in people living with HIV who are virologically suppressed on antiretroviral therapy. The two companies are assessing whether a different dosing of islatravir in combination with lenacapavir may provide a once-weekly oral therapy option for people living with HIV. Merck and Gilead remain committed to their collaboration.

In January 2021, Merck entered into an exclusive license and research collaboration agreement with Artiva Biotherapeutics, Inc. (Artiva) to discover, develop and manufacture CAR-NK cells that target certain solid tumors using Artiva's proprietary platform. Merck and Artiva agreed to engage in up to three different research programs, each covering a collaboration target. Merck has sole responsibility for all development and commercialization activities (including regulatory filing and approval). Under the terms of the agreement, Merck made an upfront payment of $30 million, which was included in *Research and development* expenses in 2021, for license and other rights for the first two collaboration targets and agreed to make another upfront payment of $15 million for license and other rights for the third collaboration target when it is selected by Merck and accepted by Artiva. In addition, Artiva is eligible to receive future contingent milestone payments (which span all three collaboration targets), aggregating up to $217.5 million in developmental milestones, $570 million in regulatory milestones, and $1.05 billion in sales-based milestones. The agreement also provides for Merck to pay tiered royalties ranging from 7% to 14% on future sales.

2020 Transactions

In December 2020, Merck acquired OncoImmune, a privately held, clinical-stage biopharmaceutical company, for an upfront payment of $423 million. OncoImmune's lead therapeutic candidate (MK-7110) was being evaluated for the treatment of patients hospitalized with COVID-19. The transaction was accounted for as an acquisition of an asset. Under the agreement, prior to the completion of the acquisition, OncoImmune spun-out certain rights and assets unrelated to the MK-7110 program to a new entity owned by the existing shareholders of OncoImmune. In connection with the closing of the acquisition, Merck invested $50 million for a 20% ownership interest in the new entity, which was valued at $33 million resulting in a $17 million premium. Merck also recognized other net liabilities of $22 million. The Company recorded *Research and development* expenses of $462 million in 2020 related to this transaction. In 2021, Merck received feedback from the FDA that additional data would be needed to support a potential Emergency Use Authorization (EUA) application and therefore the Company did not expect MK-7110 would become available until the first half of 2022. Given this timeline and the technical, clinical and regulatory uncertainties, the availability of a number of medicines for patients hospitalized with COVID-19, and the need to concentrate Merck's resources on accelerating the development and manufacture of the most viable therapeutics and vaccines, Merck decided to discontinue development of MK-7110 for the treatment of COVID-19. Due to the discontinuation, the Company recorded charges of $207 million in 2021, which are reflected in *Cost of sales* and relate to fixed assets and materials written off, as well as the recognition of liabilities for purchase commitments.

Also in December 2020, Merck acquired VelosBio Inc. (VelosBio), a privately held, clinical-stage biopharmaceutical company, for $2.8 billion. VelosBio's lead investigational candidate is zilovertamab vedotin (MK-2140), an antibody-drug conjugate targeting receptor tyrosine kinase-like orphan receptor 1 (ROR1) that is currently being evaluated for the treatment of patients with hematologic malignancies and solid tumors. The transaction was accounted for as an acquisition of an asset. Merck recorded net assets of $180 million (primarily cash) and *Research and development* expenses of $2.7 billion in 2020 related to the transaction. During 2021, the Company recorded adjustments to these amounts which resulted in a reduction of *Research and development* expenses of $43 million, an increase to total consideration paid of $47 million, and an increase to net assets recorded of $90 million.

In September 2020, Merck and Seagen Inc. (Seagen) announced an oncology collaboration to globally develop and commercialize Seagen's ladiratuzumab vedotin (MK-6440), an investigational antibody-drug conjugate targeting LIV-1, which is currently in Phase 2 clinical trials. The collaboration will pursue a broad joint development program evaluating ladiratuzumab vedotin as monotherapy and in combination with *Keytruda* (pembrolizumab) in triple-negative breast cancer, hormone receptor-positive breast cancer and other LIV-1-expressing solid tumors. The companies will equally share profits worldwide. Under the terms of the agreement,

Merck made an upfront payment of $600 million and a $1.0 billion equity investment in 5 million shares of Seagen common stock at a price of $200 per share. Merck recorded $616 million in *Research and development* expenses in 2020 related to this transaction reflecting the upfront payment as well as a $16 million premium relating to the equity shares based on the price of Seagen common stock on the closing date. Seagen is also eligible to receive future contingent milestone payments of up to $2.6 billion, including $850 million in development milestones and $1.75 billion in sales-based milestones.

Concurrent with the above transaction, Seagen granted Merck an exclusive license to commercialize Tukysa (tucatinib), a small molecule tyrosine kinase inhibitor, for the treatment of human epidermal growth factor receptor 2 (HER2)-positive cancers, in Asia, the Middle East and Latin America and other regions outside of the U.S., Canada and Europe. Merck will be responsible for marketing applications seeking approval in its territories, supported by the positive results from the HER2CLIMB clinical trial. Merck will also co-fund a portion of the Tukysa global development plan, which encompasses several ongoing and planned trials across HER2-positive cancers, including breast, colorectal, gastric and other cancers set forth in a global product development plan. Merck will solely fund and conduct country-specific clinical trials necessary to support anticipated regulatory applications in its territories. Under the terms of the agreement, Merck made upfront payments aggregating $210 million, which were recorded as *Research and development* expenses in 2020. Seagen is also eligible to receive future contingent regulatory approval milestones of up to $65 million and will receive tiered royalties ranging from 20% to 33% based on annual sales levels of Tukysa in Merck's territories.

Additionally in September 2020, Merck acquired a biologics manufacturing facility located in Dunboyne, Ireland from Takeda Pharmaceutical Company Limited for €256 million ($302 million). The transaction was accounted for as an acquisition of an asset. Merck recorded property, plant and equipment of $289 million and other net assets of $13 million. There are no future contingent payments associated with the acquisition.

In July 2020, Merck acquired the U.S. rights to Sentinel Flavor Tabs and Sentinel Spectrum Chews from Virbac Corporation for $410 million. Sentinel products provide protection against common parasites in dogs. The transaction was accounted for as an acquisition of an asset. Merck recognized intangible assets of $401 million related to currently marketed products and inventory of $9 million at the acquisition date. The estimated fair values of the identifiable intangible assets related to currently marketed products were determined using an income approach. Actual cash flows are likely to be different than those assumed. The intangible assets related to currently marketed products will be amortized over their estimated useful lives of 15 years. There are no future contingent payments associated with the acquisition.

Also in July 2020, Merck and Ridgeback Biotherapeutics LP (Ridgeback), a closely held biotechnology company, closed a collaboration agreement to develop molnupiravir (MK-4482), an orally available antiviral candidate in clinical development for the treatment of patients with COVID-19. See Note 5 for additional information related to this collaboration.

In June 2020, Merck acquired privately held Themis Bioscience GmbH (Themis), a company focused on vaccines (including a COVID-19 vaccine candidate, V591) and immune-modulation therapies for infectious diseases and cancer for $366 million. The acquisition originally provided for Merck to make additional contingent payments of up to $740 million. The transaction was accounted for as a business combination. The Company determined the fair value of the contingent consideration was $85 million at the acquisition date utilizing a probability-weighted estimated cash flow stream using an appropriate discount rate dependent on the nature and timing of the milestone payments. Merck recognized intangible assets for IPR&D of $113 million, cash of $59 million, deferred tax assets of $72 million and other net liabilities of $32 million. The excess of the consideration transferred over the fair value of net assets acquired of $239 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair values of the identifiable intangible assets related to IPR&D were determined using an income approach. Actual cash flows are likely to be different than those assumed. In January 2021, the Company announced it was discontinuing development of V591 as discussed below. As a result, in 2020, the Company recorded an IPR&D impairment charge of $90 million within *Research and development* expenses. The Company also recorded a reduction in *Research and development* expenses resulting from a decrease in the related liability for contingent consideration of $45 million since future contingent milestone payments have been reduced to $450 million in the aggregate, including up to $60 million for development milestones, up to $196 million for regulatory approval milestones, and up to $194 million for commercial milestones.

In May 2020, Merck and the International AIDS Vaccine Initiative, Inc. (IAVI), a nonprofit scientific research organization dedicated to addressing urgent, unmet global health challenges, announced a collaboration to develop V590, an investigational vaccine against SARS-CoV-2 being studied for the prevention of COVID-19. The agreement provided for an upfront payment by Merck of $6.5 million and also provided for future contingent payments based on sales. Merck also signed an agreement with the Biomedical Advanced Research and Development Authority (BARDA), part of the office of the Assistant Secretary for Preparedness and Response within an agency of the U.S. Department of Health and Human Services, to provide initial funding support to Merck for this effort. In January 2021, the Company announced it was discontinuing development of V590 as discussed below.

In January 2021, the Company announced the discontinuation of the development programs for its COVID-19 vaccine candidates, V590 and V591, following Merck's review of findings from Phase 1 clinical studies for the vaccines. In these studies, both V590 and V591 were generally well tolerated, but the immune responses were inferior to those seen following natural infection and those reported for other SARS-CoV-2/COVID-19 vaccines. Due to the discontinuation, the Company recorded a charge of $305 million in 2020, of which $260 million was reflected in *Cost of sales* and related to fixed assets and materials written off, as well as the recognition of liabilities for purchase commitments. The remaining $45 million of costs were reflected in *Research and development* expenses and represent amounts related to the Themis acquisition noted above (an IPR&D impairment charge, partially offset by a reduction in the related liability for contingent consideration).

In January 2020, Merck acquired ArQule, Inc. (ArQule), a publicly traded biopharmaceutical company focused on kinase inhibitor discovery and development for the treatment of patients with cancer and other diseases. Total consideration paid of $2.7 billion included $138 million of share-based compensation payments to settle equity awards attributable to precombination service and cash paid for transaction costs on behalf of ArQule. The Company incurred $95 million of costs directly related to the acquisition of ArQule, consisting almost entirely of share-based compensation payments to settle non-vested equity awards attributable to postcombination service. These costs were included in *Selling, general and administrative* expenses in 2020. ArQule's lead investigational candidate, nemtabrutinib (MK-1026), is a novel, oral Bruton's tyrosine kinase (BTK) inhibitor currently being evaluated for the treatment of B-cell malignancies. The transaction was accounted for as a business combination.

The estimated fair value of assets acquired and liabilities assumed from ArQule is as follows:

	January 16, 2020
Cash and cash equivalents	$ 145
IPR&D - nemtabrutinib [(1)]	2,280
Licensing arrangement for ARQ 087	80
Deferred income tax liabilities	(361)
Other assets and liabilities, net	34
Total identifiable net assets	2,178
Goodwill [(2)]	512
Consideration transferred	$ 2,690

[(1)] *The estimated fair value of nemtabrutinib was determined using an income approach. The future probability-weighted net cash flows were discounted to present value utilizing a discount rate of 12.5%. Actual cash flows are likely to be different than those assumed.*

[(2)] *The goodwill was allocated to the Pharmaceutical segment and is not deductible for tax purposes.*

In 2021, Merck recorded a $275 million intangible asset impairment charge related to nemtabrutinib (see Note 9).

2019 Transactions

In July 2019, Merck acquired Peloton Therapeutics, Inc. (Peloton), a clinical-stage biopharmaceutical company focused on the development of novel small molecule therapeutic candidates targeting hypoxia-inducible factor-2α (HIF-2α) for the treatment of patients with cancer and other non-oncology diseases. Merck made an upfront payment of $1.2 billion. The transaction was accounted for as an acquisition of an asset. Merck recorded cash of $157 million, deferred tax liabilities of $52 million, and other net liabilities of $4 million at the acquisition

date, as well as *Research and development* expenses of $993 million in 2019 related to the transaction. Former Peloton shareholders received a $50 million milestone payment from Merck in 2021 upon first commercial sale of Peloton's lead candidate, *Welireg* (belzutifan), which was approved as monotherapy in the U.S. in August 2021. Former Peloton shareholders are also eligible to receive $50 million upon U.S. regulatory approval as a combination therapy, as well as up to $1.05 billion of sales-based milestones.

On April 1, 2019, Merck acquired Antelliq Corporation (Antelliq), a leader in digital animal identification, traceability and monitoring solutions. These solutions help veterinarians, farmers and pet owners gather critical data to improve management, health and well-being of livestock and pets. Merck paid $2.3 billion to acquire all outstanding shares of Antelliq and spent $1.3 billion to repay Antelliq's debt. The transaction was accounted for as a business combination.

The estimated fair value of assets acquired and liabilities assumed from Antelliq is as follows:

	April 1, 2019
Cash and cash equivalents	$ 31
Accounts receivable	73
Inventories	93
Property, plant and equipment	60
Identifiable intangible assets (useful lives ranging from 18-24 years) [(1)]	2,689
Deferred income tax liabilities	(589)
Other assets and liabilities, net	(82)
Total identifiable net assets	2,275
Goodwill [(2)]	1,376
Consideration transferred	$ 3,651

[(1)] *The estimated fair values of identifiable intangible assets relate primarily to trade names and were determined using an income approach. The future probability-weighted net cash flows were discounted to present value utilizing a discount rate of 11.5%. Actual cash flows are likely to be different than those assumed.*

[(2)] *The goodwill recognized is largely attributable to anticipated synergies expected to arise after the acquisition and was allocated to the Animal Health segment. The goodwill is not deductible for tax purposes.*

The Company incurred $47 million of transaction costs directly related to the acquisition of Antelliq, consisting largely of advisory fees, which are reflected in *Selling, general and administrative* expenses in 2019.

Also in April 2019, Merck acquired Immune Design, a late-stage immunotherapy company employing next-generation *in vivo* approaches to enable the body's immune system to fight disease, for $301 million in cash. The transaction was accounted for as a business combination. Merck recognized intangible assets of $156 million, cash of $83 million and other net assets of $42 million. The excess of the consideration transferred over the fair value of net assets acquired of $20 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair values of the identifiable intangible assets related to IPR&D were determined using an income approach. Actual cash flows are likely to be different than those assumed.

5. Collaborative Arrangements

Merck has entered into collaborative arrangements that provide the Company with varying rights to develop, produce and market products together with its collaborative partners. Both parties in these arrangements are active participants and exposed to significant risks and rewards dependent on the commercial success of the activities of the collaboration. Merck's more significant collaborative arrangements are discussed below.

AstraZeneca

In 2017, Merck and AstraZeneca PLC (AstraZeneca) entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza (olaparib) for multiple cancer types.

Independently, Merck and AstraZeneca will develop and commercialize Lynparza in combinations with their respective PD-1 and PD-L1 medicines, *Keytruda* and Imfinzi. The companies are also jointly developing and

commercializing AstraZeneca's Koselugo (selumetinib) for multiple indications. Under the terms of the agreement, AstraZeneca and Merck will share the development and commercialization costs for Lynparza and Koselugo monotherapy and non-PD-L1/PD-1 combination therapy opportunities.

Profits from Lynparza and Koselugo product sales generated through monotherapies or combination therapies are shared equally. AstraZeneca is the principal on Lynparza and Koselugo sales transactions. Merck records its share of Lynparza and Koselugo product sales, net of cost of sales and commercialization costs, as alliance revenue, and its share of development costs associated with the collaboration as part of *Research and development* expenses. Reimbursements received from AstraZeneca for research and development expenses are recognized as reductions to *Research and development* costs.

As part of the agreement, Merck made an upfront payment to AstraZeneca and also made payments over a multi-year period for certain license options. In addition, the agreement provides for contingent payments from Merck to AstraZeneca related to the successful achievement of sales-based and regulatory milestones. Merck made sales-based milestone payments to AstraZeneca aggregating $550 million and $200 million in 2020 and 2019, respectively. As of December 31, 2021, sales-based milestone payments accrued but not yet paid totaled $400 million. Potential future sales-based milestone payments of $2.7 billion have not yet been accrued as they are not deemed by the Company to be probable at this time.

In 2020 and 2019, Lynparza received regulatory approvals triggering capitalized milestone payments of $160 million and $60 million, respectively, in the aggregate from Merck to AstraZeneca. Potential future regulatory milestone payments of $1.4 billion remain under the agreement.

The intangible asset balance related to Lynparza (which includes capitalized sales-based and regulatory milestone payments) was $1.1 billion at December 31, 2021 and is included in *Other Intangibles, Net*. The amount is being amortized over its estimated useful life through 2028 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

Years Ended December 31	**2021**	2020	2019
Alliance revenue - Lynparza	**$ 989**	$ 725	$ 444
Alliance revenue - Koselugo	**29**	8	—
Total alliance revenue	**$ 1,018**	$ 733	$ 444
Cost of sales [(1)]	**167**	247	148
Selling, general and administrative	**178**	160	138
Research and development	**120**	133	168

December 31	**2021**	2020
Receivables from AstraZeneca included in *Other current assets*	**$ 271**	$ 215
Payables to AstraZeneca included in *Trade accounts payable* and *Accrued and other current liabilities* [(2)]	**415**	423

[(1)] *Represents amortization of capitalized milestone payments.*

[(2)] *Includes accrued milestone payments.*

Eisai

In 2018, Merck and Eisai Co., Ltd. (Eisai) announced a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima (lenvatinib), an orally available tyrosine kinase inhibitor discovered by Eisai. Under the agreement, Merck and Eisai will develop and commercialize Lenvima jointly, both as monotherapy and in combination with *Keytruda*. Eisai records Lenvima product sales globally (Eisai is the principal on Lenvima sales transactions) and Merck and Eisai share applicable profits equally. Merck records its share of Lenvima product sales, net of cost of sales and commercialization costs, as alliance revenue. Expenses incurred during co-development are shared by the two companies in accordance with the collaboration agreement and reflected in *Research and development* expenses. Certain expenses incurred solely by Merck or Eisai are not

shareable under the collaboration agreement, including costs incurred in excess of agreed upon caps and costs related to certain combination studies of *Keytruda* and Lenvima.

Under the agreement, Merck made an upfront payment to Eisai and also made payments over a multi-year period for certain option rights (of which the final $125 million option payment was made in March 2021). In addition, the agreement provides for contingent payments from Merck to Eisai related to the successful achievement of sales-based and regulatory milestones. Merck made sales-based milestone payments to Eisai aggregating $200 million, $500 million and $50 million in 2021, 2020 and 2019, respectively. As of December 31, 2021, sales-based milestone payments accrued but not yet paid totaled $600 million. Potential future sales-based milestone payments of $2.6 billion have not yet been accrued as they are not deemed by the Company to be probable at this time.

In 2021 and 2020, Lenvima received regulatory approvals triggering capitalized milestone payments of $75 million and $10 million, respectively, from Merck to Eisai. As of December 31, 2021, a regulatory approval milestone payment of $25 million was accrued but not yet paid. Potential future regulatory milestone payments of $25 million remain under the agreement.

The intangible asset balance related to Lenvima (which includes capitalized sales-based and regulatory milestone payments) was $1.0 billion at December 31, 2021 and is included in *Other Intangibles, Net*. The amount is being amortized over its estimated useful life through 2026 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

Years Ended December 31	**2021**	2020	2019
Alliance revenue - Lenvima	**$ 704**	$ 580	$ 404
Cost of sales [(1)]	**195**	271	206
Selling, general and administrative	**127**	73	80
Research and development	**173**	185	189

December 31	**2021**	2020
Receivables from Eisai included in *Other current assets*	**$ 200**	$ 157
Payables to Eisai included in *Accrued and other current liabilities* [(2)]	**625**	335
Payables to Eisai included in *Other Noncurrent Liabilities* [(3)]	**—**	600

[(1)] *Represents amortization of capitalized milestone payments.*

[(2)] *Includes accrued milestone and future option payments.*

[(3)] *Includes accrued milestone payments.*

Bayer AG

In 2014, the Company entered into a worldwide clinical development collaboration with Bayer AG (Bayer) to market and develop soluble guanylate cyclase (sGC) modulators including Bayer's Adempas (riociguat). The two companies have implemented a joint development and commercialization strategy. The collaboration also includes development of Bayer's Verquvo (vericiguat), which was approved in the U.S. in January 2021, in Japan in June 2021 and in the EU in July 2021. Under the agreement, Bayer commercializes Adempas in the Americas, while Merck commercializes in the rest of the world. For Verquvo, Merck commercializes in the U.S. and Bayer commercializes in the rest of the world. Both companies share in development costs and profits on sales. Merck records sales of Adempas and Verquvo in its marketing territories, as well as alliance revenue. Alliance revenue represents Merck's share of profits from sales of Adempas and Verquvo in Bayer's marketing territories, which are product sales net of cost of sales and commercialization costs. Cost of sales includes Bayer's share of profits from sales in Merck's marketing territories.

In addition, the agreement provided for contingent payments from Merck to Bayer related to the successful achievement of sales-based milestones. Merck made a sales-based milestone payment to Bayer of

$375 million in 2020. In 2021, following the approval of Verquvo noted above, Merck determined it was probable that sales of Adempas and Verquvo in the future would trigger the remaining $400 million sales-based milestone

payment that was outstanding under this agreement. Accordingly, Merck recorded a liability of $400 million and a corresponding increase to the intangible assets related to this collaboration. Merck also recognized $153 million of cumulative amortization catch-up expense related to the recognition of this milestone in 2021. In January 2022, Merck made this final milestone payment to Bayer.

The intangible asset balances related to Adempas (which includes the acquired intangible asset balance, as well as capitalized sales-based milestone payments attributed to Adempas) and Verquvo (which reflects the portion of the final sales-based milestone payment that was attributed to Verquvo) were $806 million and $68 million, respectively, at December 31, 2021 and are included in *Other Intangibles, Net*. The assets are being amortized over their estimated useful lives (through 2027 for Adempas and through 2031 for Verquvo) as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

Years Ended December 31	**2021**	2020	2019
Alliance revenue - Adempas/Verquvo	**$ 342**	$ 281	$ 204
Net sales of Adempas recorded by Merck	**252**	220	215
Net sales of Verquvo recorded by Merck	**7**	—	—
Total sales	**$ 601**	$ 501	$ 419
Cost of sales [(1)]	**424**	196	188
Selling, general and administrative	**126**	47	34
Research and development	**53**	63	126

December 31	**2021**	2020
Receivables from Bayer included in *Other current assets*	**$ 114**	$ 65
Payables to Bayer included in *Accrued and other current Liabilities* [(2)]	**472**	—

[(1)] *Includes amortization of intangible assets. Amount in 2021 includes $153 million of cumulative amortization catch-up expense as noted above. In addition, cost of sales in all periods now includes Bayer's share of profits from sales in Merck's marketing territories.*

[(2)] *Includes accrued milestone payment.*

Ridgeback Biotherapeutics LP

In July 2020, Merck and Ridgeback, a closely held biotechnology company, entered into a collaboration agreement to develop molnupiravir (MK-4482), an orally available antiviral candidate in clinical development for the treatment of patients with COVID-19. Merck gained exclusive worldwide rights to develop and commercialize molnupiravir and related molecules. Under the terms of the agreement, Ridgeback received an upfront payment and is eligible to receive future contingent payments dependent upon the achievement of certain developmental and regulatory approval milestones. The agreement also provides for Merck to reimburse Ridgeback for a portion of certain third-party contingent milestone payments and royalties on net sales, which is part of the profit share calculation. Merck is the principal on sales transactions, recognizing sales and related costs, with profit sharing amounts recorded within *Cost of sales*. Profits from the collaboration are split equally between the partners. Reimbursements from Ridgeback for its share of research and development costs (deducted from Ridgeback's share of profits) are reflected as decreases to *Research and development* expenses.

In December 2021, the FDA granted EUA for molnupiravir. Under a previously announced procurement agreement with the U.S. government, Merck agreed to supply 3.1 million courses of molnupiravir to the U.S. government upon EUA or approval from the FDA, of which approximately 888,000 courses were delivered in 2021. This procurement of molnupiravir is being supported in whole or in part with federal funds. Additionally, in December 2021, Japan's Ministry of Health, Labor and Welfare granted Special Approval for Emergency in Japan for molnupiravir. Under a supply agreement, the Japanese government will purchase 1.6 million courses of molnupiravir, of which approximately 200,000 courses were delivered in 2021. Also, in November 2021, the Medicines and Healthcare products Regulatory Agency in the United Kingdom (UK) granted conditional marketing authorization for molnupiravir. The UK government has committed to purchase a total of 2.23 million courses of molnupiravir, of

which approximately 152,000 courses were delivered in 2021. Merck has entered into advance purchase and supply agreements for molnupiravir in more than 30 markets.

Merck and Ridgeback are committed to providing timely access to molnupiravir globally through a comprehensive supply and access approach, which includes investing at risk to produce millions of courses of therapy; tiered pricing based on the ability of governments to finance health care; entering into supply agreements with governments as noted above; allocating up to 3 million courses of therapy to the United Nations Children's Fund (UNICEF) for use in adults; and granting voluntary licenses to generic manufacturers and to the Medicines Patent Pool (MPP) to make generic molnupiravir available in more than 100 low- and middle-income countries following local regulatory authorizations or approvals. Merck, Ridgeback and Emory University will not receive royalties for sales of molnupiravir under the MPP agreement (molnupiravir was invented at Emory University and licensed to Ridgeback) for as long as COVID-19 remains classified as a Public Health Emergency of International Concern by the World Health Organization.

Summarized financial information related to this collaboration is as follows:

Years Ended December 31	**2021**	2020
Molnupiravir sales	**$ 952**	$ —
Cost of sales [(1)]	**494**	13
Selling, general and administrative	**33**	6
Research and development [(2)]	**60**	323

December 31	**2021**	2020
Payables to Ridgeback included in *Accrued and other current liabilities* [(3)]	**$ 283**	$ 3

[(1)] *Includes royalty expense and amortization of capitalized milestone payments.*

[(2)] *Amount in 2020 includes upfront payment.*

[(3)] *Includes accrued royalty and milestone payments.*

6. Restructuring

In 2019, Merck approved a global restructuring program (Restructuring Program) as part of a worldwide initiative focused on further optimizing the Company's manufacturing and supply network, as well as reducing its global real estate footprint. This program is a continuation of the Company's plant rationalization and builds on prior restructuring programs. The actions currently contemplated under the Restructuring Program are expected to be substantially completed by the end of 2023, with the cumulative pretax costs to be incurred by the Company to implement the program estimated to be approximately $3.5 billion. The Company estimates that approximately 70% of the cumulative pretax costs will result in cash outlays, primarily related to employee separation expense and facility shut-down costs. Approximately 30% of the cumulative pretax costs will be non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested.

The Company recorded total pretax costs of $868 million in 2021, $880 million in 2020 and $915 million in 2019 related to restructuring program activities. Since inception of the Restructuring Program through December 31, 2021, Merck has recorded total pretax accumulated costs of approximately $2.7 billion. The Company expects to record charges of approximately $400 million in 2022 related to the Restructuring Program. For segment reporting, restructuring charges are unallocated expenses.

The following table summarizes the charges related to restructuring program activities by type of cost:

	Separation Costs	Accelerated Depreciation	Other	Total
Year Ended December 31, 2021				
Cost of sales	**$ —**	**$ 52**	**$ 108**	**$ 160**
Selling, general and administrative	**—**	**12**	**7**	**19**
Research and development	**—**	**27**	**1**	**28**
Restructuring costs	**451**	**—**	**210**	**661**
	$ 451	**$ 91**	**$ 326**	**$ 868**
Year Ended December 31, 2020				
Cost of sales	$ —	$ 143	$ 32	$ 175
Selling, general and administrative	—	44	3	47
Research and development	—	81	2	83
Restructuring costs	385	—	190	575
	$ 385	$ 268	$ 227	$ 880
Year Ended December 31, 2019				
Cost of sales	$ —	$ 198	$ 53	$ 251
Selling, general and administrative	—	33	1	34
Research and development	—	2	2	4
Restructuring costs	572	—	54	626
	$ 572	$ 233	$ 110	$ 915

Separation costs are associated with actual headcount reductions, as well as those headcount reductions which were probable and could be reasonably estimated.

Accelerated depreciation costs primarily relate to manufacturing, research and administrative facilities and equipment to be sold or closed as part of the programs. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the asset, based upon the anticipated date the site will be closed or divested or the equipment disposed of, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. All the sites have and will continue to operate up through the respective closure dates and, since future undiscounted cash flows are sufficient to recover the respective book values, Merck is recording accelerated depreciation over the revised useful life of the site assets. Anticipated site closure dates, particularly related to manufacturing locations, have been and may continue to be adjusted to reflect changes resulting from regulatory or other factors.

Other activity in 2021, 2020 and 2019 includes asset abandonment, facility shut-down and other related costs, as well as pretax gains and losses resulting from the sales of facilities and related assets. Additionally, other activity includes certain employee-related costs associated with pension and other postretirement benefit plans (see Note 14) and share-based compensation.

The following table summarizes the charges and spending relating to restructuring program activities:

	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2020	$ 690	$ —	$ 25	$ 715
Expenses	385	268	227	880
(Payments) receipts, net	(508)	—	(271)	(779)
Non-cash activity	—	(268)	38	(230)
Restructuring reserves December 31, 2020	567	—	19	586
Expenses	**451**	**91**	**326**	**868**
(Payments) receipts, net	**(422)**	**—**	**(186)**	**(608)**
Non-cash activity	**—**	**(91)**	**(118)**	**(209)**
Restructuring reserves December 31, 2021 [1]	**$ 596**	**$ —**	**$ 41**	**$ 637**

[1] *The remaining cash outlays are expected to be substantially completed by the end of 2023.*

7. Financial Instruments

Derivative Instruments and Hedging Activities

The Company manages the impact of foreign exchange rate movements and interest rate movements on its earnings, cash flows and fair values of assets and liabilities through operational means and through the use of various financial instruments, including derivative instruments.

A significant portion of the Company's revenues and earnings in foreign affiliates is exposed to changes in foreign exchange rates. The objectives of and accounting related to the Company's foreign currency risk management program, as well as its interest rate risk management activities are discussed below.

Foreign Currency Risk Management

The Company has established revenue hedging, balance sheet risk management and net investment hedging programs to protect against volatility of future foreign currency cash flows and changes in fair value caused by changes in foreign exchange rates.

The objective of the revenue hedging program is to reduce the variability caused by changes in foreign exchange rates that would affect the U.S. dollar value of future cash flows derived from foreign currency denominated sales, primarily the euro, Japanese yen and Chinese renminbi. To achieve this objective, the Company will hedge a portion of its forecasted foreign currency denominated third-party and intercompany distributor entity sales (forecasted sales) that are expected to occur over its planning cycle, typically no more than two years into the future. The Company will layer in hedges over time, increasing the portion of forecasted sales hedged as it gets closer to the expected date of the forecasted sales. The portion of forecasted sales hedged is based on assessments of cost-benefit profiles that consider natural offsetting exposures, revenue and exchange rate volatilities and correlations, and the cost of hedging instruments. The Company manages its anticipated transaction exposure principally with purchased local currency put options, forward contracts, and purchased collar options.

The fair values of these derivative contracts are recorded as either assets (gain positions) or liabilities (loss positions) in the Consolidated Balance Sheet. Changes in the fair value of derivative contracts are recorded each period in either current earnings or *OCI* depending on whether the derivative is designated as part of a hedge transaction and, if so, the type of hedge transaction. For derivatives that are designated as cash flow hedges, the unrealized gains or losses on these contracts are recorded in *AOCL* and reclassified into *Sales* when the hedged anticipated revenue is recognized. For those derivatives which are not designated as cash flow hedges, but serve as economic hedges of forecasted sales, unrealized gains or losses are recorded in *Sales* each period. The cash flows from both designated and non-designated contracts are reported as operating activities in the Consolidated Statement of Cash Flows. The Company does not enter into derivatives for trading or speculative purposes.

The Company manages operating activities and net asset positions at each local subsidiary in order to mitigate the effects of exchange on monetary assets and liabilities. The Company also uses a balance sheet risk management program to mitigate the exposure of net monetary assets that are denominated in a currency other than a subsidiary's functional currency from the effects of volatility in foreign exchange. In these instances, Merck principally utilizes forward exchange contracts to offset the effects of exchange on exposures denominated in developed country currencies, primarily the euro, Japanese yen, British pound, Canadian dollar and Swiss franc. For exposures in developing country currencies, including the Chinese renminbi, the Company will enter into forward contracts to offset the effects of exchange on exposures when it is deemed economical to do so based on a cost-benefit analysis that considers the magnitude of the exposure, the volatility of the exchange rate and the cost of the hedging instrument. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

Monetary assets and liabilities denominated in a currency other than the functional currency of a given subsidiary are remeasured at spot rates in effect on the balance sheet date with the effects of changes in spot rates reported in *Other (income) expense, net*. The forward contracts are not designated as hedges and are marked to market through *Other (income) expense, net*. Accordingly, fair value changes in the forward contracts help mitigate the changes in the value of the remeasured assets and liabilities attributable to changes in foreign currency exchange rates, except to the extent of the spot-forward differences. These differences are not significant due to the short-term nature of the contracts, which typically have average maturities at inception of less than one year.

The Company also uses forward exchange contracts to hedge a portion of its net investment in foreign operations against movements in exchange rates. The forward contracts are designated as hedges of the net investment in a foreign operation. The unrealized gains or losses on these contracts are recorded in foreign currency translation adjustment within *OCI*, and remain in *AOCL* until either the sale or complete or substantially complete liquidation of the subsidiary. The Company excludes certain portions of the change in fair value of its derivative instruments from the assessment of hedge effectiveness (excluded components). Changes in fair value of the excluded components are recognized in *OCI*. The Company recognizes in earnings the initial value of the excluded components on a straight-line basis over the life of the derivative instrument, rather than using the mark-to-market approach. The cash flows from these contracts are reported as investing activities in the Consolidated Statement of Cash Flows.

Foreign exchange risk is also managed through the use of foreign currency debt. The Company's senior unsecured euro-denominated notes have been designated as, and are effective as, economic hedges of the net investment in a foreign operation. Accordingly, foreign currency transaction gains or losses due to spot rate fluctuations on the euro-denominated debt instruments are included in foreign currency translation adjustment within *OCI*.

The effects of the Company's net investment hedges on *OCI* and the Consolidated Statement of Income are shown below:

	Amount of Pretax (Gain) Loss Recognized in Other Comprehensive Income [1]			Amount of Pretax (Gain) Loss Recognized in *Other (income) expense, net* for Amounts Excluded from Effectiveness Testing		
Years Ended December 31	**2021**	2020	2019	**2021**	2020	2019
Net Investment Hedging Relationships						
Foreign exchange contracts	**$ (49)**	$ 26	$ (10)	**$ (13)**	$ (19)	$ (31)
Euro-denominated notes	**(296)**	385	(75)	**—**	—	—

[1] *No amounts were reclassified from AOCL into income related to the sale of a subsidiary.*

Interest Rate Risk Management

The Company may use interest rate swap contracts on certain investing and borrowing transactions to manage its net exposure to interest rate changes and to reduce its overall cost of borrowing. The Company does not use leveraged swaps and, in general, does not leverage any of its investment activities that would put principal capital at risk.

In January 2021, five interest rate swaps with a total notional amount of $1.15 billion matured. These swaps effectively converted the Company's $1.15 billion, 3.875% fixed-rate notes due 2021 to variable rate debt. At December 31, 2021, the Company was a party to nine pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes as detailed in the table below:

	2021		
Debt Instrument	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
2.40% notes due 2022	$ 1,000	4	$ 1,000
2.35% notes due 2022 [1]	1,250	5	1,250

[1] *These interest rate swaps matured in February 2022.*

The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in the benchmark LIBOR swap rate. The fair value changes in the notes attributable to changes in the LIBOR swap rate are recorded in interest expense along with the offsetting fair value changes in the swap contracts. See Note 2 for a discussion of the pending discontinuation of LIBOR as part of reference rate reform. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

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The table below presents the location of amounts recorded on the Consolidated Balance Sheet related to cumulative basis adjustments for fair value hedges as of December 31:

	Carrying Amount of Hedged Liabilities		Cumulative Amount of Fair Value Hedging Adjustment Increase (Decrease) Included in the Carrying Amount	
	2021	2020	**2021**	2020
Balance Sheet Line Item in which Hedged Item is Included				
Loans payable and current portion of long-term debt	**$ 2,263**	$ 1,150	**$ 13**	$ —
Long-Term Debt	**—**	2,301	**—**	53

Presented in the table below is the fair value of derivatives on a gross basis segregated between those derivatives that are designated as hedging instruments and those that are not designated as hedging instruments as of December 31:

		2021			2020		
		Fair Value of Derivative			Fair Value of Derivative		
	Balance Sheet Caption	**Asset**	**Liability**	**U.S. Dollar Notional**	Asset	Liability	U.S. Dollar Notional
Derivatives Designated as Hedging Instruments							
Interest rate swap contracts	Other current assets	**$ 14**	**$ —**	**$ 2,250**	$ 1	$ —	$ 1,150
Interest rate swap contracts	Other Assets	**—**	**—**	**—**	54	—	2,250
Foreign exchange contracts	Other current assets	**271**	**—**	**6,778**	12	—	3,183
Foreign exchange contracts	Other Assets	**43**	**—**	**1,551**	45	—	2,030
Foreign exchange contracts	Accrued and other current liabilities	**—**	**24**	**1,623**	—	217	5,049
Foreign exchange contracts	Other Noncurrent Liabilities	**—**	**1**	**43**	—	1	52
		$ 328	**$ 25**	**$ 12,245**	$ 112	$ 218	$ 13,714
Derivatives Not Designated as Hedging Instruments							
Foreign exchange contracts	Other current assets	**$ 221**	**$ —**	**$ 10,073**	$ 70	$ —	$ 7,260
Foreign exchange contracts	Accrued and other current liabilities	**—**	**96**	**10,640**	—	307	11,810
		$ 221	**$ 96**	**$ 20,713**	$ 70	$ 307	$ 19,070
		$ 549	**$ 121**	**$ 32,958**	$ 182	$ 525	$ 32,784

As noted above, the Company records its derivatives on a gross basis in the Consolidated Balance Sheet. The Company has master netting agreements with several of its financial institution counterparties (see *Concentrations of Credit Risk* below). The following table provides information on the Company's derivative positions subject to these master netting arrangements as if they were presented on a net basis, allowing for the right of offset by counterparty and cash collateral exchanged per the master agreements and related credit support annexes at December 31:

	2021		2020	
	Asset	**Liability**	Asset	Liability
Gross amounts recognized in the consolidated balance sheet	**$ 549**	**$ 121**	$ 182	$ 525
Gross amounts subject to offset in master netting arrangements not offset in the consolidated balance sheet	**(110)**	**(110)**	(156)	(156)
Cash collateral posted/received	**(164)**	**—**	—	(36)
Net amounts	**$ 275**	**$ 11**	$ 26	$ 333

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The table below provides information regarding the location and amount of pretax (gains) losses of derivatives designated in fair value or cash flow hedging relationships:

	Sales			Other (income) expense, net [1]			Other comprehensive income (loss)		
Years Ended December 31	**2021**	2020	2019	**2021**	2020	2019	**2021**	2020	2019
Financial Statement Line Items in which Effects of Fair Value or Cash Flow Hedges are Recorded	**$ 48,704**	$ 41,518	$ 39,121	**$ (1,341)**	(890)	129	**$ 1,756**	$ (441)	$ (648)
(Gain) loss on fair value hedging relationships									
Interest rate swap contracts									
Hedged items	**—**	—	—	**(40)**	40	95	**—**	—	—
Derivatives designated as hedging instruments	**—**	—	—	**1**	(76)	(65)	**—**	—	—
Impact of cash flow hedging relationships									
Foreign exchange contracts									
Amount of gain (loss) recognized in *OCI* on derivatives	**—**	—	—	**—**	—	—	**333**	(383)	87
(Decrease) increase in *Sales* as a result of *AOCL* reclassifications	**(194)**	(6)	255	**—**	—	—	**194**	6	(255)
Interest rate contracts									
Amount of gain recognized in *Other (income) expense, net* on derivatives	**—**	—	—	**(2)**	(4)	(4)	**—**	—	—
Amount of loss recognized in *OCI* on derivatives	**—**	—	—	**—**	—	—	**(2)**	(4)	(6)

[1] *Interest expense is a component of* Other (income) expense, net.

The table below provides information regarding the income statement effects of derivatives not designated as hedging instruments:

		Amount of Derivative Pretax (Gain) Loss Recognized in Income		
Years Ended December 31		**2021**	2020	2019
Derivatives Not Designated as Hedging Instruments	*Income Statement Caption*			
Foreign exchange contracts [1]	Other (income) expense, net	**$ 313**	$ (12)	$ 174
Foreign exchange contracts [2]	Sales	**9**	13	1
Interest rate contracts [3]	Other (income) expense, net	**—**	9	—
Forward contract related to Seagen common stock	Research and development expenses	**—**	15	—

[1] *These derivative contracts primarily mitigate changes in the value of remeasured foreign currency denominated monetary assets and liabilities attributable to changes in foreign currency exchange rates. Amount in 2021 includes a loss on forward exchange contracts entered into in conjunction with the spin-off of Organon.*

[2] *These derivatives serve as economic hedges of forecasted transactions.*

[3] *These derivatives serve as economic hedges against rising treasury rates.*

At December 31, 2021, the Company estimates $170 million of pretax net unrealized gains on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be

reclassified from *AOCL* to *Sales*. The amount ultimately reclassified to *Sales* may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.

Investments in Debt and Equity Securities

Information on investments in debt and equity securities at December 31 is as follows:

	2021				2020			
		Gross Unrealized				Gross Unrealized		
	Amortized Cost	Gains	Losses	Fair Value	Amortized Cost	Gains	Losses	Fair Value
U.S. government and agency securities	$ 80	$ —	$ —	$ 80	$ 84	$ —	$ —	$ 84
Foreign government bonds	2	—	—	2	5	—	—	5
Corporate notes and bonds	4	—	—	4	—	—	—	—
Total debt securities	86	—	—	86	89	—	—	89
Publicly traded equity securities [1]				1,647				1,787
Total debt and publicly traded equity securities				$ 1,733				$ 1,876

[1] *Unrealized net losses recorded in* Other (income) expense, net *on equity securities still held at December 31, 2021 were $232 million during 2021. Unrealized net gains recorded in* Other (income) expense, net *on equity securities still held at December 31, 2020 were $163 million during 2020.*

At December 31, 2021 and 2020, the Company also had $596 million and $586 million, respectively, of equity investments without readily determinable fair values included in *Other Assets*. The Company records unrealized gains on these equity investments based on favorable observable price changes from transactions involving similar investments of the same investee and records unrealized losses based on unfavorable observable price changes, which are included in *Other (income) expense, net*. During 2021, the Company recorded unrealized gains of $110 million and unrealized losses of $1 million related to certain of these equity investments still held at December 31, 2021. During 2020, the Company recorded unrealized gains of $62 million and unrealized losses of $3 million related to certain of these investments still held at December 31, 2020. Cumulative unrealized gains and cumulative unrealized losses based on observable price changes for investments in equity investments without readily determinable fair values still held at December 31, 2021 were $234 million and $7 million, respectively.

At December 31, 2021 and 2020, the Company also had $1.7 billion and $800 million, respectively, recorded in *Other Assets* for equity securities held through ownership interests in investment funds. (Gains) losses recorded in *Other (income) expense, net* relating to these investment funds were $(1.4) billion, $(583) million and $113 million for the years ended December 31, 2021, 2020 and 2019, respectively.

Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company uses a fair value hierarchy which maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest:

Level 1 — Quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 — Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity. Level 3 assets or liabilities are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as assets or liabilities for which the determination of fair value requires significant judgment or estimation.

If the inputs used to measure the financial assets and liabilities fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

Financial assets and liabilities measured at fair value on a recurring basis at December 31 are summarized below:

	Fair Value Measurements Using				Fair Value Measurements Using			
	Level 1	**Level 2**	**Level 3**	**Total**	Level 1	Level 2	Level 3	Total
	2021				2020			
Assets								
Investments								
Foreign government bonds	**$ —**	**$ 2**	**$ —**	**$ 2**	$ —	$ 5	$ —	$ 5
Publicly traded equity securities	**368**	**—**	**—**	**368**	780	—	—	780
	368	**2**	**—**	**370**	780	5	—	785
Other assets [1]								
U.S. government and agency securities	**80**	**—**	**—**	**80**	84	—	—	84
Corporate notes and bonds	**4**	**—**	**—**	**4**	—	—	—	—
Publicly traded equity securities	**1,279**	**—**	**—**	**1,279**	1,007	—	—	1,007
	1,363	**—**	**—**	**1,363**	1,091	—	—	1,091
Derivative assets [2]								
Forward exchange contracts	**—**	**351**	**—**	**351**	—	90	—	90
Purchased currency options	**—**	**184**	**—**	**184**	—	37	—	37
Interest rate swaps	**—**	**14**	**—**	**14**	—	55	—	55
	—	**549**	**—**	**549**	—	182	—	182
Total assets	**$ 1,731**	**$ 551**	**$ —**	**$ 2,282**	$ 1,871	$ 187	$ —	$ 2,058
Liabilities								
Other liabilities								
Contingent consideration	**$ —**	**$ —**	**$ 777**	**$ 777**	$ —	$ —	$ 841	$ 841
Derivative liabilities [2]								
Forward exchange contracts	**—**	**120**	**—**	**120**	—	505	—	505
Written currency options	**—**	**1**	**—**	**1**	—	20	—	20
	—	**121**	**—**	**121**	—	525	—	525
Total liabilities	**$ —**	**$ 121**	**$ 777**	**$ 898**	$ —	$ 525	$ 841	$ 1,366

[1] *Investments included in other assets are restricted as to use, including for the payment of benefits under employee benefit plans.*

[2] *The fair value determination of derivatives includes the impact of the credit risk of counterparties to the derivatives and the Company's own credit risk, the effects of which were not significant.*

As of December 31, 2021 and 2020, *Cash and cash equivalents* include cash equivalents of $6.8 billion (which would be considered Level 2 in the fair value hierarchy).

Contingent Consideration

Summarized information about the changes in the fair value of liabilities for contingent consideration associated with business combinations is as follows:

	2021	2020
Fair value January 1	**$ 841**	$ 767
Additions	**—**	97
Changes in estimated fair value [1]	**57**	83
Payments	**(109)**	(106)
Other	**(12)**	—
Fair value December 31 [2][3]	**$ 777**	$ 841

[1] *Recorded in* Cost of sales, Research and development *expenses, and* Other (income) expense, net. *Includes cumulative translation adjustments.*

[2] *Balance at December 31, 2021 includes $151 million recorded as a current liability for amounts expected to be paid within the next 12 months.*

[3] *At December 31, 2021 and 2020, $620 million and $711 million, respectively, of the liabilities relate to the termination of the Sanofi Pasteur MSD joint venture in 2016. As part of the termination, Merck recorded a liability for contingent future royalty payments of 11.5% on net sales of all Merck products that were previously sold by the joint venture through December 31, 2024. The fair value of this liability is determined utilizing the estimated amount and timing of projected cash flows using a risk-adjusted discount rate of 8% to present value the cash flows.*

The additions to contingent consideration in 2020 relate to the acquisition of Themis (see Note 4). The payments of contingent consideration in both years relate to the Sanofi Pasteur MSD liabilities described above.

Other Fair Value Measurements

Some of the Company's financial instruments, such as cash and cash equivalents, receivables and payables, are reflected in the balance sheet at carrying value, which approximates fair value due to their short-term nature.

The estimated fair value of loans payable and long-term debt (including current portion) at December 31, 2021, was $35.7 billion compared with a carrying value of $33.1 billion and at December 31, 2020, was $36.0 billion compared with a carrying value of $31.8 billion. Fair value was estimated using recent observable market prices and would be considered Level 2 in the fair value hierarchy.

Concentrations of Credit Risk

On an ongoing basis, the Company monitors concentrations of credit risk associated with corporate and government issuers of securities and financial institutions with which it conducts business. Credit exposure limits are established to limit a concentration with any single issuer or institution. Cash and investments are placed in instruments that meet high credit quality standards, as specified in the Company's investment policy guidelines.

The majority of the Company's accounts receivable arise from product sales in the U.S., Europe and China and are primarily due from drug wholesalers and retailers, hospitals, government agencies, managed health care providers and pharmacy benefit managers. The Company monitors the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in their credit profile. The Company also continues to monitor global economic conditions, including the volatility associated with international sovereign economies, and associated impacts on the financial markets and its business.

The Company's customers with the largest accounts receivable balances are: McKesson Corporation, AmerisourceBergen Corporation and Cardinal Health, Inc., which represented approximately 20%, 15% and 10%, respectively, of total accounts receivable at December 31, 2021. The Company monitors the creditworthiness of its customers to which it grants credit terms in the normal course of business. Bad debts have been minimal. The Company does not normally require collateral or other security to support credit sales.

The Company has accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable. The Company factored $2.8 billion and $2.1 billion of accounts receivable as of December 31, 2021 and 2020, respectively, under these factoring arrangements, which reduced outstanding accounts receivable. The cash received from the financial institutions is reported within operating activities in the

Consolidated Statement of Cash Flows. In certain of these factoring arrangements, for ease of administration, the Company will collect customer payments related to the factored receivables, which it then remits to the financial institutions. At December 31, 2021 and 2020, the Company had collected $62 million and $102 million,

respectively, on behalf of the financial institutions, which is reflected as restricted cash in *Other current assets* and the related obligation to remit the cash within *Accrued and other current liabilities*. The Company remitted the cash to the financial institutions in January 2022 and 2021, respectively. The net cash flows relating to these collections are reported as financing activities in the Consolidated Statement of Cash Flows. The cost of factoring such accounts receivable was *de minimis*.

Derivative financial instruments are executed under International Swaps and Derivatives Association master agreements. The master agreements with several of the Company's financial institution counterparties also include credit support annexes. These annexes contain provisions that require collateral to be exchanged depending on the value of the derivative assets and liabilities, the Company's credit rating, and the credit rating of the counterparty. Cash collateral received by the Company from various counterparties was $164 million at December 31, 2021. The obligation to return such collateral is recorded in *Accrued and other current liabilities*. Cash collateral advanced by the Company to counterparties was $36 million at December 31, 2020.

8. Inventories

Inventories at December 31 consisted of:

	2021	2020
Finished goods	**$ 1,747**	$ 1,610
Raw materials and work in process	**6,220**	5,949
Supplies	**196**	146
Total (approximates current cost)	**8,163**	7,705
Decrease to LIFO cost	**(16)**	(81)
	$ 8,147	$ 7,624
Recognized as:		
Inventories	**$ 5,953**	$ 5,554
Other assets	**2,194**	2,070

Inventories valued under the LIFO method comprised approximately $3.3 billion and $2.8 billion at December 31, 2021 and 2020, respectively. Amounts recognized as *Other assets* are comprised almost entirely of raw materials and work in process inventories. At December 31, 2021 and 2020, these amounts included $1.9 billion and $1.8 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included $256 million and $279 million at December 31, 2021 and 2020, respectively, of inventories produced in preparation for product launches.

9. Goodwill and Other Intangibles

The following table summarizes goodwill activity by segment:

	Pharmaceutical	Animal Health	All Other	Total
Balance January 1, 2020	$ 14,825	$ 3,192	$ 52	$ 18,069
Acquisitions	742	105	—	847
Divestitures	—	—	(54)	(54)
Other [(1)]	47	(29)	2	20
Balance December 31, 2020 [(2)]	15,614	3,268	—	18,882
Acquisitions	**2,431**	**5**	**—**	**2,436**
Other [(1)]	**(48)**	**(6)**	**—**	**(54)**
Balance December 31, 2021 [(2)]	**$ 17,997**	**$ 3,267**	**$ —**	**$ 21,264**

[(1)] *Includes cumulative translation adjustments on goodwill balances.*

[(2)] *Accumulated goodwill impairment losses were $531 million at both December 31, 2021 and 2020.*

The additions to goodwill in the Pharmaceutical segment in 2021 were primarily related to the acquisition of Acceleron. The additions to goodwill in the Pharmaceutical segment in 2020 were primarily related to the acquisitions of ArQule and Themis. See Note 4 for more information on these acquisitions.

Other acquired intangibles at December 31 consisted of:

	2021			2020		
	Gross Carrying Amount	**Accumulated Amortization**	**Net**	Gross Carrying Amount	Accumulated Amortization	Net
Products and product rights	**$ 23,671**	**$ 15,776**	**$ 7,895**	$ 20,928	$ 16,138	$ 4,790
IPR&D	**9,281**	**—**	**9,281**	3,228	—	3,228
Trade names	**2,882**	**493**	**2,389**	2,882	352	2,530
Licenses and other	**6,604**	**3,236**	**3,368**	6,199	2,646	3,553
	$ 42,438	**$ 19,505**	**$ 22,933**	$ 33,237	$ 19,136	$ 14,101

Acquired intangibles include products and product rights, IPR&D, trade names and patents, licenses and other, which are initially recorded at fair value, assigned an estimated useful life, and amortized primarily on a straight-line basis over their estimated useful lives. Some of the more significant acquired intangibles, on a net basis, related to human health marketed products (included in products and product rights above) at December 31, 2021 include *Reblozyl*, $3.8 billion; *Zerbaxa*, $478 million; *Gardasil/Gardasil* 9, $191 million; *Bridion*, $145 million; *Dificid*, $145 million; *Sivextro*, $138 million; and *Simponi*, $101 million. Additionally, the Company had $5.0 billion of net acquired intangibles related to animal health marketed products at December 31, 2021, of which $2.3 billion relate primarily to trade names obtained through the 2019 acquisition of Antelliq (see Note 4). At December 31, 2021, IPR&D primarily relates to MK-7962 (sotatercept), $6.4 billion, obtained through the acquisition of Acceleron in 2021 (see Note 4); MK-1026 (nemtabrutinib), $2.0 billion, obtained through the acquisition of ArQule in 2020 (see below and Note 4); and MK-7264 (gefapixant) $832 million, obtained through the acquisition of Afferent Pharmaceuticals in 2016. Some of the more significant net intangible assets included in licenses and other above at December 31, 2021 include Lynparza, $1.1 billion, related to a collaboration with AstraZeneca; Lenvima, $1.0 billion, related to a collaboration with Eisai; Adempas, $806 million related to a collaboration with Bayer; and Verquvo, $68 million, also related to a collaboration with Bayer. See Note 5 for additional information related to the intangible assets associated with these collaborations.

In 2020, the Company recorded an impairment charge of $1.6 billion within *Cost of sales* related to *Zerbaxa* (ceftolozane and tazobactam) for injection, a combination antibacterial and beta-lactamase inhibitor for the treatment of certain bacterial infections. In December 2020, the Company temporarily suspended sales of *Zerbaxa*, and subsequently issued a product recall, following the identification of product sterility issues. The recall constituted a triggering event requiring the evaluation of the *Zerbaxa* intangible asset for impairment. The Company revised its cash flow forecasts for *Zerbaxa* utilizing certain assumptions around the return to market timeline and anticipated uptake in sales thereafter. These revised cash flow forecasts indicated that the *Zerbaxa* intangible asset value was not fully recoverable on an undiscounted cash flows basis. The Company utilized market participant assumptions to determine its best estimate of the fair value of the intangible asset related to *Zerbaxa* that, when compared with its related carrying value, resulted in the impairment charge noted above. The Company also wrote-off inventory of $120 million to *Cost of sales* in 2020 related to the *Zerbaxa* recall. A phased resupply of *Zerbaxa* was initiated in the fourth quarter of 2021.

In 2019, the Company recorded impairment charges related to marketed products and other intangibles of $705 million. Of this amount, $612 million related to *Sivextro* (tedizolid phosphate), a product for the treatment of acute bacterial skin and skin structure infections caused by designated susceptible Gram-positive organisms. As part of a reorganization and reprioritization of its internal sales force, the Company made the decision to cease promotion of *Sivextro* in the U.S. market by the end of 2019. This decision resulted in reduced cash flow projections for *Sivextro*, which indicated that the *Sivextro* intangible asset value was not fully recoverable on an undiscounted cash flows basis. The Company utilized market participant assumptions to determine its best estimate of the fair value of the intangible asset related to *Sivextro* that, when compared with its related carrying value, resulted in the impairment charge noted above.

IPR&D that the Company acquires through business combinations represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. Amounts capitalized as IPR&D are accounted for as indefinite-lived intangible assets, subject to impairment testing until

completion or abandonment of the projects. Upon successful completion of each IPR&D project, the Company will make a separate determination as to the then-useful life of the asset and begin amortization.

In 2021, the Company recorded a $275 million IPR&D impairment charge within *Research and development* expenses related to nemtabrutinib (MK-1026), a novel, oral BTK inhibitor currently being evaluated for the treatment of B-cell malignancies, obtained in connection with the acquisition of ArQule (see Note 4). As part of Merck's annual impairment assessment of IPR&D intangible assets, the Company estimated the current fair value of nemtabrutinib utilizing projected future cash flows. The market participant assumptions used to derive the forecasted cash flows were updated to reflect the current competitive landscape for nemtabrutinib, including increased expected development costs for additional clinical trial data needed to develop nemtabrutinib, as well as a delay in the anticipated launch date for nemtabrutinib, which collectively reduced the projected future cash flows and estimated fair value. Additionally, the discount rate utilized to determine the current fair value of the asset was reduced to 8.5% to reflect the current risk profile of the asset. The revised estimated fair value of nemtabrutinib when compared with its related carrying value resulted in the IPR&D impairment charge noted above. The remaining IPR&D intangible asset related to nemtabrutinib is $2.0 billion. If the assumptions used to estimate the fair value of nemtabrutinib prove to be incorrect and the development of nemtabrutinib does not progress as anticipated thereby adversely affecting projected future cash flows, the Company may record an additional impairment charge in the future and such charge could be material.

In 2020, the Company recorded a $90 million IPR&D impairment charge related to a decision to discontinue the development program for COVID-19 vaccine candidate V591 following Merck's review of findings from a Phase 1 clinical study for the vaccine. In the study, V591 was generally well tolerated, but the immune responses were inferior to those seen following natural infection and those reported for other SARS-CoV-2/ COVID-19 vaccines. The discontinuation of this development program also resulted in a reversal of the related liability for contingent consideration of $45 million.

In 2019, the Company recorded $172 million of IPR&D impairment charges. Of this amount, $155 million relates to the write-off of the intangible asset balance for programs obtained in connection with the acquisition of IOmet Pharma Ltd following a review of clinical trial results conducted by Merck, along with external clinical trial results for similar compounds. The discontinuation of this clinical development program also resulted in a reversal of the related liability for contingent consideration of $11 million.

The IPR&D projects that remain in development are subject to the inherent risks and uncertainties in drug development and it is possible that the Company will not be able to successfully develop and complete the IPR&D programs and profitably commercialize the underlying product candidates.

The Company may recognize additional non-cash impairment charges in the future related to other marketed products or pipeline programs and such charges could be material.

Aggregate amortization expense primarily recorded within *Cost of sales* was $1.6 billion in 2021, $1.8 billion in 2020 and $1.7 billion in 2019. The estimated aggregate amortization expense for each of the next five years is as follows: 2022, $1.7 billion; 2023, $1.6 billion; 2024, $1.6 billion; 2025, $1.4 billion; 2026, $1.4 billion.

10. Loans Payable, Long-Term Debt and Leases

Loans Payable

Loans payable at December 31, 2021 included $2.3 billion of notes due in 2022 and $149 million of long-dated notes that are subject to repayment at the option of the holders. Loans payable at December 31, 2020 included $2.3 billion of notes due in 2021, $4.0 billion of commercial paper borrowings and $73 million of long-dated notes that are subject to repayment at the option of the holders. The weighted-average interest rate of commercial paper borrowings was 0.08% and 0.79% for the years ended December 31, 2021 and 2020, respectively.

Long-Term Debt

Long-term debt at December 31 consisted of:

	2021	2020
2.75% notes due 2025	**$ 2,495**	$ 2,493
2.15% notes due 2031	**1,986**	—
2.75% notes due 2051	**1,979**	—
3.70% notes due 2045	**1,977**	1,976
2.80% notes due 2023	**1,749**	1,748
3.40% notes due 2029	**1,736**	1,734
1.70% notes due 2027	**1,493**	—
2.90% notes due 2061	**1,484**	—
4.00% notes due 2049	**1,470**	1,469
4.15% notes due 2043	**1,239**	1,238
1.45% notes due 2030	**1,235**	1,233
2.45% notes due 2050	**1,212**	1,211
1.875% euro-denominated notes due 2026	**1,123**	1,218
1.90% notes due 2028	**994**	—
0.75% notes due 2026	**993**	991
3.90% notes due 2039	**984**	983
2.35% notes due 2040	**983**	982
2.90% notes due 2024	**748**	746
6.50% notes due 2033	**715**	719
0.50% euro-denominated notes due 2024	**563**	611
1.375% euro-denominated notes due 2036	**559**	606
2.50% euro-denominated notes due 2034	**558**	605
3.60% notes due 2042	**491**	491
6.55% notes due 2037	**409**	411
5.75% notes due 2036	**338**	338
5.95% debentures due 2028	**306**	306
5.85% notes due 2039	**271**	271
6.40% debentures due 2028	**250**	250
6.30% debentures due 2026	**135**	135
2.35% notes due 2022	—	1,269
2.40% notes due 2022	—	1,032
Other	**215**	294
	$ 30,690	$ 25,360

Other (as presented in the table above) includes borrowings at variable rates that resulted in effective interest rates of zero and 0.45% for 2021 and 2020, respectively.

With the exception of the 6.30% debentures due 2026, the notes listed in the table above are redeemable in whole or in part, at Merck's option at any time, at varying redemption prices.

In December 2021, the Company issued $8.0 billion principal amount of senior unsecured notes consisting of $1.5 billion of 1.70% notes due 2027, $1.0 billion of 1.90% notes due 2028, $2.0 billion of 2.15% notes due 2031, $2.0 billion of 2.75% notes due 2051 and $1.5 billion of 2.90% notes due 2061. Merck used the net proceeds from the offering of the 2027 notes, the 2031 notes, the 2051 notes and the 2061 notes for general corporate purposes, including the repayment of outstanding commercial paper borrowings (including commercial paper borrowings in connection with Merck's acquisition of Acceleron), and other indebtedness. Merck allocated an

amount equal to the net proceeds of the offering of the notes due in 2028 to finance or refinance, in whole or in part, projects and partnerships in the Company's priority environmental, social and governance (ESG) areas.

Effective as of November 3, 2009, the Company executed a full and unconditional guarantee of the then existing debt of its subsidiary Merck Sharp & Dohme Corp. (MSD) and MSD executed a full and unconditional guarantee of the then existing debt of the Company (excluding commercial paper), including for payments of principal and interest. These guarantees do not extend to debt issued subsequent to that date.

Certain of the Company's borrowings require that Merck comply with covenants and, at December 31, 2021, the Company was in compliance with these covenants.

The aggregate maturities of long-term debt for each of the next five years are as follows: 2022, $2.3 billion; 2023, $1.7 billion; 2024, $1.3 billion; 2025, $2.5 billion; 2026, $2.3 billion. Interest payments related to these debt obligations are as follows: 2022, $910 million; 2023, $875 million; 2024, $838 million; 2025, $771 million; 2026, $743 million.

The Company has a $6.0 billion credit facility that matures in June 2026. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

Leases

The Company has operating leases primarily for manufacturing facilities, research and development facilities, corporate offices, employee housing, vehicles and certain equipment. The Company determines if an arrangement is a lease at inception. When evaluating contracts for embedded leases, the Company exercises judgment to determine if there is an explicit or implicit identified asset in the contract and if Merck controls the use of that asset. Embedded leases, primarily associated with contract manufacturing organizations, are immaterial. The lease term includes options to extend or terminate the lease when it is reasonably certain that Merck will exercise that option. Real estate leases for facilities have an average remaining lease term of seven years, which include options to extend the leases for up to four years where applicable. Vehicle leases are generally in effect for four years. The Company does not record short-term leases (leases with an initial term of 12 months or less) on the balance sheet; however, Merck currently has no short-term leases.

Lease expense for operating lease payments is recognized on a straight-line basis over the term of the lease. Operating lease assets and liabilities are recognized based on the present value of lease payments over the lease term. Since the Company's leases do not have a readily determinable implicit discount rate, the Company uses its incremental borrowing rate to calculate the present value of lease payments by asset class. On a quarterly basis, an updated incremental borrowing rate is determined based on the average remaining lease term of each asset class and the Company's pretax cost of debt for that same term. The updated rates for each asset class are applied prospectively to new leases. The Company does not separate lease components (e.g. payments for rent, real estate taxes and insurance costs) from non-lease components (e.g. common-area maintenance costs) in the event that the agreement contains both. Merck includes both the lease and non-lease components for purposes of calculating the right-of-use asset and related lease liability (if the non-lease components are fixed). For vehicle leases and employee housing, the Company applies a portfolio approach to account for the operating lease assets and liabilities.

Certain of the Company's lease agreements contain variable lease payments that are adjusted periodically for inflation or for actual operating expense true-ups compared with estimated amounts; however, these amounts are immaterial. Sublease income and activity related to sale and leaseback transactions are immaterial. Merck's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

Operating lease cost was $343 million in 2021, $340 million in 2020 and $333 million in 2019. Cash paid for amounts included in the measurement of operating lease liabilities was $340 million in 2021, $334 million in 2020 and $275 million in 2019. Operating lease assets obtained in exchange for lease obligations were $117 million in 2021, $473 million in 2020 and $125 million in 2019.

Supplemental balance sheet information related to operating leases is as follows:

December 31	**2021**	2020
Assets		
Other Assets [1]	**$ 1,586**	$ 1,688
Liabilities		
Accrued and other current liabilities	**304**	291
Other Noncurrent Liabilities	**1,225**	1,335
	$ 1,529	$ 1,626
Weighted-average remaining lease term (years)	**7.0**	8.0
Weighted-average discount rate	**2.6 %**	2.8 %

[1] *Includes prepaid leases that have no related lease liability.*

Maturities of operating leases liabilities are as follows:

2022	$ 336
2023	292
2024	242
2025	178
2026	146
Thereafter	511
Total lease payments	1,705
Less: Imputed interest	176
	$ 1,529

At December 31, 2021, the Company had entered into additional real estate operating leases that had not yet commenced; the obligations associated with these leases total $86 million.

11. Contingencies and Environmental Liabilities

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property, and commercial litigation, as well as certain additional matters including governmental and environmental matters. In the opinion of the Company, it is unlikely that the resolution of these matters will be material to the Company's financial condition, results of operations or cash flows.

Given the nature of the litigation discussed below and the complexities involved in these matters, the Company is unable to reasonably estimate a possible loss or range of possible loss for such matters until the Company knows, among other factors, (i) what claims, if any, will survive dispositive motion practice, (ii) the extent of the claims, including the size of any potential class, particularly when damages are not specified or are indeterminate, (iii) how the discovery process will affect the litigation, (iv) the settlement posture of the other parties to the litigation and (v) any other factors that may have a material effect on the litigation.

The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. For product liability claims, a portion of the overall accrual is actuarially determined and considers such factors as past experience, number of claims reported and estimates of claims incurred but not yet reported. Individually significant contingent losses are accrued when probable and reasonably estimable. Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable.

The Company's decision to obtain insurance coverage is dependent on market conditions, including cost and availability, existing at the time such decisions are made. The Company has evaluated its risks and has

determined that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and, as such, has no insurance for most product liabilities.

Product Liability Litigation

Fosamax

As previously disclosed, Merck is a defendant in product liability lawsuits in the U.S. involving Fosamax (Fosamax Litigation). As of December 31, 2021, approximately 3,470 cases are pending against Merck in either a federal multidistrict litigation (Femur Fracture MDL) or state court. Plaintiffs in the vast majority of these cases generally allege that they sustained femur fractures and/or other bone injuries (Femur Fractures) in association with the use of Fosamax.

In March 2014, the Femur Fracture MDL court dismissed with prejudice approximately 650 cases on preemption grounds. Plaintiffs in approximately 515 of those cases appealed that decision to the U.S. Court of Appeals for the Third Circuit (Third Circuit). In March 2017, the Third Circuit issued a decision reversing the Femur Fracture MDL court's preemption ruling and remanding the appealed cases back to the Femur Fracture MDL court. In May 2019, the U.S. Supreme Court decided that the Third Circuit had incorrectly concluded that the issue of preemption should be resolved by a jury, and accordingly vacated the judgment of the Third Circuit and remanded the proceedings back to the Third Circuit to address the issue in a manner consistent with the Supreme Court's opinion. In November 2019, the Third Circuit remanded the cases back to the District Court in order to allow that court to determine in the first instance whether the plaintiffs' state law claims are preempted by federal law under the standards described by the Supreme Court in its opinion. Briefing on the issue is closed, and the parties await the decision of the District Court.

Discovery is presently stayed in the Femur Fracture MDL. As part of the spin-off of Organon, Organon is required to indemnify Merck for all liabilities relating to, arising from, or resulting from the Fosamax Litigation.

Januvia/Janumet

As previously disclosed, Merck is a defendant in product liability lawsuits in the U.S. involving *Januvia* and/or *Janumet*. As of December 31, 2021, Merck is aware of approximately 675 product users alleging that *Januvia* and/or *Janumet* caused the development of pancreatic cancer and other injuries.

Most claims have been filed in multidistrict litigation before the U.S. District Court for the Southern District of California (MDL). On March 9, 2021, the MDL Court issued an omnibus order granting defendants' summary judgment motions based on preemption and failure to establish general causation, as well as granting defendants' motions to exclude plaintiffs' expert witnesses. The plaintiffs appealed that order. Since that time, more than half of these claims have been dismissed with prejudice as to Merck, and on October 5, 2021, the U.S. Court of Appeals for the Ninth Circuit dismissed the appeal as to Merck and two of its codefendants.

Outside of the MDL, the majority of claims have been filed in coordinated proceedings before the Superior Court of California, County of Los Angeles (California State Court). On April 6, 2021, the court in California issued an omnibus order granting defendants' summary judgment motions and also granting defendants' motions to exclude plaintiffs' expert witnesses.

As of December 31, 2021, six product users have claims pending against Merck in state courts other than California, including Illinois. In June 2017, the Illinois trial court denied Merck's motion for summary judgment based on federal preemption. Merck appealed, and the Illinois appellate court affirmed in December 2018. Merck filed a petition for leave to appeal to the Illinois Supreme Court in February 2019. In April 2019, the Illinois Supreme Court stayed consideration of the pending petition to appeal until the U.S. Supreme Court issued its opinion in *Merck Sharp & Dohme Corp. v. Albrecht* (relating to the Fosamax matter discussed above). Merck filed the opinion in *Albrecht* with the Illinois Supreme Court in June 2019. The petition for leave to appeal was decided in September 2019, in which the Illinois Supreme Court directed the intermediate appellate court to reconsider its earlier ruling. The Illinois Appellate Court issued a favorable decision concluding, consistent with *Albrecht*, that preemption presents a legal question to be resolved by the court. In May 2020, the Illinois Appellate Court issued a mandate to the state trial court, which, as of December 31, 2021, had not scheduled a case management conference or otherwise taken action.

In addition to the claims noted above, the Company has agreed to toll the statute of limitations for approximately 50 additional claims. The Company intends to continue defending against any remaining lawsuits.

Governmental Proceedings

As previously disclosed, in the fall of 2018, the Company received a records subpoena from the U.S. Attorney's Office for the District of Vermont (VT USAO) pursuant to Section 248 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) relating to an investigation of potential health care offenses. The subpoena sought information relating to any actual or potential business relationship or arrangement Merck has had with Practice Fusion, Inc. (PFI), a cloud-based, electronic health records (EHR) company that was acquired by Allscripts in January 2018. The Company cooperated with the government and responded to that subpoena. Subsequently, in May 2019, Merck received a second records subpoena from the VT USAO that broadened the government's information request by seeking information relating to Merck's relationship with any EHR company. Shortly thereafter, the VT USAO served a Civil Investigation Demand (CID) upon Merck similarly seeking information on the Company's relationships with EHR vendors. The CID explains that the government is conducting a False Claims Act investigation concerning whether Merck and/or PFI submitted claims to federal health care programs that violate the Federal Anti-Kickback Statute. Merck is cooperating with the government's investigation.

As previously disclosed, in April 2019, Merck received a set of investigative interrogatories from the California Attorney General's Office pursuant to its investigation of conduct and agreements that allegedly affected or delayed competition to Lantus in the insulin market. The interrogatories seek information concerning Merck's development of an insulin glargine product, and its subsequent termination, as well as Merck's patent litigation against Sanofi S.A. concerning Lantus and the resolution of that litigation. Merck is cooperating with the California Attorney General's investigation.

As previously disclosed, in June 2020, Merck received a CID from the U.S. Department of Justice. The CID requests answers to interrogatories, as well as various documents, regarding temperature excursions at a third-party storage facility containing certain Merck products. Merck is cooperating with the government's investigation and intends to produce information and/or documents as necessary in response to the CID.

As previously disclosed, the Company's subsidiaries in China have received and may continue to receive inquiries regarding their operations from various Chinese governmental agencies. Some of these inquiries may be related to matters involving other multinational pharmaceutical companies, as well as Chinese entities doing business with such companies. The Company's policy is to cooperate with these authorities and to provide responses as appropriate.

As previously disclosed, from time to time, the Company receives inquiries and is the subject of preliminary investigation activities from competition and other governmental authorities in markets outside the U.S. These authorities may include regulators, administrative authorities, and law enforcement and other similar officials, and these preliminary investigation activities may include site visits, formal or informal requests or demands for documents or materials, inquiries or interviews and similar matters. Certain of these preliminary inquiries or activities may lead to the commencement of formal proceedings. Should those proceedings be determined adversely to the Company, monetary fines and/or remedial undertakings may be required.

Commercial and Other Litigation

Zetia Antitrust Litigation

As previously disclosed, Merck, MSD, Schering Corporation, Schering-Plough Corporation, and MSP Singapore Company LLC (collectively, the Merck Defendants) are defendants in putative class action and opt-out lawsuits filed in 2018 on behalf of direct and indirect purchasers of Zetia alleging violations of federal and state antitrust laws, as well as other state statutory and common law causes of action. The cases have been consolidated for pretrial purposes in a federal multidistrict litigation before Judge Rebecca Beach Smith in the Eastern District of Virginia. In December 2018, the court denied the Merck Defendants' motions to dismiss or stay the direct purchaser putative class actions pending bilateral arbitration. In August 2019, the district court adopted in full the report and recommendation of the magistrate judge with respect to the Merck Defendants' motions to dismiss on non-arbitration issues, thereby granting in part and denying in part Merck Defendants' motions to dismiss. In addition, in June 2019, the representatives of the putative direct purchaser class filed an amended complaint, and in August 2019, retailer opt-out plaintiffs filed an amended complaint. In December 2019, the district court granted the Merck Defendants' motion to dismiss to the extent the motion sought dismissal of claims for overcharges paid by entities

that purchased generic ezetimibe from Par Pharmaceutical, Inc. (Par Pharmaceutical) and dismissed any claims for such overcharges.

In November 2019, the direct purchaser plaintiffs and the indirect purchaser plaintiffs filed motions for class certification. In August 2020, the district court granted in part the direct purchasers' motion for class certification and certified a class of 35 direct purchasers. In August 2020, the Fourth Circuit vacated the district court's class certification order and remanded for further proceedings consistent with the court's ruling. In September 2021, the direct purchaser plaintiffs filed a renewed motion for class certification. On January 25, 2022, the magistrate judge recommended that the district court deny the motion for class certification. On February 8, 2022, the direct purchaser plaintiffs filed objections to the recommendation. Briefing on these objections is ongoing.

In August 2020, the Merck Defendants filed a motion for summary judgment and other motions, and plaintiffs filed a motion for partial summary judgment, and other motions. Those motions are now fully briefed, and the court has heard argument on certain of the motions. The court may hold additional hearings on the other motions. Trial in this matter has been adjourned.

Also, in August 2020, the magistrate judge recommended that the court grant the motion for class certification filed by the putative indirect purchaser class. In August 2021, the district court granted certification of a class of indirect purchasers. In September 2021, the Merck Defendants petitioned to appeal the class certification decision to the Fourth Circuit. The Fourth Circuit denied that petition on September 30, 2021.

In September 2020, United Healthcare Services, Inc. filed a lawsuit in the U.S. District Court for the District of Minnesota against the Merck Defendants and others (the UHC Action). The UHC Action makes similar allegations as those made in the Zetia class action, as well as allegations about Vytorin. In September 2020, the U.S. Judicial Panel on Multidistrict Litigation transferred the case to the Eastern District of Virginia to proceed with the multidistrict Zetia litigation already in progress.

In December 2020, Humana Inc. filed a lawsuit in the Superior Court of the State of California, County of San Francisco, against Merck and others, alleging defendants violated state antitrust laws in multiple states. Also, in December 2020, Centene Corporation and others filed a lawsuit in the Superior Court of the State of California, County of San Francisco, against the same defendants as Humana. Both lawsuits allege similar anticompetitive acts to those alleged in the Zetia class action. In July 2021, the California Court ruled on defendants' Motion to Quash for lack of personal jurisdiction, granting the motion as to the out-of-state claims against defendants, and ordering limited jurisdictional discovery with regard to the California claims.

Also, on July 16, 2021, Humana and Centene filed actions against the Merck Defendants in New Jersey in the Bergen County Superior Court, re-asserting the claims that were dismissed in their California action. In September 2021, the parties reached an agreement that Humana and Centene would file their claims in New Jersey federal court, seek a transfer of those claims to the multidistrict Zetia litigation already in progress, and subsequently dismiss the actions previously filed in California and New Jersey state courts.

In June 2021, Kaiser Foundation Health Plan, Inc. similarly filed a lawsuit in the Superior Court of the State of California, County of San Francisco, against the same defendants as Humana and Centene. The Kaiser lawsuit alleges similar anticompetitive acts to those alleged in the Zetia class action. The Kaiser action was removed to the U.S. District Court for the Northern District of California on July 16, 2021. In September 2021, the U.S. Judicial Panel on Multidistrict Litigation transferred the case to the Eastern District of Virginia to proceed with the multidistrict Zetia litigation already in progress.

As of December 2021, all of the insurer plaintiffs (Kaiser, Humana, and Centene) are part of the multidistrict Zetia litigation, and are proceeding with discovery in that action. On February 9, 2022, United Healthcare, Kaiser, and Humana each filed an amended complaint.

Rotavirus Vaccines Antitrust Litigation

As previously disclosed, MSD is a defendant in putative class action lawsuits filed in 2018 on behalf of direct purchasers of *RotaTeq*, alleging violations of federal antitrust laws. The cases were consolidated in the Eastern District of Pennsylvania. In January 2019, the court denied MSD's motions to compel arbitration and to dismiss the consolidated complaint. In February 2019, MSD appealed the court's order on arbitration to the Third Circuit. In October 2019, the Third Circuit vacated the district court's order and remanded for limited discovery on the issue of

arbitrability. On July 6, 2020, MSD filed a renewed motion to compel arbitration, and plaintiffs filed a cross motion for summary judgment as to arbitrability. On November 20, 2020, the district court denied MSD's motion and granted plaintiffs' motion. On December 4, 2020, MSD filed a notice of appeal to the Third Circuit. MSD's appeal is fully briefed, and the Third Circuit heard argument on September 24, 2021.

Bravecto Litigation

As previously disclosed, in January 2020, the Company was served with a complaint in the U.S. District Court for the District of New Jersey. Following motion practice, the plaintiffs filed a second amended complaint on July 1, 2021, seeking to certify a nationwide class action of purchasers or users of *Bravecto* (fluralaner) products in the U.S. or its territories between May 1, 2014 and July 1, 2021. Plaintiffs contend *Bravecto* causes neurological events in dogs and cats and alleges violations of the New Jersey Consumer Fraud Act, Breach of Warranty, Product Liability, and related theories. The Company moved to dismiss or, alternatively, to strike the class allegations from the second amended complaint, and that motion is pending. A similar case was filed in Quebec, Canada in May 2019. The Superior Court certified a class of dog owners in Quebec who gave *Bravecto* Chew to their dogs between February 16, 2017 and November 2, 2018 whose dogs experienced one of the conditions in the post-marketing adverse reactions section of the labeling approved on November 2, 2018. The Company and plaintiffs each appealed the class certification decision. The Court of Appeal of Quebec heard the appeal on February 7, 2022 and took the matter under advisement.

Qui Tam Litigation

As previously disclosed, in June 2012, the U.S. District Court for the Eastern District of Pennsylvania unsealed a complaint that had been filed against the Company under the federal False Claims Act by two former employees alleging, among other things, that the Company defrauded the U.S. government by falsifying data in connection with a clinical study conducted on the mumps component of the Company's *M-M-R* II vaccine. The complaint alleges the fraud took place between 1999 and 2001. The U.S. government had the right to participate in and take over the prosecution of this lawsuit but notified the court that it declined to exercise that right. The two former employees are pursuing the lawsuit without the involvement of the U.S. government. In addition, as previously disclosed, two putative class action lawsuits on behalf of direct purchasers of the *M-M-R* II vaccine, which charge that the Company misrepresented the efficacy of the *M-M-R* II vaccine in violation of federal antitrust laws and various state consumer protection laws, are pending in the Eastern District of Pennsylvania. In September 2014, the court denied Merck's motion to dismiss the False Claims Act suit and granted in part and denied in part its motion to dismiss the then-pending antitrust suit. As a result, both the False Claims Act suit and the antitrust suits have proceeded into discovery, which is now complete, and the parties have filed and briefed cross-motions for summary judgment, which are currently pending before the court.

Merck KGaA Litigation

As previously disclosed, in January 2016, to protect its long-established brand rights in the U.S., the Company filed a lawsuit against Merck KGaA, Darmstadt, Germany (KGaA), historically operating as the EMD Group in the U.S., alleging it improperly uses the name "Merck" in the U.S. KGaA has filed suit against the Company in France, the UK, Germany, Switzerland, Mexico, India, Australia, Singapore, Hong Kong, SAR, PRC, and China alleging, among other things, unfair competition, trademark infringement and/or corporate name infringement. In the UK, Australia, Singapore, Hong Kong, SAR, PRC, and India, KGaA also alleges breach of the parties' coexistence agreement. The litigation is ongoing in the U.S. with no trial date set, and also ongoing in numerous jurisdictions outside of the U.S.

Patent Litigation

From time to time, generic manufacturers of pharmaceutical products file abbreviated New Drug Applications (NDAs) with the FDA seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned by the Company. To protect its patent rights, the Company may file patent infringement lawsuits against such generic companies. Similar lawsuits defending the Company's patent rights may exist in other countries. The Company intends to vigorously defend its patents, which it believes are valid, against infringement by companies attempting to market products prior to the expiration of such patents. As with any litigation, there can be no assurance of the outcomes, which, if adverse, could result in significantly shortened

periods of exclusivity for these products and, with respect to products acquired through acquisitions, potentially significant intangible asset impairment charges.

Bridion — As previously disclosed, between January and November 2020, the Company received multiple Paragraph IV Certification Letters under the Hatch-Waxman Act notifying the Company that generic drug companies have filed applications to the FDA seeking pre-patent expiry approval to sell generic versions of *Bridion* (sugammadex) Injection. In March, April and December 2020, the Company filed patent infringement lawsuits in the U.S. District Courts for the District of New Jersey and the Northern District of West Virginia against those generic companies. All actions in the District of New Jersey have been consolidated. These lawsuits, which assert one or more patents covering sugammadex and methods of using sugammadex, automatically stay FDA approval of the generic applications until June 2023 or until adverse court decisions, if any, whichever may occur earlier.

Mylan Pharmaceuticals Inc., Mylan API US LLC, and Mylan Inc. (Mylan) have filed motions to dismiss in the District of New Jersey for lack of venue and failure to state a claim against certain defendants, and in the Northern District of West Virginia for failure to state a claim against certain defendants. The New Jersey motion has not yet been decided, and the West Virginia action is stayed pending resolution of the New Jersey motion.

The Company has settled with four generic companies providing that these generic companies can bring their generic versions of *Bridion* to the market in January 2026 (which may be delayed by any applicable pediatric exclusivity) or earlier under certain circumstances. The Company has agreed to stay the lawsuit filed against one generic company, which in exchange agreed to be bound by a judgment on the merits of the consolidated action in the District of New Jersey. One of the generic companies in the consolidated action requested dismissal of the action against it and the Company did not oppose this request, which was subsequently granted by the court. The Company does not expect this company to bring its generic version of *Bridion* to the market before January 2026 or later, depending on any applicable pediatric exclusivity, unless the Company receives an adverse court decision.

Januvia, Janumet, Janumet XR — As previously disclosed, the FDA has granted pediatric exclusivity with respect to *Januvia*, *Janumet*, and *Janumet XR*, which provides a further six months of exclusivity in the U.S. beyond the expiration of all patents listed in the FDA's Orange Book. Adding this exclusivity to the term of the key patent protection extends exclusivity on these products to January 2023. The Company currently anticipates that sales of *Januvia* and *Janumet* in the U.S. will decline significantly after this date. However, *Januvia*, *Janumet*, and *Janumet XR* contain sitagliptin phosphate monohydrate and the Company has another patent covering certain phosphate salt and polymorphic forms of sitagliptin (2027 salt/polymorph patent), which, if determined to be valid, would preclude generic manufacturers from making sitagliptin phosphate salt and polymorphic forms until 2027 with the expiration of that patent, plus pediatric exclusivity. In 2019, Par Pharmaceutical filed suit against the Company in the U.S. District Court for the District of New Jersey, seeking a declaratory judgment of invalidity of the 2027 salt/polymorph patent. In response, the Company filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Par Pharmaceutical and additional companies that also indicated an intent to market generic versions of *Januvia*, *Janumet*, and *Janumet XR* following expiration of key patent protection, but prior to the expiration of the 2027 salt/polymorph patent, and a later granted patent owned by the Company covering the *Janumet* formulation where its term plus the pediatric exclusivity, ends in 2029. The Company also filed a patent infringement lawsuit against Mylan in the Northern District of West Virginia. The Judicial Panel on Multidistrict Litigation entered an order transferring the Company's lawsuit against Mylan to the U.S. District Court for the District of Delaware for coordinated and consolidated pretrial proceedings with the other cases pending in that district.

Prior to the beginning of the scheduled October 2021 trial in the U.S. District Court for the District of Delaware on invalidity issues, the Company settled with all defendants scheduled to participate in that trial. In the Company's case against Mylan, a bench trial was held in December 2021 in the U.S. District Court for the Northern District of West Virginia, with closing arguments scheduled for April 13, 2022.

In total, the Company has settled with 21 generic companies providing that these generic companies can bring their generic versions of *Januvia* and *Janumet* to the market in May 2026 or earlier under certain circumstances, and their generic versions of *Janumet XR* to the market in July 2026 or earlier under certain circumstances.

Additionally, in 2019, Mylan filed a petition for *Inter Partes* Review (IPR) at the U.S. Patent and Trademark Office (USPTO) seeking invalidity of some, but not all, of the claims of the 2027 salt/polymorph patent. The USPTO instituted IPR proceedings in May 2020, finding a reasonable likelihood that the challenged claims are not valid. A trial was held in February 2021 and a final decision was rendered in May 2021, holding that all of the challenged claims were not invalid. Mylan has appealed the USPTO's decision to the U.S. Court of Appeals for the Federal Circuit.

In March 2021, the Company filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Cadila Healthcare Ltd. (collectively, Zydus). In that lawsuit, the Company alleged infringement of the 2027 salt/polymorph patent based on the filing of Zydus's application seeking approval of its sitagliptin tablets. The U.S. District Court for the District of Delaware has set a three-day bench trial in this matter beginning on October 31, 2022.

In Germany, generic companies have sought the revocation of the Supplementary Protection Certificate (SPC) for *Janumet*. If the generic companies are successful, *Janumet* could lose market exclusivity in Germany at the same time as the expiry of *Januvia* pediatric market exclusivity in September 2022. A hearing was held in June 2021 and the court decided that the SPC for *Janumet* is invalid, which decision the Company has appealed. Challenges to the *Janumet* SPC have also occurred in the following European countries: Austria, Czech Republic, Finland, France, Hungary, Italy, Portugal, Romania, Slovakia, and Sweden.

Other Litigation

There are various other pending legal proceedings involving the Company, principally product liability and intellectual property lawsuits. While it is not feasible to predict the outcome of such proceedings, in the opinion of the Company, either the likelihood of loss is remote or any reasonably possible loss associated with the resolution of such proceedings is not expected to be material to the Company's financial condition, results of operations or cash flows either individually or in the aggregate.

Legal Defense Reserves

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of December 31, 2021 and 2020 of approximately $230 million and $235 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

Environmental Matters

The Company and its subsidiaries are parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund, and other federal and state equivalents. These proceedings seek to require the operators of hazardous waste disposal facilities, transporters of waste to the sites and generators of hazardous waste disposed of at the sites to clean up the sites or to reimburse the government for cleanup costs. The Company has been made a party to these proceedings as an alleged generator of waste disposed of at the sites. In each case, the government alleges that the defendants are jointly and severally liable for the cleanup costs. Although joint and several liability is alleged, these proceedings are frequently resolved so that the allocation of cleanup costs among the parties more nearly reflects the relative contributions of the parties to the site situation. The Company's potential liability varies greatly from site to site. For some sites the potential liability is *de minimis* and for others the final costs of cleanup have not yet been determined.

While it is not feasible to predict the outcome of many of these proceedings brought by federal or state agencies or private litigants, in the opinion of the Company, such proceedings should not ultimately result in any liability which

would have a material adverse effect on the financial condition, results of operations or liquidity of the Company. The Company has taken an active role in identifying and accruing for these costs and such amounts do not include any reduction for anticipated recoveries of cleanup costs from former site owners or operators or other recalcitrant potentially responsible parties.

In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $40 million and $43 million at December 31, 2021 and 2020, respectively. These liabilities are undiscounted, do not consider potential recoveries from other parties and will be paid out over the periods of remediation for the applicable sites, which are expected to occur primarily over the next 15 years. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed approximately $40 million in the aggregate. Management also does not believe that these expenditures should result in a material adverse effect on the Company's financial condition, results of operations or liquidity for any year.

12. Equity

The Merck certificate of incorporation authorizes 6,500,000,000 shares of common stock and 20,000,000 shares of preferred stock.

Capital Stock

A summary of common stock and treasury stock transactions (shares in millions) is as follows:

	2021		2020		2019	
	Common Stock	**Treasury Stock**	Common Stock	Treasury Stock	Common Stock	Treasury Stock
Balance January 1	**3,577**	**1,047**	3,577	1,038	3,577	985
Purchases of treasury stock	**—**	**11**	—	16	—	66
Issuances [(1)]	**—**	**(9)**	—	(7)	—	(13)
Balance December 31	**3,577**	**1,049**	3,577	1,047	3,577	1,038

[(1)] *Issuances primarily reflect activity under share-based compensation plans.*

13. Share-Based Compensation Plans

The Company has share-based compensation plans under which the Company grants restricted stock units (RSUs) and performance share units (PSUs) to certain management level employees. In addition, employees and non-employee directors may be granted options to purchase shares of Company common stock at the fair market value at the time of grant. These plans were approved by the Company's shareholders.

At December 31, 2021, 93 million shares collectively were authorized for future grants under the Company's share-based compensation plans. These awards are settled with treasury shares.

Employee stock options are granted to purchase shares of Company stock at the fair market value at the time of grant. These awards generally vest one-third each year over a three-year period, with a contractual term of 7-10 years. RSUs are stock awards that are granted to employees and entitle the holder to shares of common stock as the awards vest. The fair value of the stock option and RSU awards is determined and fixed on the grant date based on the Company's stock price. PSUs are stock awards where the ultimate number of shares issued will be contingent on the Company's performance against a pre-set objective or set of objectives. The fair value of each PSU is determined on the date of grant based on the Company's stock price. For RSUs and PSUs, dividends declared during the vesting period are payable to the employees only upon vesting. Over the PSU performance period, the number of shares of stock that are expected to be issued will be adjusted based on the probability of achievement of a performance target and final compensation expense will be recognized based on the ultimate number of shares issued. RSU and PSU distributions will be in shares of Company stock after the end of the vesting or performance period, subject to the terms applicable to such awards. PSU awards generally vest after three years. RSU awards generally vest one-third each year over a three-year period.

Total pretax share-based compensation cost recorded in 2021, 2020 and 2019 was $498 million, $475 million and $417 million, respectively, including $479 million, $441 million and $388 million, respectively, related to continuing operations. Income tax benefits for share-based compensation expense recognized in 2021, 2020 and 2019 were $69 million, $65 million and $57 million, respectively.

The Company uses the Black-Scholes option pricing model for determining the fair value of option grants. In applying this model, the Company uses both historical data and current market data to estimate the fair value of its options. The Black-Scholes model requires several assumptions including expected dividend yield, risk-free interest rate, volatility, and term of the options. The expected dividend yield is based on historical patterns of dividend payments. The risk-free interest rate is based on the rate at grant date of zero-coupon U.S. Treasury Notes with a term equal to the expected term of the option. Expected volatility is estimated using a blend of historical and implied volatility. The historical component is based on historical monthly price changes. The implied volatility is obtained from market data on the Company's traded options. The expected life represents the amount of time that options granted are expected to be outstanding, based on historical and forecasted exercise behavior.

The weighted average exercise price of options granted in 2021, 2020 and 2019 was $75.99, $77.67 and $80.05 per option, respectively. The weighted average fair value of options granted in 2021, 2020 and 2019 was $9.80, $9.93 and $10.63 per option, respectively, and were determined using the following assumptions:

Years Ended December 31	**2021**	2020	2019
Expected dividend yield	**3.1 %**	3.1 %	3.2 %
Risk-free interest rate	**1.0 %**	0.4 %	2.4 %
Expected volatility	**20.9 %**	22.1 %	18.7 %
Expected life (years)	**5.9**	5.8	5.9

Summarized information relative to stock option plan activity (options in thousands) is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2021 [(1)]	19,446	$ 63.64		
Granted [(1)]	**4,781**	**75.99**		
Exercised [(1)]	**(3,728)**	**54.14**		
Forfeited [(1)]	**(626)**	**73.97**		
Awards transferred to Organon in the spin-off	**(1,947)**	**72.15**		
Adjustment to Merck awards related to the spin-off of Organon [(2)]	**646**	**—**		
Outstanding December 31, 2021	**18,572**	**$ 65.27**	**6.3**	**$ 213**
Vested and expected to vest December 31, 2021	**17,829**	**$ 64.90**	**6.2**	**$ 212**
Exercisable December 31, 2021	**12,136**	**$ 60.41**	**5.0**	**$ 198**

[(1)] *Activity prior to the Organon spin-off has not been restated.*

[(2)] *In connection with the spin-off of Organon, all outstanding Merck stock options (whether vested or unvested) were converted into adjusted Merck awards for current and former Merck employees or Organon awards for Organon employees. Such adjusted awards preserved the same intrinsic value and general terms and conditions (including vesting) as were in place immediately prior to the adjustments.*

Additional information pertaining to stock option plans is provided in the table below:

Years Ended December 31	**2021**	2020	2019
Total intrinsic value of stock options exercised	**$ 106**	$ 51	$ 295
Fair value of stock options vested	**27**	25	27
Cash received from the exercise of stock options	**202**	89	361

A summary of nonvested RSU and PSU activity (shares in thousands) is as follows:

	RSUs		PSUs	
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested January 1, 2021 [1]	11,915	$ 74.17	2,100	$ 75.08
Granted [1]	**7,897**	**76.16**	**1,487**	**69.33**
Vested [1]	**(6,066)**	**70.25**	**(1,284)**	**57.14**
Forfeited [1]	**(1,015)**	**76.62**	**(149)**	**79.33**
Awards transferred to Organon in the spin-off	**(1,309)**	**76.99**	**(248)**	**77.39**
Adjustment to Merck awards related to the spin-off of Organon [2]	**368**	**—**	**60**	**—**
Nonvested December 31, 2021	**11,790**	**$ 74.88**	**1,966**	**$ 77.13**
Expected to vest December 31, 2021	**10,499**	**$ 74.93**	**1,832**	**$ 77.40**

[1] *Activity prior to the Organon spin-off has not been restated.*

[2] *In connection with the spin-off of Organon, all outstanding Merck RSUs and PSUs (whether vested or unvested) were converted into adjusted Merck awards for current and former Merck employees or Organon awards for Organon employees. Such adjusted awards preserved the same intrinsic value and general terms and conditions (including vesting) as were in place immediately prior to the adjustments.*

At December 31, 2021, there was $699 million of total pretax unrecognized compensation expense related to nonvested stock options, RSU and PSU awards which will be recognized over a weighted average period of 1.9 years. For segment reporting, share-based compensation costs are unallocated expenses.

14. Pension and Other Postretirement Benefit Plans

The Company has defined benefit pension plans covering eligible employees in the U.S. and in certain of its international subsidiaries. In addition, the Company provides medical benefits, principally to its eligible U.S. retirees and their dependents, through its other postretirement benefit plans. The Company uses December 31 as the year-end measurement date for all of its pension plans and other postretirement benefit plans.

Net Periodic Benefit Cost

The net periodic benefit cost (credit) for pension and other postretirement benefit plans (including certain costs reported as part of discontinued operations) consisted of the following components:

	Pension Benefits								
	U.S.			International			Other Postretirement Benefits		
Years Ended December 31	**2021**	2020	2019	**2021**	2020	2019	**2021**	2020	2019
Service cost	**$ 403**	$ 360	$ 293	**$ 328**	$ 297	$ 235	**$ 48**	$ 52	$ 48
Interest cost	**404**	431	458	**123**	136	176	**45**	57	69
Expected return on plan assets	**(755)**	(774)	(817)	**(416)**	(414)	(425)	**(79)**	(75)	(72)
Amortization of unrecognized prior service cost	**(38)**	(49)	(49)	**(16)**	(18)	(12)	**(63)**	(73)	(78)
Net loss (gain) amortization	**298**	303	151	**142**	127	64	**(42)**	(18)	(10)
Termination benefits	**56**	10	31	**5**	3	8	**37**	2	5
Curtailments	**16**	10	14	**(26)**	—	6	**(29)**	(4)	(11)
Settlements	**216**	13	—	**8**	15	1	**—**	—	—
Net periodic benefit cost (credit)	**$ 600**	$ 304	$ 81	**$ 148**	$ 146	$ 53	**$ (83)**	$ (59)	$ (49)

Net periodic benefit cost (credit) for pension and other postretirement benefit plans in 2021 includes expenses for curtailments, settlements and termination benefits provided to certain employees in connection with the spin-off of Organon.

In connection with restructuring actions (see Note 6), termination charges were recorded in 2021, 2020 and 2019 on pension and other postretirement benefit plans related to expanded eligibility for certain employees exiting Merck. Also, in connection with these restructuring activities, curtailments and settlements were recorded on

certain pension plans. An increase in lump sum payments to U.S. pension plan participants also contributed to the settlements recorded during 2021.

The components of net periodic benefit cost (credit) other than the service cost component are included in *Other (income) expense, net* (see Note 15), with the exception of certain amounts for termination benefits, curtailments and settlements, which are recorded in *Restructuring costs* if the event giving rise to the termination benefits, curtailment or settlement is related to restructuring actions or in *Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests* if related to the spin-off of Organon (each as noted above).

Obligations and Funded Status

Summarized information about the changes in plan assets and benefit obligations, the funded status and the amounts recorded at December 31 is as follows:

	Pension Benefits				Other Postretirement Benefits	
	U.S.		International			
	2021	2020	**2021**	2020	**2021**	2020
Fair value of plan assets January 1	**$ 12,672**	$ 11,361	**$ 12,009**	$ 10,135	**$ 1,221**	$ 1,102
Actual return on plan assets	**1,250**	1,908	**891**	1,026	**118**	175
Company contributions	**305**	199	**189**	383	**33**	19
Effects of exchange rate changes	**—**	—	**(671)**	743	**—**	—
Benefits paid	**(219)**	(751)	**(233)**	(214)	**(86)**	(93)
Settlements	**(941)**	(45)	**(55)**	(117)	**—**	—
Spin-off of Organon	**—**	—	**(55)**	—	**—**	—
Other	**—**	—	**120**	53	**6**	18
Fair value of plan assets December 31	**$ 13,067**	$ 12,672	**$ 12,195**	$ 12,009	**$ 1,292**	$ 1,221
Benefit obligation January 1	**$ 14,613**	$ 13,003	**$ 12,458**	$ 10,558	**$ 1,607**	$ 1,673
Service cost	**403**	360	**328**	297	**48**	52
Interest cost	**404**	431	**123**	136	**45**	57
Actuarial (gains) losses [(1)]	**(332)**	1,594	**(240)**	1,032	**(103)**	(98)
Benefits paid	**(219)**	(751)	**(233)**	(214)	**(86)**	(93)
Effects of exchange rate changes	**—**	—	**(678)**	788	**(1)**	(3)
Plan amendments	**—**	—	**4**	(64)	**—**	—
Curtailments	**15**	11	**(38)**	(8)	**(12)**	(1)
Termination benefits	**56**	10	**5**	3	**37**	2
Settlements	**(941)**	(45)	**(55)**	(117)	**—**	—
Spin-off of Organon	**—**	—	**(118)**	—	**—**	—
Other	**—**	—	**19**	47	**6**	18
Benefit obligation December 31	**$ 13,999**	$ 14,613	**$ 11,575**	$ 12,458	**$ 1,541**	$ 1,607
Funded status December 31	**$ (932)**	$ (1,941)	**$ 620**	$ (449)	**$ (249)**	$ (386)
Recognized as:						
Other Assets	**$ 9**	$ —	**$ 1,395**	$ 941	**$ —**	$ —
Accrued and other current liabilities	**(64)**	(82)	**(22)**	(13)	**(8)**	(9)
Other Noncurrent Liabilities	**(877)**	(1,859)	**(753)**	(1,377)	**(241)**	(377)

[(1)] *Actuarial (gains) losses primarily reflect changes in discount rates.*

At December 31, 2021 and 2020, the accumulated benefit obligation was $24.9 billion and $26.3 billion, respectively, for all pension plans, of which $13.8 billion and $14.4 billion, respectively, related to U.S. pension plans.

Information related to the funded status of selected pension plans at December 31 is as follows:

	U.S.		International	
	2021	2020	**2021**	2020
Pension plans with a projected benefit obligation in excess of plan assets				
Projected benefit obligation	**$ 13,013**	$ 14,613	**$ 2,507**	$ 8,875
Fair value of plan assets	**12,072**	12,672	**1,731**	7,488
Pension plans with an accumulated benefit obligation in excess of plan assets				
Accumulated benefit obligation	**$ 12,916**	$ 13,489	**$ 2,462**	$ 4,234
Fair value of plan assets	**12,072**	11,685	**1,723**	2,995

Plan Assets

Entities are required to use a fair value hierarchy which maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest:

Level 1 — Quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 — Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity. The Level 3 assets are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as instruments for which the determination of fair value requires significant judgment or estimation. At December 31, 2021 and 2020, $943 million and $942 million, respectively, or approximately 4% of the Company's pension investments were categorized as Level 3 assets.

If the inputs used to measure the financial assets fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

The fair values of the Company's pension plan assets at December 31 by asset category are as follows:

	Fair Value Measurements Using					Fair Value Measurements Using				
	Level 1	**Level 2**	**Level 3**	**NAV [1]**	**Total**	Level 1	Level 2	Level 3	NAV [1]	Total
	2021					2020				
U.S. Pension Plans										
Cash and cash equivalents	**$ 3**	**$ —**	**$ —**	**$ 289**	**$ 292**	$ 5	$ —	$ —	$ 303	$ 308
Investment funds										
Developed markets equities	**236**	**—**	**—**	**3,799**	**4,035**	206	—	—	3,884	4,090
Emerging markets equities	**—**	**—**	**—**	**919**	**919**	169	—	—	927	1,096
Mortgage and asset-backed securities	**—**	**—**	**—**	**—**	**—**	—	89	—	—	89
Equity securities										
Developed markets	**2,915**	**—**	**—**	**—**	**2,915**	2,819	—	—	—	2,819
Fixed income securities										
Government and agency obligations	**—**	**2,870**	**—**	**—**	**2,870**	—	2,236	—	—	2,236
Corporate obligations	**—**	**2,005**	**—**	**—**	**2,005**	—	1,994	—	—	1,994
Mortgage and asset-backed securities	**—**	**23**	**—**	**—**	**23**	—	33	—	—	33
Other investments	**2**	**—**	**6**	**—**	**8**	—	—	7	—	7
Plan assets at fair value	**$ 3,156**	**$ 4,898**	**$ 6**	**$ 5,007**	**$ 13,067**	$ 3,199	$ 4,352	$ 7	$ 5,114	$ 12,672
International Pension Plans										
Cash and cash equivalents	**$ 82**	**$ 10**	**$ —**	**$ 18**	**$ 110**	$ 110	$ 1	$ —	$ 20	$ 131
Investment funds										
Developed markets equities	**531**	**4,292**	**—**	**121**	**4,944**	475	4,286	—	118	4,879
Government and agency obligations	**240**	**4,025**	**—**	**171**	**4,436**	1,516	2,614	—	172	4,302
Emerging markets equities	**137**	**—**	**—**	**72**	**209**	154	—	—	92	246
Corporate obligations	**9**	**8**	**—**	**171**	**188**	5	12	—	172	189
Other fixed income obligations	**15**	**8**	**—**	**3**	**26**	9	11	—	4	24
Real estate	**—**	**1**	**—**	**16**	**17**	—	1	—	15	16
Equity securities										
Developed markets	**369**	**—**	**—**	**—**	**369**	505	—	—	—	505
Fixed income securities										
Government and agency obligations	**3**	**591**	**—**	**3**	**597**	3	481	—	3	487
Corporate obligations	**—**	**223**	**—**	**2**	**225**	1	174	—	2	177
Mortgage and asset-backed securities	**—**	**90**	**—**	**—**	**90**	—	70	—	—	70
Other investments										
Insurance contracts [2]	**—**	**44**	**937**	**1**	**982**	—	42	935	1	978
Other	**1**	**1**	**—**	**—**	**2**	1	4	—	—	5
Plan assets at fair value	**$ 1,387**	**$ 9,293**	**$ 937**	**$ 578**	**$ 12,195**	$ 2,779	$ 7,696	$ 935	$ 599	$ 12,009

[1] *Certain investments that were measured at net asset value (NAV) per share or its equivalent have not been classified in the fair value hierarchy. The NAV amounts presented in this table are intended to permit reconciliation of the fair value hierarchy to the fair value of plan assets at December 31, 2021 and 2020.*

[2] *The plans' Level 3 investments in insurance contracts are generally valued using a crediting rate that approximates market returns and invest in underlying securities whose market values are unobservable and determined using pricing models, discounted cash flow methodologies, or similar techniques.*

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The table below provides a summary of the changes in fair value, including transfers in and/or out, of all financial assets measured at fair value using significant unobservable inputs (Level 3) for the Company's pension plan assets:

	2021				2020			
	Insurance Contracts	**Real Estate**	**Other**	**Total**	Insurance Contracts	Real Estate	Other	Total
U.S. Pension Plans								
Balance January 1	**$ —**	**$ —**	**$ 7**	**$ 7**	$ —	$ —	$ 9	$ 9
Actual return on plan assets:								
Relating to assets still held at December 31	**—**	**—**	**(5)**	**(5)**	—	—	(5)	(5)
Relating to assets sold during the year	**—**	**—**	**7**	**7**	—	—	5	5
Purchases and sales, net	**—**	**—**	**(3)**	**(3)**	—	—	(2)	(2)
Balance December 31	**$ —**	**$ —**	**$ 6**	**$ 6**	$ —	$ —	$ 7	$ 7
International Pension Plans								
Balance January 1	**$ 935**	**$ —**	**$ —**	**$ 935**	$ 851	$ —	$ —	$ 851
Actual return on plan assets:								
Relating to assets still held at December 31	**(34)**	**—**	**—**	**(34)**	103	—		103
Purchases and sales, net	**(42)**	**—**	**—**	**(42)**	(17)	—	—	(17)
Transfers in (out) of Level 3	**78**	**—**	**—**	**78**	(2)	—	—	(2)
Balance December 31	**$ 937**	**$ —**	**$ —**	**$ 937**	$ 935	$ —	$ —	$ 935

The fair values of the Company's other postretirement benefit plan assets at December 31 by asset category are as follows:

	Fair Value Measurements Using					Fair Value Measurements Using				
	Level 1	**Level 2**	**Level 3**	**NAV [1]**	**Total**	Level 1	Level 2	Level 3	NAV [1]	Total
	2021					2020				
Cash and cash equivalents	**$ 11**	**$ —**	**$ —**	**$ 28**	**$ 39**	$ 31	$ —	$ —	$ 28	$ 59
Investment funds										
Developed markets equities	**24**	**—**	**—**	**378**	**402**	19	—	—	355	374
Emerging markets equities	**—**	**—**	**—**	**92**	**92**	16	—	—	85	101
Government and agency obligations	**1**	**—**	**—**		**1**	1	—	—	—	1
Mortgage and asset-backed securities	**—**	**—**	**—**	**—**	**—**	—	8	—	—	8
Equity securities										—
Developed markets	**290**	**—**	**—**	**—**	**290**	258	—	—	—	258
Fixed income securities										
Government and agency obligations	**—**	**275**	**—**	**—**	**275**	—	221	—	—	221
Corporate obligations	**—**	**191**	**—**	**—**	**191**	—	196	—	—	196
Mortgage and asset-backed securities	**—**	**2**	**—**	**—**	**2**	—	3	—	—	3
Plan assets at fair value	**$ 326**	**$ 468**	**$ —**	**$ 498**	**$ 1,292**	$ 325	$ 428	$ —	$ 468	$ 1,221

[1] *Certain investments that were measured at net asset value (NAV) per share or its equivalent have not been classified in the fair value hierarchy. The NAV amounts presented in this table are intended to permit reconciliation of the fair value hierarchy to the fair value of plan assets at December 31, 2021 and 2020.*

The Company has established investment guidelines for its U.S. pension and other postretirement plans to create an asset allocation that is expected to deliver a rate of return sufficient to meet the long-term obligation of each plan, given an acceptable level of risk. The target investment portfolio of the Company's U.S. pension and other postretirement benefit plans is allocated 30% to 45% in U.S. equities, 15% to 30% in international equities, 35% to 45% in fixed-income investments, and up to 5% in cash and other investments. The portfolio's equity weighting is consistent with the long-term nature of the plans' benefit obligations. The expected annual standard deviation of returns of the target portfolio, which approximates 11%, reflects both the equity allocation and the diversification benefits among the asset classes in which the portfolio invests. For international pension plans, the

targeted investment portfolio varies based on the duration of pension liabilities and local government rules and regulations. Although a significant percentage of plan assets are invested in U.S. equities, concentration risk is mitigated through the use of strategies that are diversified within management guidelines.

Expected Contributions

Contributions during 2022 are expected to be approximately $280 million for U.S. pension plans, approximately $150 million for international pension plans and approximately $50 million for other postretirement benefit plans.

Expected Benefit Payments

Expected benefit payments are as follows:

	U.S. Pension Benefits	International Pension Benefits	Other Postretirement Benefits
2022	$ 724	$ 289	$ 84
2023	745	275	85
2024	731	278	87
2025	748	280	89
2026	770	308	90
2027 — 2031	4,230	1,715	469

Expected benefit payments are based on the same assumptions used to measure the benefit obligations and include estimated future employee service.

Amounts Recognized in Other Comprehensive Income

Net loss amounts reflect differences between expected and actual returns on plan assets as well as the effects of changes in actuarial assumptions. Net loss amounts in excess of certain thresholds are amortized into net periodic benefit cost over the average remaining service life of employees. The following amounts were reflected as components of *OCI*:

	Pension Plans								
	U.S.			International			Other Postretirement Benefit Plans		
Years Ended December 31	**2021**	2020	2019	**2021**	2020	2019	**2021**	2020	2019
Net gain (loss) arising during the period	**$ 1,048**	$ (448)	$ (816)	**$ 815**	$ (407)	$ (227)	**$ 144**	$ 198	$ 112
Prior service (cost) credit arising during the period	**(3)**	(1)	(4)	**(29)**	62	(1)	**(17)**	(3)	(11)
	$ 1,045	$ (449)	$ (820)	**$ 786**	$ (345)	$ (228)	**$ 127**	$ 195	$ 101
Net loss (gain) amortization included in benefit cost	**$ 298**	$ 303	$ 151	**$ 142**	$ 127	$ 64	**$ (42)**	$ (18)	$ (10)
Prior service credit amortization included in benefit cost	**(38)**	(49)	(49)	**(16)**	(18)	(12)	**(63)**	(73)	(78)
	$ 260	$ 254	$ 102	**$ 126**	$ 109	$ 52	**$ (105)**	$ (91)	$ (88)

Actuarial Assumptions

The Company reassesses its benefit plan assumptions on a regular basis. The weighted average assumptions used in determining U.S. pension and other postretirement benefit plan and international pension plan information are as follows:

	U.S. Pension and Other Postretirement Benefit Plans			International Pension Plans		
December 31	**2021**	2020	2019	**2021**	2020	2019
Net periodic benefit cost						
Discount rate	**2.70 %**	3.40 %	4.40 %	**1.10 %**	1.50 %	2.20 %
Expected rate of return on plan assets	**6.70 %**	7.30 %	8.10 %	**3.80 %**	4.40 %	4.90 %
Salary growth rate	**4.60 %**	4.20 %	4.30 %	**2.80 %**	2.80 %	2.80 %
Interest crediting rate	**4.70 %**	4.90 %	3.40 %	**3.00 %**	2.80 %	2.90 %
Benefit obligation						
Discount rate	**3.00 %**	2.70 %	3.40 %	**1.50 %**	1.10 %	1.50 %
Salary growth rate	**4.60 %**	4.60 %	4.20 %	**2.90 %**	2.80 %	2.80 %
Interest crediting rate	**5.00 %**	4.70 %	4.90 %	**3.00 %**	3.00 %	2.80 %

For both the pension and other postretirement benefit plans, the discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due. The expected rate of return for both the pension and other postretirement benefit plans represents the average rate of return to be earned on plan assets over the period the benefits included in the benefit obligation are to be paid and is determined on a plan basis. The expected rate of return for each plan is developed considering long-term historical returns data, current market conditions, and actual returns on the plan assets. Using this reference information, the long-term return expectations for each asset category and a weighted-average expected return for each plan's target portfolio is developed according to the allocation among those investment categories. The expected portfolio performance reflects the contribution of active management as appropriate. For 2022, the expected rate of return for the Company's U.S. pension and other postretirement benefit plans will be 6.70%, as compared to a range of 6.50% to 6.70% in 2021.

The health care cost trend rate assumptions for other postretirement benefit plans are as follows:

December 31	**2021**	2020
Health care cost trend rate assumed for next year	**6.4 %**	6.6 %
Rate to which the cost trend rate is assumed to decline	**4.5 %**	4.5 %
Year that the trend rate reaches the ultimate trend rate	**2032**	2032

Savings Plans

The Company also maintains defined contribution savings plans in the U.S. The Company matches a percentage of each employee's contributions consistent with the provisions of the plan for which the employee is eligible. Total employer contributions to these plans in 2021, 2020 and 2019 were $158 million, $158 million and $143 million, respectively.

15. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

Years Ended December 31	**2021**	2020	2019
Interest income	**$ (36)**	$ (59)	$ (274)
Interest expense	**806**	831	893
Exchange losses	**297**	145	187
Income from investments in equity securities, net [(1)]	**(1,940)**	(1,338)	(170)
Net periodic defined benefit plan (credit) cost other than service cost	**(212)**	(339)	(545)
Other, net	**(256)**	(130)	38
	$ (1,341)	$ (890)	$ 129

[(1)] *Includes net realized and unrealized gains and losses from investments in equity securities either owned directly or through ownership interests in investment funds. Unrealized gains and losses from investments that are directly owned are determined at the end of the reporting period, while gains and losses from ownership interests in investment funds are accounted for on a one quarter lag. The Company estimates losses of approximately $500 million will be recorded in the first quarter of 2022 from ownership interests in investment funds.*

Other, net (as presented in the table above) in 2019 includes $162 million of goodwill impairment charges related to certain businesses in the Healthcare Services segment, which were fully divested by the first quarter of 2020.

Interest paid was $779 million in 2021, $822 million in 2020 and $841 million in 2019.

16. Taxes on Income

A reconciliation between the effective tax rate for income from continuing operations and the U.S. statutory rate is as follows:

	2021		2020		2019	
	Amount	**Tax Rate**	Amount	Tax Rate	Amount	Tax Rate
U.S. statutory rate applied to income from continuing operations before taxes	**$ 2,915**	**21.0 %**	$ 1,231	21.0 %	$ 1,506	21.0 %
Differential arising from:						
Foreign earnings	**(1,446)**	**(10.4)**	(965)	(16.5)	(461)	(6.4)
GILTI and the foreign-derived intangible income deduction	**(75)**	**(0.5)**	349	6.0	323	4.5
Tax settlements	**(275)**	**(2.0)**	(13)	(0.2)	(139)	(1.9)
R&D tax credit	**(81)**	**(0.6)**	(108)	(1.8)	(116)	(1.6)
Acquisition of VelosBio	**(9)**	**(0.1)**	559	9.5	—	—
Acquisition of Pandion	**356**	**2.6**	—	—	—	—
Valuation allowances	**102**	**0.7**	37	0.6	115	1.6
Restructuring	**61**	**0.4**	105	1.8	39	0.5
Acquisition-related costs, including amortization	**8**	**0.1**	38	0.6	70	1.0
State taxes	**2**	**—**	57	1.0	(12)	(0.2)
Acquisition of OncoImmune	**—**	**—**	97	1.7	—	—
Acquisition of Peloton	**—**	**—**	—	—	209	2.9
Tax Cuts and Jobs Act of 2017	**—**	**—**	—	—	117	1.6
Other	**(37)**	**(0.2)**	(47)	(0.8)	(86)	(1.2)
	$ 1,521	**11.0 %**	$ 1,340	22.9 %	$ 1,565	21.8 %

The Tax Cuts and Jobs Act (TCJA) was enacted in December 2017 and the Company reflected the impact of the TCJA in its 2017 financial statements. However, since application of certain provisions of the TCJA

remained subject to further interpretation, in certain instances the Company made reasonable estimates of the effects of the TCJA, which were since finalized and resulted in additional income tax expense in 2018 and 2019. The Company's remaining transition tax liability under the TCJA, which has been reduced by payments and the utilization of foreign tax credits, was $2.6 billion at December 31, 2021, of which $390 million is included in *Income taxes payable* and the remainder of $2.2 billion is included in *Other Noncurrent Liabilities*. As a result of the transition tax under the TCJA, the Company is no longer indefinitely reinvested with respect to its undistributed earnings from foreign subsidiaries and has provided a deferred tax liability for foreign withholding taxes that would apply. The Company remains indefinitely reinvested with respect to its financial statement basis in excess of tax basis of its foreign subsidiaries. A determination of the deferred tax liability with respect to this basis difference is not practicable.

The foreign earnings tax rate differentials in the tax rate reconciliation above primarily reflect the impacts of operations in jurisdictions with different tax rates than the U.S., particularly Ireland and Switzerland, as well as Singapore and Puerto Rico which operate under tax incentive grants (which begin to expire in 2022), thereby yielding a favorable impact on the effective tax rate compared with the U.S. statutory rate of 21%. Beginning in 2021, the Company has an additional tax incentive in the form of a tax holiday in Switzerland for a newly active legal entity which is effective through 2030.

Income from continuing operations before taxes consisted of:

Years Ended December 31	**2021**	2020	2019
Domestic	**$ 1,854**	$ (3,814)	$ (66)
Foreign	**12,025**	9,677	7,237
	$ 13,879	$ 5,863	$ 7,171

Taxes on income from continuing operations consisted of:

Years Ended December 31	**2021**	2020	2019
Current provision			
Federal	**$ 74**	$ 893	$ 642
Foreign	**1,273**	969	1,523
State	**(13)**	44	(40)
	1,334	1,906	2,125
Deferred provision			
Federal	**240**	(605)	(328)
Foreign	**(77)**	64	(228)
State	**24**	(25)	(4)
	187	(566)	(560)
	$ 1,521	$ 1,340	$ 1,565

Deferred income taxes at December 31 consisted of:

	2021		2020	
	Assets	**Liabilities**	Assets	Liabilities
Product intangibles and licenses	**$ —**	**$ 2,933**	$ 109	$ 1,250
Inventory related	**119**	**370**	43	315
Accelerated depreciation	**—**	**589**	—	587
Equity investments	**—**	**335**	—	175
Pensions and other postretirement benefits	**487**	**338**	826	248
Compensation related	**301**	**—**	235	—
Unrecognized tax benefits	**75**	**—**	117	—
Net operating losses and other tax credit carryforwards	**867**	**—**	764	—
Other	**434**	**180**	743	81
Subtotal	**2,283**	**4,745**	2,837	2,656
Valuation allowance	**(287)**		(404)	
Total deferred taxes	**$ 1,996**	**$ 4,745**	$ 2,433	$ 2,656
Net deferred income taxes		**$ 2,749**		$ 223
Recognized as:				
Other Assets	**$ 692**		$ 782	
Deferred Income Taxes		**$ 3,441**		$ 1,005

The Company has net operating loss (NOL) carryforwards in several jurisdictions. As of December 31, 2021, $181 million of deferred tax assets on NOL carryforwards relate to foreign jurisdictions. Valuation allowances of $164 million have been established on these foreign NOL carryforwards and other foreign deferred tax assets. In addition, the Company has $686 million of deferred tax assets relating to various U.S. tax credit carryforwards and NOL carryforwards. Valuation allowances of $123 million have been established on these U.S. tax credit carryforwards and NOL carryforwards.

Income taxes paid in 2021, 2020 and 2019 (including amounts attributable to discontinued operations) were $2.4 billion, $2.7 billion and $4.5 billion, respectively. Tax benefits relating to stock option exercises were $21 million in 2021, $12 million in 2020 and $65 million in 2019.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	2021	2020	2019
Balance January 1	**$ 1,537**	$ 1,225	$ 1,893
Additions related to current year positions	**306**	298	199
Additions related to prior year positions	**63**	110	46
Reductions for tax positions of prior years [(1)]	**(230)**	(4)	(454)
Settlements [(1)]	**(46)**	(70)	(356)
Lapse of statute of limitations [(2)]	**(58)**	(22)	(103)
Spin-off of Organon	**(43)**	—	—
Balance December 31	**$ 1,529**	$ 1,537	$ 1,225

[(1)] *Amounts in 2021 and 2019 reflect settlements with the IRS discussed below.*

[(2)] *Amount in 2019 includes $78 million related to the divestiture of Merck's Consumer Care business in 2014.*

If the Company were to recognize the unrecognized tax benefits of $1.5 billion at December 31, 2021, the income tax provision would reflect a favorable net impact of $1.5 billion.

The Company is under examination by numerous tax authorities in various jurisdictions globally. The Company believes that it is reasonably possible that the total amount of unrecognized tax benefits as of

December 31, 2021 could decrease by up to approximately $11 million in the next 12 months as a result of various audit closures, settlements or the expiration of the statute of limitations. The ultimate finalization of the Company's

examinations with relevant taxing authorities can include formal administrative and legal proceedings, which could have a significant impact on the timing of the reversal of unrecognized tax benefits. The Company believes that its reserves for uncertain tax positions are adequate to cover existing risks or exposures.

Interest and penalties associated with uncertain tax positions amounted to a (benefit) expense of $(37) million in 2021, $16 million in 2020 and $(53) million in 2019. These amounts reflect the beneficial impacts of various tax settlements, including the settlements discussed below. Liabilities for accrued interest and penalties were $192 million and $205 million as of December 31, 2021 and 2020, respectively.

In 2021, the Internal Revenue Service (IRS) concluded its examinations of Merck's 2015-2016 U.S. federal income tax returns. As a result, the Company was required to make a payment of $190 million (of which $172 million related to continuing operations and $18 million related to discontinued operations). The Company's reserves for unrecognized tax benefits for the years under examination exceeded the adjustments relating to this examination period and therefore the Company recorded a $236 million net tax benefit in 2021 (of which $207 million related to continuing operations and $29 million related to discontinued operations). This net benefit reflects reductions in reserves for unrecognized tax benefits and other related liabilities for tax positions relating to the years that were under examination.

In 2019, the IRS concluded its examinations of Merck's 2012-2014 U.S. federal income tax returns. As a result, the Company was required to make a payment of $107 million (of which $142 million related to discontinued operations with an offsetting credit of $35 million related to continuing operations). The Company's reserves for unrecognized tax benefits for the years under examination exceeded the adjustments relating to this examination period and therefore the Company recorded a $364 million net tax benefit in 2019 (of which $106 million related to continuing operations and $258 million related to discontinued operations). This net benefit reflects reductions in reserves for unrecognized tax benefits for tax positions relating to the years that were under examination, partially offset by additional reserves for tax positions not previously reserved for.

The IRS is currently conducting examinations of the Company's tax returns for the years 2017 and 2018. In addition, various state and foreign tax examinations are in progress and for these jurisdictions, the Company's income tax returns are open for examination for the period 2003 through 2021.

17. Earnings per Share

The calculations of earnings per share (shares in millions) are as follows:

Years Ended December 31	**2021**	2020	2019
Net Income from Continuing Operations Attributable to Merck & Co., Inc.	**$ 12,345**	$ 4,519	$ 5,690
Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests	**704**	2,548	4,153
Net income attributable to Merck & Co., Inc.	**$ 13,049**	$ 7,067	$ 9,843
Average common shares outstanding	**2,530**	2,530	2,565
Common shares issuable [(1)]	**8**	11	15
Average common shares outstanding assuming dilution	**2,538**	2,541	2,580
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders:			
Income from Continuing Operations	**$ 4.88**	$ 1.79	$ 2.22
Income from Discontinued Operations	**0.28**	1.01	1.62
Net Income	**$ 5.16**	$ 2.79	$ 3.84
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders:			
Income from Continuing Operations	**$ 4.86**	$ 1.78	$ 2.21
Income from Discontinued Operations	**0.28**	1.00	1.61
Net Income	**$ 5.14**	$ 2.78	$ 3.81

(1) *Issuable primarily under share-based compensation plans.*

In 2021, 2020 and 2019, 9 million, 5 million and 2 million, respectively, of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

18. Other Comprehensive Income (Loss)

Changes in each component of other comprehensive income (loss) are as follows:

	Derivatives	Investments	Employee Benefit Plans	Foreign Currency Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance January 1, 2019, net of taxes	$ 166	$ (78)	$ (3,556)	$ (2,077)	$ (5,545)
Other comprehensive income (loss) before reclassification adjustments, pretax	86	140	(948)	112	(610)
Tax	(15)	—	192	(16)	161
Other comprehensive income (loss) before reclassification adjustments, net of taxes	71	140	(756)	96	(449)
Reclassification adjustments, pretax	(261) [(1)]	(44) [(2)]	66 [(3)]	—	(239)
Tax	55	—	(15)	—	40
Reclassification adjustments, net of taxes	(206)	(44)	51	—	(199)
Other comprehensive income (loss), net of taxes	(135)	96	(705)	96	(648)
Balance at December 31, 2019, net of taxes	31	18	(4,261)	(1,981)	(6,193)
Other comprehensive income (loss) before reclassification adjustments, pretax	(383)	3	(599)	64	(915)
Tax	84	—	111	89	284
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(299)	3	(488)	153	(631)
Reclassification adjustments, pretax	2 [(1)]	(21) [(2)]	272 [(3)]	—	253
Tax	—	—	(63)	—	(63)
Reclassification adjustments, net of taxes	2	(21)	209	—	190
Other comprehensive income (loss), net of taxes	(297)	(18)	(279)	153	(441)
Balance at December 31, 2020, net of taxes	(266)	—	(4,540) [(4)]	(1,828)	(6,634)
Other comprehensive income (loss) before reclassification adjustments, pretax	**333**	**—**	**1,922**	**(304)**	**1,951**
Tax	**(75)**	**—**	**(374)**	**(119)**	**(568)**
Other comprehensive income (loss) before reclassification adjustments, net of taxes	**258**	**—**	**1,548**	**(423)**	**1,383**
Reclassification adjustments, pretax	**192** [(1)]	**—**	**281** [(3)]	**—**	**473**
Tax	**(40)**	**—**	**(60)**	**—**	**(100)**
Reclassification adjustments, net of taxes	**152**	**—**	**221**	**—**	**373**
Other comprehensive income (loss), net of taxes	**410**	**—**	**1,769**	**(423)**	**1,756**
Spin-off of Organon (see Note 3)	**—**	**—**	**28**	**421**	**449**
Balance at December 31, 2021, net of taxes	**$ 144**	**$ —**	**$ (2,743)** [(4)]	**$ (1,830)**	**$ (4,429)**

[(1)] *Primarily relates to foreign currency cash flow hedges that were reclassified from* AOCL *to* Sales.

[(2)] *Represents net realized gains on the sales of available-for-sale debt securities that were reclassified from* AOCL *to* Other (income) expense, net.

[(3)] *Includes net amortization of prior service cost and actuarial gains and losses included in net periodic benefit cost (see Note 14).*

[4] *Includes pension plan net loss of $3.6 billion and $5.4 billion at December 31, 2021 and 2020, respectively, and other postretirement benefit plan net gain of $473 million and $391 million at December 31, 2021 and 2020, respectively, as well as pension plan prior service credit of $190 million and $255 million at December 31, 2021 and 2020, respectively, and other postretirement benefit plan prior service credit of $181 million and $244 million at December 31, 2021 and 2020, respectively.*

19. Segment Reporting

The Company's operations are principally managed on a products basis and include two operating segments, which are the Pharmaceutical and Animal Health segments, both of which are reportable segments.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. A large component of pediatric and adolescent vaccine sales are made to the U.S. Centers for Disease Control and Prevention Vaccines for Children program, which is funded by the U.S. government. Additionally, the Company sells vaccines to the Federal government for placement into vaccine stockpiles.

The Animal Health segment discovers, develops, manufactures and markets a wide range of veterinary pharmaceutical and vaccine products, as well as health management solutions and services, for the prevention, treatment and control of disease in all major livestock and companion animal species. The Company also offers an extensive suite of digitally connected identification, traceability and monitoring products. The Company sells its products to veterinarians, distributors and animal producers.

Beginning in 2021, the amortization of intangible assets previously included as part of the calculation of segment profits is now included in unallocated non-segment corporate expenses. Prior period Pharmaceutical and Animal Health segment profits have been recast to reflect this change on a comparable basis.

The Company previously had a Healthcare Services segment that provided services and solutions focused on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company divested the remaining businesses in this segment during the first quarter of 2020.

Sales of the Company's products were as follows:

Years Ended December 31	**2021**			2020			2019		
	U.S.	**Int'l**	**Total**	U.S.	Int'l	Total	U.S.	Int'l	Total
Pharmaceutical:									
Oncology									
Keytruda	**$ 9,765**	**$ 7,421**	**$ 17,186**	$ 8,352	$ 6,028	$ 14,380	$ 6,305	$ 4,779	$ 11,084
Alliance revenue - Lynparza [(1)]	**515**	**473**	**989**	417	308	725	269	176	444
Alliance revenue - Lenvima [(1)]	**417**	**287**	**704**	359	220	580	239	165	404
Vaccines									
Gardasil/Gardasil 9	**1,881**	**3,792**	**5,673**	1,755	2,184	3,938	1,831	1,905	3,737
ProQuad/M-M-R II/Varivax	**1,629**	**506**	**2,135**	1,378	500	1,878	1,683	592	2,275
Pneumovax 23	**547**	**346**	**893**	727	359	1,087	679	247	926
RotaTeq	**473**	**334**	**807**	486	311	797	506	284	791
Vaqta	**100**	**79**	**179**	103	67	170	130	108	238
Hospital Acute Care									
Bridion	**762**	**770**	**1,532**	583	615	1,198	533	598	1,131
Prevymis	**153**	**218**	**370**	119	162	281	84	81	165
Primaxin	**2**	**258**	**259**	2	248	251	2	271	273
Noxafil	**60**	**199**	**259**	42	287	329	282	380	662
Cancidas	**4**	**208**	**212**	7	207	213	6	242	249
Invanz	**(5)**	**207**	**202**	9	202	211	30	233	263
Zerbaxa	**4**	**(5)**	**(1)**	74	56	130	63	58	121
Immunology									
Simponi	**—**	**825**	**825**	—	838	838	—	830	830
Remicade	**—**	**299**	**299**	—	330	330	—	411	411
Neuroscience									
Belsomra	**78**	**241**	**318**	81	247	327	92	214	306
Virology									
Molnupiravir	**632**	**320**	**952**	—	—	—	—	—	—
Isentress/Isentress HD	**294**	**474**	**769**	326	531	857	398	576	975
Cardiovascular									
Alliance revenue - Adempas/Verquvo [(2)]	**312**	**30**	**342**	259	22	281	194	10	204
Adempas	**—**	**252**	**252**	—	220	220	—	215	215
Diabetes									
Januvia	**1,404**	**1,920**	**3,324**	1,470	1,836	3,306	1,724	1,758	3,482
Janumet	**367**	**1,597**	**1,964**	477	1,494	1,971	589	1,452	2,041
Other pharmaceutical [(3)]	**1,007**	**1,302**	**2,310**	984	1,328	2,312	1,215	1,661	2,873
Total Pharmaceutical segment sales	**20,401**	**22,353**	**42,754**	18,010	18,600	36,610	16,854	17,246	34,100
Animal Health:									
Livestock	**667**	**2,628**	**3,295**	612	2,327	2,939	582	2,201	2,784
Companion Animals	**1,091**	**1,182**	**2,273**	872	892	1,764	724	885	1,609
Total Animal Health segment sales	**1,758**	**3,810**	**5,568**	1,484	3,219	4,703	1,306	3,086	4,393
Other segment sales [(4)]	**—**	**—**	**—**	23	—	23	174	1	175
Total segment sales	**22,159**	**26,163**	**48,322**	19,517	21,819	41,336	18,334	20,333	38,668
Other [(5)]	**266**	**116**	**382**	71	111	182	86	368	453
	$ 22,425	**$ 26,279**	**$ 48,704**	$ 19,588	$ 21,930	$ 41,518	$ 18,420	$ 20,701	$ 39,121

U.S. plus international may not equal total due to rounding.

(1) *Alliance revenue represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs (see Note 5).*

(2) *Alliance revenue represents Merck's share of profits from sales in Bayer's marketing territories, which are product sales net of cost of sales and commercialization costs (see Note 5).*

(3) *Other pharmaceutical primarily reflects sales of other human health pharmaceutical products, including products within the franchises not listed separately.*

[4] *Represents sales for the Healthcare Services segment. All the businesses in the Healthcare Services segment were fully divested by the first quarter of 2020.*

[5] *Other is primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, as well as third-party manufacturing sales (including sales to Organon). Other for 2021 also includes $185 million related to the achievement of milestones for an out-licensed product that triggered contingent payments to Merck.*

Consolidated sales by geographic area where derived are as follows:

Years Ended December 31	**2021**	2020	2019
United States	**$ 22,425**	$ 19,588	$ 18,420
Europe, Middle East and Africa	**13,341**	11,547	10,496
China	**4,378**	2,751	2,180
Japan	**2,726**	2,602	2,609
Asia Pacific (other than China and Japan)	**2,407**	2,113	2,126
Latin America	**2,206**	1,890	2,015
Other	**1,221**	1,027	1,275
	$ 48,704	$ 41,518	$ 39,121

A reconciliation of segment profits to *Income from Continuing Operations Before Taxes* is as follows:

Years Ended December 31	**2021**	2020	2019
Segment profits:			
Pharmaceutical segment	**$ 30,977**	$ 26,106	$ 23,448
Animal Health segment	**1,950**	1,669	1,612
Other segments	**—**	1	(7)
Total segment profits	**32,927**	27,776	25,053
Other profits	**156**	75	295
Unallocated:			
Interest income	**36**	59	274
Interest expense	**(806)**	(831)	(893)
Amortization	**(1,636)**	(1,817)	(1,695)
Depreciation	**(1,414)**	(1,519)	(1,491)
Research and development	**(11,692)**	(12,911)	(9,351)
Restructuring costs	**(661)**	(575)	(626)
Other unallocated, net	**(3,031)**	(4,394)	(4,395)
	$ 13,879	$ 5,863	$ 7,171

Pharmaceutical segment profits are comprised of segment sales less standard costs, as well as selling, general and administrative expenses directly incurred by the segment. Animal Health segment profits are comprised of segment sales, less all cost of sales, as well as selling, general and administrative expenses and research and development costs directly incurred by the segment. For internal management reporting presented to the chief operating decision maker, Merck does not allocate the remaining cost of sales not included in segment profits as described above, research and development expenses incurred in Merck Research Laboratories, the Company's research and development division that focuses on human health-related activities, or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. In addition, costs related to restructuring activities, as well as the amortization of intangible assets and purchase accounting adjustments are not allocated to segments.

Other profits are primarily comprised of miscellaneous corporate profits, as well as operating profits related to third-party manufacturing sales.

Other unallocated, net, includes expenses from corporate and manufacturing cost centers, goodwill and other intangible asset impairment charges, gains or losses on sales of businesses, expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration, and other miscellaneous income or expense items.

Equity loss from affiliates and depreciation included in segment profits is as follows:

	Pharmaceutical	Animal Health	All Other	Total
Year Ended December 31, 2021				
Included in segment profits:				
Equity loss from affiliates	**$ 11**	**$ —**	**$ —**	**$ 11**
Depreciation	**6**	**158**	**—**	**164**
Year Ended December 31, 2020				
Included in segment profits:				
Equity loss from affiliates	$ 6	$ —	$ —	$ 6
Depreciation	6	143	1	150
Year Ended December 31, 2019				
Included in segment profits:				
Equity loss from affiliates	$ —	$ —	$ —	$ —
Depreciation	9	105	10	124

Property, plant and equipment, net, by geographic area where located is as follows:

December 31	**2021**	2020	2019
United States	**$ 11,759**	$ 10,394	$ 8,963
Europe, Middle East and Africa	**6,081**	5,314	4,129
Asia Pacific (other than China and Japan)	**857**	737	692
China	**220**	216	174
Latin America	**199**	169	180
Japan	**159**	166	152
Other	**4**	4	7
	$ 19,279	$ 17,000	$ 14,297

The Company does not disaggregate assets on a products and services basis for internal management reporting and, therefore, such information is not presented.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Merck & Co., Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheet of Merck & Co., Inc. and its subsidiaries (the "Company") as of December 31, 2021 and 2020, and the related consolidated statements of income, of comprehensive income, of equity and of cash flows for each of the three years in the period ended December 31, 2021, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

U.S. Rebate Accruals - Medicaid, Managed Care and Medicare Part D

As described in Note 2 to the consolidated financial statements, the Company records certain variable consideration including discounts, which are estimated at the time of sale generally using the expected value method. Amounts accrued for aggregate customer discounts are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal and state agencies, and other customers to the amounts accrued. Certain of these discounts representing a portion of the accrual take the form of rebates, which are amounts owed based upon definitive contractual agreements or legal requirements with private sector (Managed Care) and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product to a benefit plan participant. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. Management uses historical customer segment utilization mix, sales forecasts, changes to product mix and price, inventory levels in the distribution channel, government pricing calculations and prior payment history in order to estimate the expected provision. The accrued balance relative to the provision for rebates included in accrued and other current liabilities was $2.6 billion as of December 31, 2021, of which the majority relates to U.S. rebate accruals – Medicaid, Managed Care and Medicare Part D.

The principal considerations for our determination that performing procedures relating to U.S. rebate accruals - Medicaid, Managed Care, and Medicare Part D is a critical audit matter are the significant judgment by management due to the significant measurement uncertainty involved in developing the rebate accruals, as the accruals are based on assumptions developed using pricing information and historical customer segment utilization mix, and a high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating evidence related to these assumptions.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to U.S. rebate accruals - Medicaid, Managed Care, and Medicare Part D, including management's controls over the assumptions used to estimate the corresponding rebate accruals. These procedures also included, among others (i) developing an independent estimate of the rebate accruals by utilizing third party data on historical customer segment utilization mix in the U.S., pricing information, the terms of the specific rebate programs, and the historical trend of actual rebate claims paid, (ii) comparing the independent estimate to the rebate accruals recorded by management, and (iii) testing rebate claims paid, including evaluating those claims for consistency with the contractual terms of the Company's rebate agreements.

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PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 25, 2022

We have served as the Company's auditor since 2002.

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(b) Supplementary Data

Selected Quarterly Financial Data (Unaudited)

($ in millions except per share amounts)	4th Q [1]	3rd Q [2]	2nd Q [3]	1st Q
2021[4]				
Sales	**$ 13,521**	**$ 13,154**	**$ 11,402**	**$ 10,627**
Gross Profit	**9,648**	**9,704**	**8,298**	**7,428**
Net Income from Continuing Operations Attributable to Merck & Co., Inc.	**3,820**	**4,567**	**1,213**	**2,745**
(Loss) Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests	**(62)**	**—**	**332**	**434**
Net Income Attributable to Merck & Co., Inc.	**3,758**	**4,567**	**1,545**	**3,179**
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders				
Income from Continuing Operations	**$ 1.51**	**$ 1.81**	**$ 0.48**	**$ 1.08**
(Loss) Income from Discontinued Operations	**(0.02)**	**—**	**0.13**	**0.17**
Net Income	**$ 1.49**	**$ 1.81**	**$ 0.61**	**$ 1.26**
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders				
Income from Continuing Operations	**$ 1.51**	**$ 1.80**	**$ 0.48**	**$ 1.08**
(Loss) Income from Discontinued Operations	**(0.02)**	**—**	**0.13**	**0.17**
Net Income	**$ 1.48**	**$ 1.80**	**$ 0.61**	**$ 1.25**
2020 [4]				
Sales	$ 10,948	$ 10,929	$ 9,353	$ 10,288
Gross Profit	5,919	7,916	6,606	7,459
Net (Loss) Income from Continuing Operations Attributable to Merck & Co., Inc.	(2,617)	2,324	2,341	2,471
Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests	523	617	661	748
Net (Loss) Income Attributable to Merck & Co., Inc.	(2,094)	2,941	3,002	3,219
Basic (Loss) Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders				
(Loss) Income from Continuing Operations	$ (1.03)	$ 0.92	$ 0.93	$ 0.98
Income from Discontinued Operations	0.21	0.24	0.26	0.30
Net (Loss) Income	$ (0.83)	$ 1.16	$ 1.19	$ 1.27
(Loss) Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders				
(Loss) Income from Continuing Operations	$ (1.03)	$ 0.92	$ 0.92	$ 0.97
Income from Discontinued Operations	0.21	0.24	0.26	0.29
Net (Loss) Income	$ (0.83)	$ 1.16	$ 1.18	$ 1.26

[1] *Amounts in the fourth quarter of 2020 include charges related to the acquisitions of VelosBio Inc. and OncoImmune (see Note 4) and an intangible asset impairment charge related to* Zerbaxa *(see Note 9).*

[2] *Amounts in the third quarter of 2020 include charges related to transactions with Seagen Inc (see Note 4).*

[3] *Amounts in the second quarter of 2021 include a charge related to the acquisition of Pandion Therapeutics, Inc. (see Note 4).*

[4] *Reflects the results of the businesses that were spun-off to Organon on June 2, 2021 as discontinued operations for all periods presented (see Note 3).*

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures. Based on their evaluation, as of the end of the period covered by this Form 10-K, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Act)) are effective. For the fourth quarter of 2021, there have been no changes in internal control over financial reporting that materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Act. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control — Integrated Framework* issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2021. PricewaterhouseCoopers LLP, an independent registered public accounting firm, has performed its own assessment of the effectiveness of the Company's internal control over financial reporting and its attestation report is included in this Form 10-K filing.

Management's Report

Management's Responsibility for Financial Statements

Responsibility for the integrity and objectivity of the Company's financial statements rests with management. The financial statements report on management's stewardship of Company assets. These statements are prepared in conformity with generally accepted accounting principles and, accordingly, include amounts that are based on management's best estimates and judgments. Nonfinancial information included in the Annual Report on Form 10-K has also been prepared by management and is consistent with the financial statements.

To assure that financial information is reliable and assets are safeguarded, management maintains an effective system of internal controls and procedures, important elements of which include: careful selection, training and development of operating and financial managers; an organization that provides appropriate division of responsibility; and communications aimed at assuring that Company policies and procedures are understood throughout the organization. A staff of internal auditors regularly monitors the adequacy and application of internal controls on a worldwide basis.

To ensure that personnel continue to understand the system of internal controls and procedures, and policies concerning good and prudent business practices, annually all employees of the Company are required to complete Code of Conduct training. This training reinforces the importance and understanding of internal controls by reviewing key corporate policies, procedures and systems. In addition, the Company has compliance programs, including an ethical business practices program to reinforce the Company's long-standing commitment to high ethical standards in the conduct of its business.

The financial statements and other financial information included in the Annual Report on Form 10-K fairly present, in all material respects, the Company's financial condition, results of operations and cash flows. Our formal certification to the Securities and Exchange Commission is included in this Form 10-K filing.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control — Integrated*

Framework issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2021.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2021, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

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Robert M. Davis
Chief Executive Officer and President

Caroline Litchfield
Executive Vice President and Chief Financial Officer

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The required information on directors and nominees is incorporated by reference from the discussion under Proposal 1. Election of Directors of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2022. Information on executive officers is set forth in Part I of this document on page 44.

The required information on compliance with Section 16(a) of the Securities Exchange Act of 1934, if applicable, is incorporated by reference from the discussion under the heading "Stock Ownership Information" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2022.

The Company has a Code of Conduct — *Our Values and Standards* applicable to all employees, including the principal executive officer, principal financial officer, principal accounting officer and Controller. The Code of Conduct is available on the Company's website at merck.com/company-overview/culture-and-values/code-of-conduct/values-and-standards. The Company intends to disclose future amendments to certain provisions of the Code of Conduct, and waivers of the Code of Conduct granted to executive officers and directors, if any, on the website within four business days following the date of any amendment or waiver. Every Merck employee is responsible for adhering to business practices that are in accordance with the law and with ethical principles that reflect the highest standards of corporate and individual behavior.

The required information on the identification of the audit committee and the audit committee financial expert is incorporated by reference from the discussion under the heading "Board Meetings and Committees" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2022.

Item 11. Executive Compensation.

The information required on executive compensation is incorporated by reference from the discussion under the headings "Compensation Discussion and Analysis," "Summary Compensation Table," "All Other Compensation" table, "Grants of Plan-Based Awards" table, "Outstanding Equity Awards" table, "Option Exercises and Stock Vested" table, "Pension Benefits" table, "Nonqualified Deferred Compensation" table, and "Potential Payments Upon Termination or a Change in Control", including the discussion under the subheadings "Separation" and "Change in Control," as well as all footnote information to the various tables, of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2022.

The required information on director compensation is incorporated by reference from the discussion under the heading "Director Compensation" and related "2021 Schedule of Director Fees" table and "2021 Director Compensation" table of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2022.

The required information under the headings "Compensation and Management Development Committee Interlocks and Insider Participation" and "Compensation and Management Development Committee Report" is incorporated by reference from the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2022.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information with respect to security ownership of certain beneficial owners and management is incorporated by reference from the discussion under the heading "Stock Ownership Information" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2022.

Equity Compensation Plan Information

The following table summarizes information about the options, warrants and rights and other equity compensation under the Company's equity compensation plans as of the close of business on December 31, 2021. The table does not include information about tax qualified plans such as the Merck U.S. Savings Plan.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders[1]	18,572,010[2]	$ 65.27	92,994,903
Equity compensation plans not approved by security holders	—	—	—
Total	18,572,010	$ 65.27	92,994,903

[1] *Includes options to purchase shares of Company Common Stock and other rights under the following shareholder-approved plans: the Merck & Co., Inc. 2010 and 2019 Incentive Stock Plans, and the Merck & Co., Inc. 2010 Non-Employee Directors Stock Option Plan.*

[2] *Excludes approximately 11,790,206 shares of restricted stock units and 1,965,983 performance share units (assuming maximum payouts) under the Merck Sharp & Dohme 2010 and 2019 Incentive Stock Plans. Also excludes 193,107 shares of phantom stock deferred under the MSD Employee Deferral Program and 468,633 shares of phantom stock deferred under the Merck & Co., Inc. Plan for Deferred Payment of Directors' Compensation.*

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The required information on transactions with related persons is incorporated by reference from the discussion under the heading "Related Person Transactions" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2022.

The required information on director independence is incorporated by reference from the discussion under the heading "Independence of Directors" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2022.

Item 14. Principal Accountant Fees and Services.

The information required for this item is incorporated by reference from the discussion under Proposal 3. Ratification of Appointment of Independent Registered Public Accounting Firm for 2022 beginning with the caption "Pre-Approval Policy for Services of Independent Registered Public Accounting Firm" through "Fees for Services Provided by the Independent Registered Public Accounting Firm" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2022.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this Form 10-K

1. Financial Statements

Consolidated statement of income for the years ended December 31, 2021, 2020 and 2019

Consolidated statement of comprehensive income for the years ended December 31, 2021, 2020 and 2019

Consolidated balance sheet as of December 31, 2021 and 2020

Consolidated statement of equity for the years ended December 31, 2021, 2020 and 2019

Consolidated statement of cash flows for the years ended December 31, 2021, 2020 and 2019

Notes to consolidated financial statements

Report of PricewaterhouseCoopers LLP, independent registered public accounting firm (PCAOB ID 238)

2. Financial Statement Schedules

Schedules are omitted because they are either not required or not applicable.

Financial statements of affiliates carried on the equity basis have been omitted because, considered individually or in the aggregate, such affiliates do not constitute a significant subsidiary.

3. Exhibits

Exhibit Number		Description
3.1	—	Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) — Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
3.2	—	By-Laws of Merck & Co., Inc. (effective July 22, 2015) — Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed July 28, 2015 (No. 1-6571)
4.1	—	Indenture, dated as of April 1, 1991, between Merck Sharp & Dohme Corp. (f/k/a Schering Corporation) and U.S. Bank Trust National Association (as successor to Morgan Guaranty Trust Company of New York), as Trustee (the 1991 Indenture) — Incorporated by reference to Exhibit 4 to MSD's Registration Statement on Form S-3 (No. 33-39349)
4.2	—	First Supplemental Indenture to the 1991 Indenture, dated as of October 1, 1997 — Incorporated by reference to Exhibit 4(b) to MSD's Registration Statement on Form S-3 filed September 25, 1997 (No. 333-36383)
4.3	—	Second Supplemental Indenture to the 1991 Indenture, dated November 3, 2009 — Incorporated by reference to Exhibit 4.3 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No.1-6571)
4.4	—	Third Supplemental Indenture to the 1991 Indenture, dated May 1, 2012 — Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the period ended March 31, 2012 (No. 1-6571)
4.5	—	Indenture, dated November 26, 2003, between Merck & Co., Inc. (f/k/a Schering-Plough Corporation) and The Bank of New York as Trustee (the 2003 Indenture) — Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed November 28, 2003 (No. 1-6571)
4.6	—	Second Supplemental Indenture to the 2003 Indenture (including Form of Note), dated November 26, 2003 — Incorporated by reference to Exhibit 4.3 to Schering-Plough's Current Report on Form 8-K filed November 28, 2003 (No. 1-6571)
4.7	—	Third Supplemental Indenture to the 2003 Indenture (including Form of Note), dated September 17, 2007 — Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed September 17, 2007 (No. 1-6571)
4.8	—	Fifth Supplemental Indenture to the 2003 Indenture, dated November 3, 2009 — Incorporated by reference to Exhibit 4.4 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
4.9	—	Indenture, dated as of January 6, 2010, between Merck & Co., Inc. and U.S. Bank Trust National Association, as Trustee — Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed December 10, 2010 (No. 1-6571)
4.10	—	Description of the Registrant's Common Stock - Incorporated by reference to Exhibit 4.10 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2020 filed February 25, 2021 (No. 1-6571)
4.11	—	Description of the Registrant's 1.125% Notes due 2021, 1.875% Notes due 2026, and 2.500% Notes due 2034 - Incorporated by reference to Exhibit 4.11 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2020 filed February 25, 2021 (No. 1-6571)
4.12	—	Description of the Registrant's 0.500% Notes due 2024 and 1.375% Notes due 2036 - Incorporated by reference to Exhibit 4.12 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2020 filed February 25, 2021 (No. 1-6571)

Exhibit Number		Description
*10.1	—	Merck & Co., Inc. Executive Incentive Plan (as amended and restated effective June 1, 2015) — Incorporated by reference to Merck & Co., Inc.'s Schedule 14A filed April 13, 2015 (No. 1-6571)
*10.2	—	Merck & Co., Inc. Deferral Program Including the Base Salary Deferral Plan (Amended and Restated effective December 1, 2019) - Incorporated by reference to Exhibit 10.2 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2019 filed February 26, 2020 (No. 1-6571)
*10.3	—	Merck & Co., Inc. 2010 Incentive Stock Plan (as amended and restated June 1, 2015) — Incorporated by reference to Merck & Co., Inc.'s Schedule 14A filed April 13, 2015 (No. 1-6571)
*10.4	—	Form of stock option terms for 2011 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.2 to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the period ended March 31, 2011 filed May 9, 2011 (No. 1-6571)
*10.5	—	Form of stock option terms for 2012 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.20 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2011 filed February 28, 2012 (No. 1-6571)
*10.6	—	Form of stock option terms for 2013 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.19 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2012 filed February 28, 2013 (No. 1-6571)
*10.7	—	Form of stock option terms for 2014 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.18 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2014 filed February 27, 2015 (No. 1-6571)
*10.8	—	Form of stock option terms for 2015 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.20 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2015 filed February 26, 2016 (No. 1-6571)
*10.9	—	Form of stock option terms for 2018 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by referent to Exhibit 10.12 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2017 filed February 27, 2018 (No. 1-6571)
*10.10	—	Form of stock option terms for 2016 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.19 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2016 filed February 28, 2017 (No. 1-6571)
*10.11	—	Form of restricted stock unit terms for 2018 quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.17 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2017 filed on February 28, 2018 (No. 1-6571)
*10.12	—	2018 Performance Share Unit Award Terms under the Merck & Co., Inc. 2010 Stock Incentive Plan — Incorporated by reference to Exhibit 10 to Merck & Co., Inc.'s Current Report on Form 10-Q Quarterly Report for the period ended March 31, 2018 filed May 8, 2018 (No. 1-6571)

Exhibit Number		Description
*10.13	—	Merck & Co., Inc. 2019 Incentive Stock Plan - Incorporated by reference to Appendix C to Merck & Co., Inc.'s Schedule 14A filed April 8, 2019 (No. 1-6571)
*10.14	—	Merck & Co., Inc. Change in Control Separation Benefits Plan (effective as amended and restated, as of January 1, 2013) — Incorporated by reference to Exhibit 10.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 29, 2012 (No. 1-6571)
*10.15	—	Merck & Co., Inc. U.S. Separation Benefits Plan (amended and restated as of January 1, 2019) - Incorporated by reference to Exhibit 10.19 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2018 filed February 27, 2019 (No. 1-6571)
*10.16	—	Retirement Plan for the Directors of Merck & Co., Inc. (amended and restated June 21, 1996) — Incorporated by reference to Exhibit 10.C to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1996 filed August 13, 1996 (No. 1-3305)
*10.17	—	Merck & Co., Inc. Plan for Deferred Payment of Directors' Compensation (Amended and Restated effective as of January 1, 2022)
10.18	—	Distribution agreement between Schering-Plough and Centocor, Inc., dated April 3, 1998 — Incorporated by reference to Exhibit 10(u) to Schering-Plough's Amended 10-K for the year ended December 31, 2003 filed May 3, 2004 (No. 1-6571)†
10.19	—	Amendment Agreement to the Distribution Agreement between Centocor, Inc., CAN Development, LLC, and Schering-Plough (Ireland) Company — Incorporated by reference to Exhibit 10.1 to Schering-Plough's Current Report on Form 8-K filed December 21, 2007 (No. 1-6571)†
10.20	—	Severance Agreement and General Release between Merck & Co., Inc. and Adam H. Schechter, dated December 1, 2018 - Incorporated by reference to Exhibit 10.27 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2018 filed February 27, 2019 (No. 1-6571)
10.21	—	Offer Letter between Merck & Co., Inc. and Jennifer Zachary, dated March 16, 2018 - Incorporated by reference to Exhibit 10.28 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2018 filed February 27, 2019 (No. 1-6571)
*10.22	—	Form of stock option terms for 2021 annual non-qualified option grants under the Merck & Co., Inc. 2019 Incentive Stock Plan - Incorporated by reference to Exhibit 10.23 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2020 filed February 25, 2021 (No. 1-6571)
*10.23	—	Form of restricted stock unit terms for 2021 annual grants under the Merck & Co., Inc. 2019 Incentive Stock Plan - Incorporated by reference to Exhibit 10.24 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2020 filed February 25, 2021 (No. 1-6571)
*10.24	—	Form of stock option terms for 2022 annual non-qualified option grants under the Merck & Co., Inc. 2019 Incentive Stock Plan
*10.25	—	Form of restricted stock unit terms for 2022 annual grants under the Merck & Co., Inc. 2019 Incentive Stock Plan
21	—	Subsidiaries of Merck & Co., Inc.
23	—	Consent of Independent Registered Public Accounting Firm
24.1	—	Power of Attorney
24.2	—	Certified Resolution of Board of Directors

31.1	—	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
31.2	—	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer
32.1	—	Section 1350 Certification of Chief Executive Officer
32.2	—	Section 1350 Certification of Chief Financial Officer

Exhibit Number		Description
101.INS	—	XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	—	XBRL Taxonomy Extension Schema Document.
101.CAL	—	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	—	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	—	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	—	XBRL Taxonomy Extension Presentation Linkbase Document.
104	—	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* *Management contract or compensatory plan or arrangement.*

† *Certain portions of the exhibit have been omitted pursuant to a request for confidential treatment. The non-public information has been filed separately with the Securities and Exchange Commission pursuant to rule 24b-2 under the Securities Exchange Act of 1934, as amended.*

Long-term debt instruments under which the total amount of securities authorized does not exceed 10% of Merck & Co., Inc.'s total consolidated assets are not filed as exhibits to this report. Merck & Co., Inc. will furnish a copy of these agreements to the Securities and Exchange Commission on request.

Item 16. Form 10-K Summary

Not applicable.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: February 25, 2022

MERCK & CO., INC.

By: ROBERT M. DAVIS
(Chief Executive Officer and Pr

By: /s/ JENNIFER ZACHA
Jennifer Zachary
(Attorney-in-Fact)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signatures	Title	Date
ROBERT M. DAVIS	Chief Executive Officer and President; Principal Executive Officer; Director	February 25, 2022
CAROLINE LITCHFIELD	Executive Vice President and Chief Financial Officer; Principal Financial Officer	February 25, 2022
RITA A. KARACHUN	Senior Vice President Finance-Global Controller; Principal Accounting Officer	February 25, 2022
KENNETH C. FRAZIER	Executive Chairman and Director	February 25, 2022
MARY ELLEN COE	Director	February 25, 2022
PAMELA J. CRAIG	Director	February 25, 2022
THOMAS H. GLOCER	Director	February 25, 2022
RISA J. LAVIZZO-MOUREY	Director	February 25, 2022
STEPHEN L. MAYO	Director	February 25, 2022
PAUL B. ROTHMAN	Director	February 25, 2022
PATRICIA F. RUSSO	Director	February 25, 2022
CHRISTINE E. SEIDMAN	Director	February 25, 2022
INGE G. THULIN	Director	February 25, 2022
KATHY J. WARDEN	Director	February 25, 2022
PETER C. WENDELL	Director	February 25, 2022

Jennifer Zachary, by signing her name hereto, does hereby sign this document pursuant to powers of attorney duly executed by the persons named, filed with the Securities and Exchange Commission as an exhibit to this document, on behalf of such persons, all in the capacities and on the date stated, such persons including a majority of the directors of the Company.

By: /S/ JENNIFER ZACHARY
Jennifer Zachary
(Attorney-in-Fact)

As filed with the Securities and Exchange Commission on February 25, 2021

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549

FORM 10-K

(MARK ONE)

☒ **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the Fiscal Year Ended December 31, 2020

OR

☐ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the transition period from _____ to _____

Commission File No. 1-6571

Merck & Co., Inc.

2000 Galloping Hill Road
Kenilworth New Jersey 07033

(908) 740-4000

New Jersey	**22-1918501**
(State or other jurisdiction of incorporation)	(I.R.S Employer Identification No.)

Securities Registered pursuant to Section 12(b) of the Act:

Title of Each Class	*Trading Symbol(s)*	*Name of Each Exchange on which Registered*
Common Stock ($0.50 par value)	MRK	New York Stock Exchange
1.125% Notes due 2021	MRK/21	New York Stock Exchange
0.500% Notes due 2024	MRK 24	New York Stock Exchange
1.875% Notes due 2026	MRK/26	New York Stock Exchange
2.500% Notes due 2034	MRK/34	New York Stock Exchange
1.375% Notes due 2036	MRK 36A	New York Stock Exchange

Number of shares of Common Stock ($0.50 par value) outstanding as of January 31, 2021: 2,530,315,668.

Aggregate market value of Common Stock ($0.50 par value) held by non-affiliates on June 30, 2020 based on closing price on June 30, 2020: $195,461,000,000.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. **Yes** ☒ **No** ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. **Yes** ☐ **No** ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. **Yes** ☒ **No** ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). **Yes** ☒ **No** ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check One):

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). **Yes** ☐ **No** ☒

Documents Incorporated by Reference:

Document	*Part of Form 10-K*
Proxy Statement for the Annual Meeting of Shareholders to be held May 25, 2021, to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this report	Part III

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PART I

Item 1. Business.

Merck & Co., Inc. (Merck or the Company) is a global health care company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies and animal health products. The Company's operations are principally managed on a products basis and include two operating segments, which are the Pharmaceutical and Animal Health segments, both of which are reportable segments.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities.

The Animal Health segment discovers, develops, manufactures and markets a wide range of veterinary pharmaceutical and vaccine products, as well as health management solutions and services, for the prevention, treatment and control of disease in all major livestock and companion animal species. The Company also offers an extensive suite of digitally connected identification, traceability and monitoring products. The Company sells its products to veterinarians, distributors and animal producers.

The Company previously had a Healthcare Services segment that provided services and solutions focused on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company divested the remaining businesses in this segment in the first quarter of 2020.

The Company previously had an Alliances segment that primarily included activity from the Company's relationship with AstraZeneca LP related to sales of Nexium and Prilosec, which concluded in 2018.

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Planned Spin-Off of Women's Health, Biosimilars and Established Brands into a New Company

In February 2020, Merck announced its intention to spin-off (the Spin-Off) products from its women's health, biosimilars and established brands businesses into a new, independent, publicly traded company named Organon & Co. (Organon) through a distribution of Organon's publicly traded stock to Company shareholders. The distribution is expected to qualify as tax-free to the Company and its shareholders for U.S. federal income tax purposes. The established brands included in the transaction consist of dermatology, non-opioid pain management, respiratory, and select cardiovascular products including *Zetia* (ezetimibe) and *Vytorin* (ezetimibe/simvastatin), as well as the rest of Merck's diversified brands franchise. Merck's existing research pipeline programs will continue to be owned and developed within Merck as planned. Organon will have development capabilities initially focused on late-stage development and life-cycle management, and is expected over time to develop research capabilities in selected therapeutic areas. The Spin-Off is expected to be completed late in the second quarter of 2021, subject to market and certain other conditions. See "Risk Factors - Risks Related to the Proposed Spin-Off of Organon."

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Product Sales

Total Company sales, including sales of the Company's top pharmaceutical products, as well as sales of animal health products, were as follows:

($ in millions)	**2020**	2019	2018
Total Sales	**$ 47,994**	$ 46,840	$ 42,294
Pharmaceutical	**43,021**	41,751	37,689
Keytruda	**14,380**	11,084	7,171
Januvia/Janumet	**5,276**	5,524	5,914
Gardasil/Gardasil 9	**3,938**	3,737	3,151
ProQuad/M-M-R II/*Varivax*	**1,878**	2,275	1,798
Bridion	**1,198**	1,131	917
Pneumovax 23	**1,087**	926	907
Isentress/Isentress HD	**857**	975	1,140
Simponi	**838**	830	893
RotaTeq	**797**	791	728
Alliance revenue - Lynparza[(1)]	**725**	444	187
Implanon/Nexplanon	**680**	787	703
Zetia/Vytorin	**664**	874	1,355
Alliance revenue - Lenvima[(1)]	**580**	404	149
Animal Health	**4,703**	4,393	4,212
Livestock	**2,939**	2,784	2,630
Companion Animals	**1,764**	1,609	1,582
Other Revenues[(2)]	**270**	696	393

[(1)] *Alliance revenue represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs.*

[(2)] *Other revenues are primarily comprised of third-party manufacturing sales and miscellaneous corporate revenues, including revenue hedging activities.*

Pharmaceutical

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. Certain of the products within the Company's franchises are as follows:

Oncology

Keytruda (pembrolizumab), the Company's anti-PD-1 (programmed death receptor-1) therapy, as monotherapy for the treatment of certain patients with cervical cancer, classical Hodgkin Lymphoma (cHL), cutaneous squamous cell carcinoma (cSCC), esophageal cancer, gastric or gastroesophageal junction adenocarcinoma, head and neck squamous cell carcinoma (HNSCC), hepatocellular carcinoma (HCC), non-small-cell lung cancer (NSCLC), small-cell lung cancer (SCLC), melanoma, Merkel cell carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer, including MSI-H/dMMR colorectal cancer, primary mediastinal large B-cell lymphoma (PMBCL), tumor mutational burden-high (TMB-H) cancer, and urothelial carcinoma, including non-muscle invasive bladder cancer. *Keytruda* is also approved for the treatment of certain patients in combination with chemotherapy for metastatic squamous and non-squamous NSCLC, in combination with chemotherapy for HNSCC, in combination with chemotherapy for triple-negative breast cancer, in combination with axitinib for renal cell carcinoma, and in combination with lenvatinib for endometrial carcinoma; and *Emend* (aprepitant) for the prevention of certain chemotherapy-induced nausea and vomiting. In addition, the Company recognizes alliance revenue related to sales of Lynparza (olaparib), an oral poly (ADP-ribose) polymerase (PARP) inhibitor, for certain types of advanced ovarian, breast, pancreatic, and prostate cancers; and Lenvima (lenvatinib) for certain types of thyroid cancer, hepatocellular carcinoma, in combination with everolimus

for certain patients with renal cell carcinoma, and in combination with *Keytruda* for certain patients with endometrial carcinoma.

Vaccines

Gardasil (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant)/*Gardasil* 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), vaccines to help prevent certain diseases

caused by certain types of human papillomavirus (HPV); *ProQuad* (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella; *M−M−R* II (Measles, Mumps and Rubella Virus Vaccine Live), a vaccine to help prevent measles, mumps and rubella; *Varivax* (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox (varicella); *Pneumovax* 23 (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease; *RotaTeq* (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children; and *Vaqta* (hepatitis A vaccine, inactivated) indicated for the prevention of disease caused by hepatitis A virus in persons 12 months of age and older.

Hospital Acute Care

Bridion (sugammadex) Injection, a medication for the reversal of two types of neuromuscular blocking agents used during surgery; *Noxafil* (posaconazole), an antifungal agent for the prevention of certain invasive fungal infections; *Prevymis* (letermovir) for the prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant; *Primaxin* (imipenem and cilastatin) for injection, an antibiotic for the treatment of certain bacterial infections; *Cancidas* (caspofungin acetate) for injection, an anti-fungal agent for the treatment of certain fungal infections; *Invanz* (ertapenem) for injection, an antibiotic for the treatment of certain bacterial infections; *Cubicin* (daptomycin for injection), an antibiotic for the treatment of certain bacterial infections; and *Zerbaxa* (ceftolozane and tazobactam) for injection, a combination antibacterial and beta-lactamase inhibitor for the treatment of certain bacterial infections.

Immunology

Simponi (golimumab), a once-monthly subcutaneous treatment for certain inflammatory diseases; and *Remicade* (infliximab), a treatment for inflammatory diseases, both of which the Company markets in Europe, Russia and Turkey.

Neuroscience

Belsomra (suvorexant), an orexin receptor antagonist indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

Virology

Isentress/Isentress HD (raltegravir), an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection; and *Zepatier* (elbasvir and grazoprevir) for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype (GT) 1 or GT4 infection, with ribavirin in certain patient populations.

Cardiovascular

Zetia (ezetimibe) (marketed as *Ezetrol* in most countries outside the United States); *Vytorin* (ezetimibe/simvastatin) (marketed as *Inegy* outside the United States); *Atozet* (ezetimibe and atorvastatin) (marketed outside of the United States) and *Rosuzet* (ezetimibe and rosuvastatin) (marketed outside of the United States), cholesterol modifying medicines; and Adempas (riociguat), a cardiovascular drug for the treatment of pulmonary arterial hypertension.

Diabetes

Januvia (sitagliptin) and *Janumet* (sitagliptin/metformin HCl) for the treatment of type 2 diabetes.

Women's Health

Implanon (etonogestrel implant), a single-rod subdermal contraceptive implant/*Nexplanon* (etonogestrel implant), a single, radiopaque, rod-shaped subdermal contraceptive implant; and *NuvaRing* (etonogestrel/ethinyl estradiol vaginal ring), a vaginal contraceptive product.

Animal Health

The Animal Health segment discovers, develops, manufactures and markets a wide range of veterinary pharmaceuticals, vaccines and health management solutions and services, as well as an extensive suite of digitally connected identification, traceability and monitoring products. Principal products in this segment include:

Livestock Products

Nuflor (Florfenicol) antibiotic range for use in cattle and swine; *Bovilis*/*Vista* vaccine lines for infectious diseases in cattle; *Banamine* (Flunixin meglumine) bovine and swine anti-inflammatory; *Estrumate* (cloprostenol

sodium) for the treatment of fertility disorders in cattle; *Matrix* (altrenogest) fertility management for swine; *Resflor* (florfenicol and flunixin meglumine), a combination broad-spectrum antibiotic and non-steroidal anti-inflammatory

drug for bovine respiratory disease; *Zuprevo* (Tildipirosin) for bovine respiratory disease; *Zilmax* (zilpaterol hydrochloride) and *Revalor* (trenbolone acetate and estradiol) to improve production efficiencies in beef cattle; *Safe-Guard* (fenbendazole) de-wormer for cattle; *M+Pac* (Mycoplasma Hyopneumoniae Bacterin) swine pneumonia vaccine; *Porcilis* (Lawsonia intracellularis baterin) and *Circumvent* (Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector) vaccine lines for infectious diseases in swine; *Nobilis*/*Innovax* (Live Marek's Disease Vector), vaccine lines for poultry; *Paracox* and *Coccivac* coccidiosis vaccines; *Exzolt*, a systemic treatment for poultry red mite infestations; *Slice* (Emamectin benzoate) parasiticide for sea lice in salmon; *Aquavac* (Avirulent Live Culture)/ *Norvax* vaccines against bacterial and viral disease in fish; *Compact PD* vaccine for salmon; *Aquaflor* (Florfenicol) antibiotic for farm-raised fish; and *Allflex Livestock Intelligence* solutions for animal identification, monitoring and traceability.

Companion Animal Products

Bravecto, a line of oral and topical parasitic control products, including the original *Bravecto* (fluralaner) products for dogs and cats that last up to 12 weeks; *Bravecto* (fluralaner) *One-Month*, a monthly product for dogs, and *Bravecto Plus* (fluralaner/moxidectin), a two-month product for cats; *Sentinel,* a line of oral parasitic products for dogs including *Sentinel Spectrum* (milbemycin oxime, lufenuron, and praziquantel) and *Sentinel Flavor Tabs* (milbemycin oxime, lufenuron); *Optimmune* (cyclosporine), an ophthalmic ointment; *Nobivac* vaccine lines for flexible dog and cat vaccination; *Otomax* (Gentamicin sulfate, USP; Betamethasone valerate USP; and Clotrimazole USP ointment)/*Mometamax* (Gentamicin sulfate, USP, Mometasone Furoate Monohydrate and Clotrimazole, USP, Otic Suspension)/*Posatex* (Orbifloxacin, Mometasone Furoate Monohydrate and Posaconazole, Suspension) ear ointments for acute and chronic otitis; *Caninsulin*/*Vetsulin* (porcine insulin zinc suspension) diabetes mellitus treatment for dogs and cats; *Panacur* (fenbendazole)/*Safeguard* (fenbendazole) broad-spectrum anthelmintic (de-wormer) for use in many animals; *Regumate* (altrenogest) fertility management for horses; *Prestige* vaccine line for horses; *Scalibor* (Deltamethrin)*/Exspot* for protecting against bites from fleas, ticks, mosquitoes and sandflies; and *Sure Petcare* products for companion animal identification and well-being, including the microchip and pet recovery system *Home Again*.

For a further discussion of sales of the Company's products, see Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" below.

2020 Product Approvals

Set forth below is a summary of significant product approvals received by the Company in 2020.

Product	Date
Dificid [(1)]	January 2020
Gardasil	November 2020
Gardasil 9	December 2020
	July 2020
	June 2020

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Keytruda	December 2020
	November 2020
	October 2020
	August 2020
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	June 2020
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	June 2020
	April 2020

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Lynparza[2]	December 2020
	December 2020
	December 2020
	November 2020
	November 2020
	July 2020
	May 2020
	May 2020

[1] *Dificid in the U.S. and Canada is a trademark of Cubist Pharmaceuticals LLC, an indirect wholly-owned subsidiary of Merck Sharp & Dohme Corp.*

[2] *In July 2017, Merck and AstraZeneca entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's* Lynparza *and* Koselugo.

[3] *Being commercialized and promoted in a worldwide, except Japan, collaboration with Pfizer Inc.*

Competition and the Health Care Environment

Competition

The markets in which the Company conducts its business and the pharmaceutical industry in general are highly competitive and highly regulated. The Company's competitors include other worldwide research-based pharmaceutical companies, smaller research companies with more limited therapeutic focus, generic drug manufacturers, and animal health care companies. The Company's operations may be adversely affected by generic and biosimilar competition as the Company's products mature, as well as technological advances of competitors, industry consolidation, patents granted to competitors, competitive combination products, new products of competitors, the generic availability of competitors' branded products, and new information from clinical trials of marketed products or post-marketing surveillance. In addition, patent rights are increasingly being challenged by competitors, and the outcome can be highly uncertain. An adverse result in a patent dispute can preclude commercialization of products or negatively affect sales of existing products and could result in the payment of royalties or in the recognition of an impairment charge with respect to intangible assets associated with certain products.

Pharmaceutical competition involves a rigorous search for technological innovations and the ability to market these innovations effectively. With its long-standing emphasis on research and development, the Company is well-positioned to compete in the search for technological innovations. The Company is active in acquiring and marketing products through external alliances, such as licensing arrangements and collaborations and has been refining its sales and marketing efforts to address changing industry conditions. However, the introduction of new products and processes by competitors may result in price reductions and product displacements, even for products protected by patents. For example, the number of compounds available to treat a particular disease typically increases over time and can result in slowed sales growth or reduced sales for the Company's products in that therapeutic category.

The highly competitive animal health business is affected by several factors including regulatory and legislative issues, scientific and technological advances, product innovation, the quality and price of the Company's products as well as competitors' products, effective promotional efforts and the frequent introduction of generic products by competitors.

Health Care Environment and Government Regulation

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access.

United States

In the United States, federal and state governments for many years have pursued methods to reduce the cost of drugs and vaccines for which they pay. For example, federal and state laws require the Company to pay specified rebates for medicines reimbursed by Medicaid and to provide discounts for medicines purchased by certain state and federal entities such as the Department of Defense, Veterans Affairs, Public Health Service entities and hospitals serving a disproportionate share of low income or uninsured patients.

Health Care Programs

The United States enacted major health care reform legislation in 2010 (the ACA). Various insurance market reforms have since advanced and state and federal insurance exchanges were launched in 2014. With respect to the effect of the law on the pharmaceutical industry, the law increased the mandated Medicaid rebate from 15.1% to 23.1%, expanded the rebate to Medicaid managed care utilization, and increased the types of entities eligible for the federal 340B drug discount program. The law also requires pharmaceutical manufacturers to pay 70% of the cost of the medicine, including biosimilar products, when Medicare Part D beneficiaries are in the Medicare Part D coverage gap (i.e., the so-called "donut hole"), which increased from 50% beginning in 2019 as a result of the Balanced Budget Act of 2018. Merck recorded approximately $700 million, $615 million and $365 million as a reduction to revenue in 2020, 2019, and 2018, respectively, related to the donut hole provision. Also, pharmaceutical manufacturers are required to pay an annual non-tax deductible health care reform fee. The total annual industry fee has been set at $2.8 billion. The fee is assessed on each company in proportion to its share of prior year branded pharmaceutical sales to certain government programs, such as Medicare and Medicaid. The Company recorded approximately $85 million, $112 million, and $124 million of costs within *Selling, general and administrative*

expenses in 2020, 2019 and 2018, respectively, for the annual health care reform fee. In February 2016, the Centers for Medicare & Medicaid Services (CMS) issued the Medicaid rebate final rule that implemented provisions of the ACA effective April 1, 2016. The rule provides comprehensive guidance on the calculation of Average Manufacturer Price and Best Price; two metrics utilized to determine the rebates drug manufacturers are required to pay to state Medicaid programs. More recently, although CMS previously declined to define what constitutes a product "line extension" (beyond the statutory definition), CMS issued a new rule on December 21, 2020 that will significantly expand the definition of the term "line extension" as of January 1, 2022 to include a broad range of products, including products reflecting new strengths, dosage forms, release mechanisms, and routes of administration. This expanded definition will increase the number of drugs subject to a higher Medicaid rebate. Effective January 1, 2023, this final rule also changes the way that manufacturers must calculate Best Price, in relation to certain patient support programs, including coupons, which also may result in an increase in the Company's Medicaid rebates. The impact of these and other provisions in this final rule could adversely impact the Company's business, cash flow, results of operations, financial condition and prospects.

The Patient Protection and Affordable Care Act

There is significant uncertainty about the future of the ACA in particular and health care laws in general in the United States. In December 2018, a Texas federal district court struck down the ACA on the grounds that the individual health insurance mandate is unconstitutional. The United States Supreme Court heard arguments in this case on November 10, 2020.

The Company is participating in the health care debate and monitoring how any proposed changes could affect its business. The Company is unable to predict the likelihood of changes to the ACA. Depending on the nature of any changes to the ACA, such actions could have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects.

Other Legislative Changes

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. A number of states have passed pharmaceutical price and cost transparency laws. These laws typically require manufacturers to report certain product price information or other financial data to the state. Some laws also require manufacturers to provide advance notification of price increases. The Company expects that states will continue their focus on pharmaceutical price transparency and that this focus will continue to exert pressure on product pricing.

Drug Pricing

The Company also faces increasing pricing pressure globally from managed care organizations, government agencies and programs that could negatively affect the Company's sales and profit margins, including, in the United States (i) practices of managed care organizations, federal and state exchanges, and institutional and governmental purchasers, and (ii) federal laws and regulations related to Medicare and Medicaid, including the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and the ACA.

In November 2020, the Department of Health and Human Services Office of Inspector General (OIG) issued a Final Rule that would, effective January 1, 2023, eliminate the Anti-Kickback Statute safe harbor for rebates paid to Medicare Part D plans or to pharmacy benefit managers (PBMs) on behalf of such plans. While the Company cannot anticipate the effects of this change to the way it currently contracts, this new framework could significantly alter the way it does business with Part D Plan Sponsors and PBMs on behalf of such plans. This rulemaking also established, effective January 1, 2021, a new safe harbor for point of sale discounts at the pharmacy counter and a new safe harbor for certain services arrangements between pharmaceutical manufacturers and PBMs.

CMS also recently issued an Interim Final Rule (the MFN Rule) that alters how physicians will be reimbursed under the Medicare program for physician administered drugs. Pursuant to the MFN Rule, which was intended to be effective January 1, 2021, rather than use the current Average Sales Price (ASP)-based payment framework for certain physician-administered drugs, the MFN Rule would institute a new pricing system for certain prescription drugs and biologic products covered by Medicare Part B in which Medicare would reimburse no more than the "most favored nation price," meaning the lowest price after adjusting for volume and differences in gross domestic product, for the top 50 Part B reimbursed products, which includes *Keytruda*, sold in 22 member countries of the Organisation for Economic Co-operation and Development (OECD). Several organizations, including two

trade groups of which Merck is a member, have filed suit challenging this regulation. Those lawsuits remain pending with a preliminary injunction having been entered in one of the cases. At this time, the Company cannot predict with any certainty if or when the MFN Rule will go into effect. Implementation of the MFN Rule could have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects.

The FDA also recently issued rulemaking allowing the commercial importation of certain prescription drugs from Canada through FDA-authorized, time-limited programs sponsored by states or Native American tribes recognized under the rule, and, in certain future circumstances, pharmacists and wholesalers. The FDA also recently released final guidance for industry detailing procedures for drug manufacturers to import FDA-approved prescription drug, biological, and combination products that were manufactured abroad and authorized and intended for sale in a foreign country. A trade organization, in which Merck is a member, brought suit, which remains pending in federal district court, challenging the commercial importation rule. These proposed changes could have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects.

Changes to the health care system enacted as part of health care reform in the United States, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, could result in further pricing pressures. As an example, health care reform has contributed to an increase in the number of patients in the Medicaid program under which sales of pharmaceutical products are subject to substantial rebates.

The pharmaceutical industry also could be considered a potential source of savings via other legislative and administrative proposals that have been debated but not enacted. These types of revenue generating or cost saving proposals include additional direct price controls.

There was active consideration of drug-pricing related legislation in the last Congress, and it remains very uncertain as to what proposals, if any, may be included as part of future federal legislative proposals that would directly or indirectly affect the Company.

In the U.S. private sector, consolidation and integration among health care providers is a major factor in the competitive marketplace for pharmaceutical products. Health plans and PBMs have been consolidating into fewer, larger entities, thus enhancing their purchasing strength and importance. Private third-party insurers, as well as governments, employ formularies to control costs by negotiating discounted prices in exchange for formulary inclusion. Failure to obtain timely or adequate pricing or formulary placement for Merck's products or obtaining such placement at unfavorable pricing could adversely affect revenue. In addition to formulary tier co-pay differentials, private health insurance companies and self-insured employers have been raising co-payments required from beneficiaries, particularly for branded pharmaceuticals and biotechnology products. Private health insurance companies also are increasingly imposing utilization management tools, such as clinical protocols, requiring prior authorization for a branded product if a generic product is available or requiring the patient to first fail on one or more generic products before permitting access to a branded medicine. These same management tools are also used in treatment areas in which the payor has taken the position that multiple branded products are therapeutically comparable. As the U.S. payor market concentrates further and as more drugs become available in generic form, pharmaceutical companies may face greater pricing pressure from private third-party payors.

In order to provide information about the Company's pricing practices, the Company annually posts on its website its Pricing Transparency Report for the United States. The report provides the Company's average annual list price, net price increases, and average discounts across the Company's U.S. portfolio dating back to 2010. In 2020, the Company's gross U.S. sales were reduced by 45.5% as a result of rebates, discounts and returns.

European Union

Efforts toward health care cost containment remain intense in the European Union (EU). The Company faces competitive pricing pressure resulting from generic and biosimilar drugs. In addition, a majority of countries in the EU attempt to contain drug costs by engaging in reference pricing in which authorities examine pre-determined markets for published prices of drugs. Reference pricing may either compare a product's prices in other markets (external reference pricing), or compare a product's price with those of other products in a national class (internal reference pricing). The authorities then use the price data to set new local prices for brand-name drugs, including the Company's drugs. Guidelines for examining reference pricing are usually set in local markets and can be changed

pursuant to local regulations. Some EU Member States have established free-pricing systems, but regulate the pricing for drugs through profit control plans. Others seek to negotiate or set prices based on the cost-effectiveness of a product or an assessment of whether it offers a therapeutic benefit over other products in the relevant class. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In some EU Member States, cross-border imports from low-priced markets also exert competitive pressure that may reduce pricing within an EU Member State.

Additionally, EU Member States have the power to restrict the range of pharmaceutical products for which their national health insurance systems provide reimbursement. In the EU, pricing and reimbursement plans vary widely from Member State to Member State. Some EU Member States provide that drug products may be marketed only after a reimbursement price has been agreed. Some EU Member States may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to already available therapies or so-called health technology assessments (HTA), in order to obtain reimbursement or pricing approval. The HTA of pharmaceutical products is becoming an increasingly common part of the pricing and reimbursement procedures in most EU Member States. The HTA process, which is governed by the national laws of these countries, involves the assessment of the cost-effectiveness, public health impact, therapeutic impact and/or the economic and social impact of use of a given pharmaceutical product in the national health care system of the individual country is conducted. Ultimately, HTA measures the added value of a new health technology compared to existing ones. The outcome of HTAs regarding specific pharmaceutical products will often influence the pricing and reimbursement status granted to these pharmaceutical products by the regulatory authorities of individual EU Member States. A negative HTA of one of the Company's products may mean that the product is not reimbursable or may force the Company to reduce its reimbursement price or offer discounts or rebates.

A negative HTA by a leading and recognized HTA body could also undermine the Company's ability to obtain reimbursement for the relevant product outside a jurisdiction. For example, EU Member States that have not yet developed HTA mechanisms may rely to some extent on the HTA performed in other countries with a developed HTA framework, to inform their pricing and reimbursement decisions. HTA procedures require additional data, reviews and administrative processes, all of which increase the complexity, timing and costs of obtaining product reimbursement and exert downward pressure on available reimbursement.

To obtain reimbursement or pricing approval in some EU Member States, the Company may be required to conduct studies that compare the cost-effectiveness of the Company's product candidates to other therapies that are considered the local standard of care. There can be no assurance that any EU Member State will allow favorable pricing, reimbursement and market access conditions for any of the Company's products, or that it will be feasible to conduct additional cost-effectiveness studies, if required.

Brexit

In 2016, the United Kingdom (UK) held a referendum in which voters approved an exit from the EU, commonly referred to as "Brexit." As a result of that referendum and subsequent negotiations, the UK left the EU on January 31, 2020. A transitional period applied from January 31, 2020 until December 31, 2020, and during this period the EU and UK operated as if the UK was an EU Member State, and the UK continued to participate in the EU Customs Union allowing for the freedom of movement for people and goods.

It was announced on December 24, 2020, that the EU and the UK agreed to a Trade and Cooperation Agreement (TCA). The TCA sets out the new arrangements for trade of goods, including medicines and vaccines, which allows goods to continue to flow between the EU and the UK. On December 29, 2020, the Council of the EU adopted the decision to sign the TCA and for the TCA to be provisionally applied from January 1, 2021. The UK and EU signed the TCA on December 30, 2020. In order for the TCA to be ratified and formally come into effect, the Council of the EU must unanimously approve the TCA and the European Parliament must consent to it, which the Company believes will occur. As a result of the TCA, the Company believes that its operations will not be materially adversely affected by Brexit.

Japan

In Japan, the pharmaceutical industry is subject to government-mandated biennial price reductions of pharmaceutical products and certain vaccines. Furthermore, the government can order re-pricings for specific products if it determines that use of such product will exceed certain thresholds defined under applicable re-pricing rules. The next government-mandated price reduction will occur in April 2021 and is expected to impact many Company products.

China

The Company's business in China has grown rapidly in the past few years, and the importance of China to the Company's overall pharmaceutical and vaccines business has increased accordingly. Continued growth of the Company's business in China is dependent upon ongoing development of a favorable environment for innovative pharmaceutical products and vaccines, sustained access for the Company's current in-line products, and the absence of trade impediments or adverse pricing controls. In recent years, the Chinese government has introduced and implemented a number of structural reforms to accelerate the shift to innovative products and reduce costs. Since 2017, there have been multiple new policies introduced by the government to improve access to new innovation, reduce the complexity of regulatory filings, and accelerate the review and approval process. This has led to a significant increase in the number of new products being approved each year. Additionally, in 2017, the Chinese government updated the National Reimbursement Drug List (NRDL) for the first time in eight years. While the mechanism for drugs being added to the list evolves, inclusion may require a price negotiation which could impact the outlook in the market for selected brands. In 2020, drugs were added to the NRDL through double-digit price reductions. While pricing pressure has always existed in China, health care reform has increased this pressure in part due to the acceleration of generic substitution through volume based procurement (VBP). In 2019, the government implemented the VBP program through a tendering process for mature products which have generic substitutes with a Generic Quality Consistency Evaluation approval. Mature products that have entered into the first three rounds of VBP have had, on average, a price reduction of 50%. The Company expects VBP to be a semi-annual process that will have a significant impact on mature products moving forward.

Emerging Markets

The Company's focus on emerging markets, in addition to China, has continued. Governments in many emerging markets are also focused on constraining health care costs and have enacted price controls and measures impacting intellectual property, including in exceptional cases, threats of compulsory licenses, that aim to put pressure on the price of innovative pharmaceuticals or result in constrained market access to innovative medicine. The Company anticipates that pricing pressures and market access challenges will continue in the future to varying degrees in the emerging markets.

Beyond pricing and market access challenges, other conditions in emerging market countries can affect the Company's efforts to continue to grow in these markets, including potential political instability, changes in trade sanctions and embargoes, significant currency fluctuation and controls, financial crises, limited or changing availability of funding for health care, credit worthiness of health care partners, such as hospitals, due to COVID-19, and other developments that may adversely impact the business environment for the Company. Further, the Company may engage third-party agents to assist in operating in emerging market countries, which may affect its ability to realize continued growth and may also increase the Company's risk exposure.

In addressing cost containment pressures, the Company engages in public policy advocacy with policymakers and continues to work to demonstrate that its medicines provide value to patients and to those who pay for health care. The Company advocates with government policymakers to encourage a long-term approach to sustainable health care financing that ensures access to innovative medicines and does not disproportionately target pharmaceuticals as a source of budget savings. In markets with historically low rates of health care spending, the Company encourages those governments to increase their investments and adopt market reforms in order to improve their citizens' access to appropriate health care, including medicines.

Operating conditions have become more challenging under the global pressures of competition, industry regulation and cost containment efforts. Although no one can predict the effect of these and other factors on the Company's business, the Company continually takes measures to evaluate, adapt and improve the organization and

its business practices to better meet customer needs and believes that it is well-positioned to respond to the evolving health care environment and market forces.

Regulation

The pharmaceutical industry is also subject to regulation by regional, country, state and local agencies around the world focused on standards and processes for determining drug safety and effectiveness, as well as conditions for sale or reimbursement.

Of particular importance is the FDA in the United States, which administers requirements covering the testing, approval, safety, effectiveness, manufacturing, labeling, and marketing of prescription pharmaceuticals. In some cases, the FDA requirements and practices have increased the amount of time and resources necessary to develop new products and bring them to market in the United States. At the same time, the FDA has committed to expediting the development and review of products bearing the "breakthrough therapy" designation, which has accelerated the regulatory review process for medicines with this designation. The FDA has also undertaken efforts to bring generic competition to market more efficiently and in a more timely manner.

The EU has adopted directives and other legislation concerning the classification, approval for marketing, labeling, advertising, manufacturing, wholesale distribution, integrity of the supply chain, pharmacovigilance and safety monitoring of medicinal products for human use. These provide mandatory standards throughout the EU, which may be supplemented or implemented with additional regulations by the EU member states. In particular, EU regulators may approve products subject to a number of post-authorization conditions. Examples of typical post-authorization commitments include additional pharmacovigilance, the conduct of clinical trials, the establishment of patient registries, physician or patient education and controlled distribution and prescribing arrangements. Non-compliance with post-authorization conditions, pharmacovigilance and other obligations can lead to regulatory action, including the variation, suspension or withdrawal of the marketing authorizations, or other enforcement or regulatory actions, including the imposition of financial penalties. The Company's policies and procedures are already consistent with the substance of these directives; consequently, it is believed that they will not have any material effect on the Company's business.

The Company believes that it will continue to be able to conduct its operations, including launching new drugs, in this regulatory environment. (See "Research and Development" below for a discussion of the regulatory approval process.)

Access to Medicines

As a global health care company, Merck's primary role is to discover and develop innovative medicines and vaccines. The Company also recognizes that it has an important role to play in helping to improve access to its medicines, vaccines, and to quality health care around the world. The Company's efforts in this regard are wide-ranging and include a set of principles that the Company strives to embed into its operations and business strategies to guide the Company's worldwide approach to expanding access to health care. In addition, through innovative social investments, including philanthropic programs and impact investing, Merck is also helping to strengthen health systems and build capacity, particularly in under-resourced communities. The Merck Patient Assistance Program provides medicines and adult vaccines for free to people in the United States who do not have prescription drug or health insurance coverage and who, without the Company's assistance, cannot afford their Merck medicines and vaccines. Merck has funded "Merck for Mothers," a long-term effort with global health partners to end preventable deaths from complications of pregnancy and childbirth. Merck has also provided funds to the Merck Foundation, an independent grantmaking organization, which has partnered with a variety of organizations dedicated to improving global health.

Privacy and Data Protection

The Company is subject to a significant number of privacy and data protection laws and regulations globally, many of which place restrictions on the Company's ability to transfer, access and use personal data across its business. The legislative and regulatory landscape for privacy and data protection continues to evolve. There has been increased attention to privacy and data protection issues in both developed and emerging markets with the potential to affect directly the Company's business, including the EU General Data Protection Regulation, (GDPR) which went into effect in May 2018 and imposes penalties of up to 4% of global revenue.

The GDPR and related implementing laws in individual EU Member States govern the collection and use of personal health data and other personal data in the EU. The GDPR increased responsibility and liability in relation to personal data that the Company processes. It also imposes a number of strict obligations and restrictions on the ability to process (which includes collection, analysis and transfer of) personal data, including health data from clinical trials and adverse event reporting. The GDPR also includes requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals prior to processing their personal data or personal health data, notification of data processing obligations to the national data protection authorities, and the security and confidentiality of the personal data. Further, the GDPR prohibits the transfer of personal data to countries outside of the EU that are not considered by the EC to provide an adequate level of data protection, including to the United States, except if the data controller meets very specific requirements. Following the Schrems II decision of the Court of Justice of the European Union on July 16, 2020, there is considerable uncertainty as to the permissibility of international data transfers under the GDPR. In light of the implications of this decision, the Company may face difficulties regarding the transfer of personal data from the EU to third countries.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU Member States may result in significant monetary fines and other administrative penalties as well as civil liability claims from individuals whose personal data was processed. Data protection authorities from the different EU Member States may still implement certain variations, enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing personal data in the EU. Guidance developed at both EU level and at the national level in individual EU Member States concerning implementation and compliance practices is often updated or otherwise revised.

There is, moreover, a growing trend towards required public disclosure of clinical trial data in the EU which adds to the complexity of obligations relating to processing health data from clinical trials. Failing to comply with these obligations could lead to government enforcement actions and significant penalties against the Company, harm to its reputation, and adversely impact its business and operating results. The uncertainty regarding the interplay between different regulatory frameworks further adds to the complexity that the Company faces with regard to data protection regulation.

Additional laws and regulations enacted in the United States (such as the California Consumer Privacy Act), Europe, Asia and Latin America, have increased enforcement and litigation activity in the United States and other developed markets, as well as increased regulatory cooperation among privacy authorities globally. The Company has adopted a comprehensive global privacy program to manage these evolving risks and facilitate the transfer of personal information across international borders.

Distribution

The Company sells its human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers, such as health maintenance organizations, PBMs and other institutions. Human health vaccines are sold primarily to physicians, wholesalers, physician distributors and government entities. The Company's professional representatives communicate the effectiveness, safety and value of the Company's pharmaceutical and vaccine products to health care professionals in private practice, group practices, hospitals and managed care organizations. The Company sells its animal health products to veterinarians, distributors and animal producers.

Patents, Trademarks and Licenses

Patent protection is considered, in the aggregate, to be of material importance to the Company's marketing of its products in the United States and in most major foreign markets. Patents may cover products *per se*, pharmaceutical formulations, processes for, or intermediates useful in, the manufacture of products, or the uses of products. Protection for individual products extends for varying periods in accordance with the legal life of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent and its scope of coverage.

The Food and Drug Administration Modernization Act includes a Pediatric Exclusivity Provision that may provide an additional six months of market exclusivity in the United States for indications of new or currently marketed drugs if certain agreed upon pediatric studies are completed by the applicant. Current U.S. patent law

provides additional patent term for periods when the patented product was under regulatory review by the FDA. The EU also provides an additional six months of pediatric market exclusivity attached to a product's Supplementary Protection Certificate (SPC). Japan provides the additional term for pediatric studies attached to market exclusivity unrelated to patent term.

Patent portfolios developed for products introduced by the Company normally provide market exclusivity. The Company has the following key patent protection in the United States, the EU, Japan and China (including the potential for patent term extensions (PTE) and SPCs where indicated) for the following marketed products:

Product	Year of Expiration (U.S.)	Year of Expiration (EU)[1]	Year of Expiration (Japan)[2]	Year of Expiration (China)
Januvia	2023	2022	2025-2026	2022
Janumet	2023	2023	N/A	2022
Janumet XR	2023	N/A	N/A	2022
Isentress	2024	2023[3]	2022-2026	2022
Simponi	N/A[4]	2024[5]	N/A[4]	N/A[4]
Lenvima[6]	2025[3] (with pending PTE)	2021 (patents), 2026[3] (SPCs)	2026	2021
Adempas[7]	2026[3]	2028[3]	2027-2028	2023
Bridion	2026[3] (with pending PTE)	2023	2024	Expired
Nexplanon	2027 (device)	2025 (device)	N/A	2025
Bravecto	2027 (with pending PTE)	2025 (patents), 2029 (SPCs)	2029	2033
Gardasil	2028	2021[3]	Expired	N/A
Gardasil 9	2028	2025 (patents), 2030[3] (SPCs)	N/A	2025
Keytruda	2028	2028 (patents), 2030[3] (SPCs)	2032-2033	2028
Lynparza[8]	2028[3] (with pending PTE)	2024 (patents), 2029[3] (SPCs)	2028-2029	2024
Zerbaxa	2028[3]	2023 (patents), 2028[3] (SPCs)	2028 (with pending PTE)	N/A
Sivextro	2028	2024 (patents), 2029 (SPCs)	2029	2024
Belsomra	2029[3]	N/A	2031	N/A
Prevymis	2029[3] (with pending PTE)	2024 (patents), 2029[3] (SPCs)	2029	N/A
Segluromet[9]	2031 (with pending PTE)	2029 (patents), 2034 (SPCs)	N/A[10]	N/A
Steglatro[9]	2031[3] (with pending PTE)	2029 (patents), 2034[3] (SPCs)	N/A[10]	2029
Steglujan[9]	2031 (with pending PTE)	2029 (patents), 2034 (SPCs)	N/A[10]	N/A
Verquvo[7]	2031 (with pending PTE)	N/A[11]	N/A[11]	N/A[11]
Delstrigo	2032 (with pending PTE)	2031 (patents), 2033 (SPCs)	N/A	N/A
Pifeltro	2032 (with pending PTE)	2031 (patents), 2033 (SPCs)	2036	2031
Recarbrio	2033[3] (with pending PTE)	N/A	N/A	N/A

Note: Compound patent unless otherwise noted. Certain of the products listed may be the subject of patent litigation. See Item 8. "Financial Statements and Supplementary Data," Note 10. "Contingencies and Environmental Liabilities" below.

N/A: Currently no marketing approval.

(1) *The EU date represents the expiration date for the following five countries: France, Germany, Italy, Spain and the United Kingdom (Major EU Markets). If SPC applications have been filed but have not been granted in all Major EU Markets, both the patent expiry date and the SPC expiry date are listed.*

(2) *The PTE system in Japan allows for a patent to be extended more than once provided the later approval is directed to a different indication from that of the previous approval. This may result in multiple PTE approvals for a given patent, each with its own expiration date.*

(3) *Eligible for 6 months Pediatric Exclusivity.*

(4) *The Company has no marketing rights in the U.S., Japan or China.*

(5) *Expiration of the distribution agreement with Janssen Pharmaceuticals, Inc.*

(6) *Part of a global strategic oncology collaboration with Eisai.*

(7) *Being commercialized in a worldwide collaboration with Bayer AG.*

(8) *Part of a global strategic oncology collaboration with AstraZeneca.*

(9) *Being commercialized and promoted in a worldwide, except Japan, collaboration with Pfizer Inc.*

(10) *The Company has no marketing rights in Japan.*

(11) *The Company has no marketing rights in the EU, Japan or China.*

The Company also has the following key U.S. patent protection for drug candidates under review or in Phase 3 development:

Phase 3 Drug Candidate	Currently Anticipated Year of Expiration (in the U.S.)
MK-7264 (gefapixant)	2027
V114 (pneumoconjugate vaccine)	2031 (vaccine composition)
MK-7110 (CD24Fc)	2031
MK-8591A (islatravir/doravirine)	2032
MK-6482 (belzutifan)	2034

Unless otherwise noted, the patents in the above charts are compound patents. Each patent may be subject to a future patent term restoration of up to five years and six month pediatric market exclusivity, either or both of which may be available. In addition, depending on the circumstances surrounding any final regulatory approval of the compound, there may be other listed patents or patent applications pending that could have relevance to the product as finally approved; the relevance of any such application would depend upon the claims that ultimately may be granted and the nature of the final regulatory approval of the product. Also, regulatory exclusivity tied to the protection of clinical data is complementary to patent protection and, in some cases, may provide more effective or longer lasting marketing exclusivity than a compound's patent estate. In the United States, the data protection generally runs five years from first marketing approval of a new chemical entity, extended to seven years for an orphan drug indication and 12 years from first marketing approval of a biological product.

While the expiration of a product patent normally results in a loss of market exclusivity for the covered pharmaceutical product, commercial benefits may continue to be derived from: (i) later-granted patents on processes and intermediates related to the most economical method of manufacture of the active ingredient of such product; (ii) patents relating to the use of such product; (iii) patents relating to novel compositions and formulations; and (iv) in the United States and certain other countries, market exclusivity that may be available under relevant law. The effect of product patent expiration on pharmaceutical products also depends upon many other factors such as the nature of the market and the position of the product in it, the growth of the market, the complexities and economics of the process for manufacture of the active ingredient of the product and the requirements of new drug provisions of the Federal Food, Drug and Cosmetic Act or similar laws and regulations in other countries.

Additions to market exclusivity are sought in the United States and other countries through all relevant laws, including laws increasing patent life. Some of the benefits of increases in patent life have been partially offset by an increase in the number of incentives for and use of generic products. Additionally, improvements in intellectual property laws are sought in the United States and other countries through reform of patent and other relevant laws and implementation of international treaties.

For further information with respect to the Company's patents, see Item 1A. "Risk Factors" and Item 8. "Financial Statements and Supplementary Data," Note 10. "Contingencies and Environmental Liabilities" below.

Worldwide, all of the Company's important products are sold under trademarks that are considered in the aggregate to be of material importance. Trademark protection continues in some countries as long as used; in other countries, as long as registered. Registration is for fixed terms and can be renewed indefinitely.

Royalty income in 2020 on patent and know-how licenses and other rights amounted to $185 million. Merck also incurred royalty expenses amounting to $2.0 billion in 2020 under patent and know-how licenses it holds.

Research and Development

The Company's business is characterized by the introduction of new products or new uses for existing products through a strong research and development program. At December 31, 2020, approximately 16,750 people were employed in the Company's research activities. The Company prioritizes its research and development efforts and focuses on candidates that it believes represent breakthrough science that will make a difference for patients and payers.

The Company maintains a number of long-term exploratory and fundamental research programs in biology and chemistry as well as research programs directed toward product development. The Company's research and development model is designed to increase productivity and improve the probability of success by prioritizing the Company's research and development resources on candidates the Company believes are capable of providing unambiguous, promotable advantages to patients and payers and delivering the maximum value of its approved medicines and vaccines through new indications and new formulations. Merck is pursuing emerging product opportunities independent of therapeutic area or modality (small molecule, biologics and vaccines) and is building its biologics capabilities. The Company is committed to ensuring that externally sourced programs remain an important component of its pipeline strategy, with a focus on supplementing its internal research with a licensing and external alliance strategy focused on the entire spectrum of collaborations from early research to late-stage compounds, as well as access to new technologies.

The Company's clinical pipeline includes candidates in multiple disease areas, including cancer, cardiovascular diseases, metabolic diseases, infectious diseases, neurosciences, respiratory diseases, and vaccines.

In the development of human health products, industry practice and government regulations in the United States and most foreign countries provide for the determination of effectiveness and safety of new chemical compounds through pre-clinical tests and controlled clinical evaluation. Before a new drug or vaccine may be marketed in the United States, recorded data on pre-clinical and clinical experience are included in the New Drug Application (NDA) for a drug or the Biologics License Application (BLA) for a vaccine or biologic submitted to the FDA for the required approval.

Once the Company's scientists discover a new small molecule compound or biologic that they believe has promise to treat a medical condition, the Company commences pre-clinical testing with that compound. Pre-clinical testing includes laboratory testing and animal safety studies to gather data on chemistry, pharmacology, immunogenicity and toxicology. Pending acceptable pre-clinical data, the Company will initiate clinical testing in accordance with established regulatory requirements. The clinical testing begins with Phase 1 studies, which are designed to assess safety, tolerability, pharmacokinetics, and preliminary pharmacodynamic activity of the compound in humans. If favorable, additional, larger Phase 2 studies are initiated to determine the efficacy of the compound in the affected population, define appropriate dosing for the compound, as well as identify any adverse effects that could limit the compound's usefulness. In some situations, the clinical program incorporates adaptive design methodology to use accumulating data to decide how to modify aspects of the ongoing clinical study as it continues, without undermining the validity and integrity of the trial. One type of adaptive clinical trial is an adaptive Phase 2a/2b trial design, a two-stage trial design consisting of a Phase 2a proof-of-concept stage and a Phase 2b dose-optimization finding stage. If data from the Phase 2 trials are satisfactory, the Company commences large-scale Phase 3 trials to confirm the compound's efficacy and safety. Another type of adaptive clinical trial is an adaptive Phase 2/3 trial design, a study that includes an interim analysis and an adaptation that changes the trial from having features common in a Phase 2 study (e.g. multiple dose groups) to a design similar to a Phase 3 trial. An adaptive Phase 2/3 trial design reduces timelines by eliminating activities which would be required to start a separate study. Upon completion of Phase 3 trials, if satisfactory, the Company submits regulatory filings with the appropriate regulatory agencies around the world to have the product candidate approved for marketing. There can

be no assurance that a compound that is the result of any particular program will obtain the regulatory approvals necessary for it to be marketed.

Vaccine development follows the same general pathway as for drugs. Pre-clinical testing focuses on the vaccine's safety and ability to elicit a protective immune response (immunogenicity). Pre-marketing vaccine clinical trials are typically done in three phases. Initial Phase 1 clinical studies are conducted in normal subjects to evaluate the safety, tolerability and immunogenicity of the vaccine candidate. Phase 2 studies are dose-ranging studies. Finally, Phase 3 trials provide the necessary data on effectiveness and safety. If successful, the Company submits regulatory filings with the appropriate regulatory agencies.

In the United States, the FDA review process begins once a complete NDA or BLA is submitted, received and accepted for review by the agency. Within 60 days after receipt, the FDA determines if the application is sufficiently complete to permit a substantive review. The FDA also assesses, at that time, whether the application will be granted a priority review or standard review. Pursuant to the Prescription Drug User Fee Act V (PDUFA), the FDA review period target for NDAs or original BLAs is either six months, for priority review, or ten months, for a standard review, from the time the application is deemed sufficiently complete. Once the review timelines are determined, the FDA will generally act upon the application within those timelines, unless a major amendment has been submitted (either at the Company's own initiative or the FDA's request) to the pending application. If this occurs, the FDA may extend the review period to allow for review of the new information, but by no more than three months. Extensions to the review period are communicated to the Company. The FDA can act on an application either by issuing an approval letter or by issuing a Complete Response Letter (CRL) stating that the application will not be approved in its present form and describing all deficiencies that the FDA has identified. Should the Company wish to pursue an application after receiving a CRL, it can resubmit the application with information that addresses the questions or issues identified by the FDA in order to support approval. Resubmissions are subject to review period targets, which vary depending on the underlying submission type and the content of the resubmission.

The FDA has four program designations — Fast Track, Breakthrough Therapy, Accelerated Approval, and Priority Review — to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening conditions. The Fast Track designation provides pharmaceutical manufacturers with opportunities for frequent interactions with FDA reviewers during the product's development and the ability for the manufacturer to do a rolling submission of the NDA/BLA. A rolling submission allows completed portions of the application to be submitted and reviewed by the FDA on an ongoing basis. The Breakthrough Therapy designation provides manufacturers with all of the features of the Fast Track designation as well as intensive guidance on implementing an efficient development program for the product and a commitment by the FDA to involve senior managers and experienced staff in the review. The Accelerated Approval designation allows the FDA to approve a product based on an effect on a surrogate or intermediate endpoint that is reasonably likely to predict a product's clinical benefit and generally requires the manufacturer to conduct required post-approval confirmatory trials to verify the clinical benefit. The Priority Review designation means that the FDA's goal is to take action on the NDA/BLA within six months, compared to ten months under standard review. More than one of these special designations can be granted for a given application (i.e., a product designated as a Breakthrough Therapy may also be eligible for Priority Review).

Due to the COVID-19 public health crisis, the United States Secretary of Health and Human Services has exercised statutory authority to determine that a public health emergency exists, and declare these circumstances justify the emergency use of drugs and biological products as authorized by the FDA. While in effect, this declaration enables the FDA to issue Emergency Use Authorizations (EUAs) permitting distribution and use of specific medical products absent NDA/BLA submission or approval, including products to treat or prevent diseases or conditions caused by the SARS-CoV-2 virus, subject to the terms of any such EUAs. The FDA must make certain findings to grant an EUA, including that it is reasonable to believe based on the totality of evidence that the drug or biologic may be effective, and that known or potential benefits when used under the terms of the EUA outweigh known or potential risks. Additionally, the FDA must find that there is no adequate, approved and available alternative to the emergency use.

The primary method the Company uses to obtain marketing authorization of pharmaceutical products in the EU is through the "centralized procedure." This procedure is compulsory for certain pharmaceutical products, in

particular those using biotechnological processes, and is also available for certain new chemical compounds and products. A company seeking to market an innovative pharmaceutical product through the centralized procedure must file a complete set of safety data and efficacy data as part of a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA). After the EMA evaluates the MAA, it provides a recommendation to the EC and the EC then approves or denies the MAA. It is also possible for new chemical products to obtain marketing authorization in the EU through a "mutual recognition procedure" in which an application is made to a single member state and, if the member state approves the pharmaceutical product under a national procedure, the applicant may submit that approval to the mutual recognition procedure of some or all other EU member states.

Outside of the United States and the EU, the Company submits marketing applications to national regulatory authorities. Examples of such are the Ministry of Health, Labour and Welfare in Japan, the National Medical Products Administration in China, Health Canada, Agência Nacional de Vigilância Sanatária in Brazil, Korea Food and Drug Administration in South Korea, and the Therapeutic Goods Administration in Australia. Each country has a separate and independent review process and timeline. In many markets, approval times can be longer as the regulatory authority requires approval in a major market, such as the United States or the EU, and issuance of a Certificate of Pharmaceutical Product from that market before initiating their local review process.

Research and Development Update

The Company currently has several candidates under regulatory review in the United States and internationally or in late-stage clinical development.

MK-7655A is combination of relebactum, a beta-lactamase inhibitor, and imipenem/cilastatin (a carbapenem antibiotic) under review in Japan for the treatment of bacterial infection. MK-7655A was approved by the FDA in 2019 and is marketed in the United States as *Recarbrio*.

MK-1242, vericiguat, is an orally administered soluble guanylate cyclase (sGC) stimulator under review in the EU and in Japan to reduce the risk of cardiovascular death and heart failure hospitalization following a worsening heart failure event in patients with symptomatic chronic heart failure with reduced ejection fraction, in combination with other heart failure therapies. The applications are based on results from the Phase 3 VICTORIA trial. Vericiguat was approved by the FDA in January 2021 and will be marketed in the United States as Verquvo. Vericiguat is being jointly developed with Bayer. Bayer will commercialize vericiguat in territories outside the United States, if approved.

MK-5618, selumetinib, is under review in the EU for the treatment of pediatric patients two years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN) based on positive results from the National Cancer Institute Cancer Therapy Evaluation Program-sponsored Phase 2 SPRINT Stratum 1 trial. Selumetinib was approved by the FDA in April 2020 and is marketed in the United States as Koselugo. Selumetinib is being jointly developed and commercialized with AstraZeneca globally.

V114 is an investigational 15-valent pneumococcal conjugate vaccine under priority review by the FDA for the prevention of invasive pneumococcal disease in adults 18 years of age and older. The FDA set a PDUFA date of July 18, 2021. The EMA is also reviewing an application for licensure of V114 in adults. Additionally, the Company has several ongoing Phase 3 trials evaluating V114 in pediatric patients. V114 previously received Breakthrough Therapy designation from the FDA for the prevention of invasive pneumococcal disease in pediatric patients 6 weeks to 18 years of age and adults 18 years of age and older. The Company is involved in litigation challenging the validity of several Pfizer Inc. patents that relate to pneumococcal vaccine technology in the United States and several foreign jurisdictions.

Keytruda is an anti-PD-1 therapy approved for the treatment of many cancers that is in clinical development for expanded indications. These approvals were the result of a broad clinical development program that currently consists of more than 1,400 clinical trials, including more than 1,000 trials that combine *Keytruda* with other cancer treatments. These studies encompass more than 30 cancer types including: biliary tract, cervical, colorectal, cutaneous squamous cell, endometrial, esophageal, estrogen receptor positive breast cancer, gastric, glioblastoma, head and neck, hepatocellular, Hodgkin lymphoma, non-Hodgkin lymphoma, non-small-cell lung, small-cell lung, melanoma, mesothelioma, ovarian, prostate, renal, triple-negative breast, and urothelial, many of which are currently in Phase 3 clinical development. Further trials are being planned for other cancers.

Keytruda in combination with chemotherapy is under review in the EU for the treatment of locally recurrent unresectable or metastatic triple negative breast cancer (TNBC) in adults whose tumors express PD-L1 with a CPS ≥ 10 and who have not received prior chemotherapy for metastatic disease based on the results of the KEYNOTE-355 trial. *Keytruda* was approved for this indication under accelerated approval based on progression-free survival (PFS) by the FDA in November 2020. *Keytruda* in combination with chemotherapy is also under review in Japan for the treatment of patients with locally recurrent unresectable or metastatic TNBC based on data from the KEYNOTE-355 trial.

In July 2020, the FDA accepted for standard review a supplemental BLA for *Keytruda* for the treatment of patients with high-risk, early-stage TNBC in combination with chemotherapy as neoadjuvant (pre-operative) treatment, and then as a single agent as adjuvant (post-operative) treatment after surgery. The application was based on data from the first and second interim analyses of the KEYNOTE-522 trial. In February 2021, the FDA's Oncologic Drugs Advisory Committee (ODAC), which discussed the Company's supplemental BLA for *Keytruda*, voted that a regulatory decision should be deferred until further data are available from the Phase 3 KEYNOTE-522 trial. The study met one of the dual primary endpoints of pathological complete response and is continuing to evaluate event-free survival. The ODAC provides the FDA with independent, expert advice and recommendations on marketed and investigational medicines for use in the treatment of cancer. The FDA is not bound by the committee's guidance but takes its advice into consideration. The PDUFA date for this application is March 29, 2021. The next interim analysis is calendar-driven, and data is expected in the third quarter of 2021.

In February 2021, Merck announced that the Committee for Medicinal Products for Human Use (CHMP) of the EMA adopted a positive opinion recommending approval of an expanded label for *Keytruda* as monotherapy for the treatment of adult and pediatric patients aged 3 years and older with relapsed or refractory cHL who have failed an earlier line of therapy. This recommendation is based on results from the pivotal Phase 3 KEYNOTE-204 trial, in which *Keytruda* monotherapy demonstrated a significant improvement in PFS compared with brentuximab vedotin, a commonly used treatment. The recommendation is also based on supportive data from an updated analysis of the KEYNOTE-087 trial, which supported EC approval of *Keytruda* for the treatment of adult patients with relapsed or refractory cHL. The CHMP's recommendation will now be reviewed by the EC for marketing authorization in the EU. *Keytruda* was approved for this indication by the FDA in October 2020.

Keytruda is also under review as monotherapy for the first-line treatment of adult patients with metastatic MSI-H or dMMR colorectal cancer in Japan based on the result of the KEYNOTE-177 trial. *Keytruda* was approved for this indication by the FDA in June 2020 and by the EU in January 2021.

In January 2021, the FDA accepted a supplemental BLA seeking use of *Keytruda* for the treatment of patients with locally advanced cSCC that is not curable by surgery or radiation based on the results of the KEYNOTE-629 trial. The FDA set a PDUFA date of September 9, 2021.

In December 2020, the FDA accepted and granted priority review for a supplemental BLA for *Keytruda* in combination with chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic carcinoma of the esophagus and gastroesophageal junction. This supplemental BLA is based on data from the pivotal Phase 3 KEYNOTE-590 trial, in which *Keytruda* plus chemotherapy demonstrated significant improvements in the primary endpoints of overall survival (OS) and PFS versus chemotherapy in these patients regardless of PD-L1 expression status and tumor histology. These data were presented at the European Society of Medical Oncology (ESMO) Virtual Congress 2020. The FDA set a PDUFA date of April 13, 2021. In December 2020, the CHMP of the EMA announced the start of a procedure to extend the indication to include in combination with chemotherapy, first-line treatment of locally advanced unresectable or metastatic carcinoma of the esophagus or HER-2 negative gastroesophageal junction adenocarcinoma in adults for *Keytruda*, based on the results from KEYNOTE-590. *Keytruda* is also under review for this indication in Japan.

Keytruda also received Breakthrough Therapy designation from the FDA in February 2020 for the combination of *Keytruda* with Padcev (enfortumab vedotin-ejfv), in the first-line setting for the treatment of patients with unresectable locally advanced or metastatic urothelial cancer who are not eligible for cisplatin-containing chemotherapy. The FDA's Breakthrough Therapy designation is intended to expedite the development and review of a candidate that is planned for use, alone or in combination, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

In January 2021, Merck announced first-time data from the Phase 3 KEYNOTE-598 study evaluating *Keytruda* in combination with ipilimumab (Yervoy) compared with *Keytruda* monotherapy as first-line treatment for patients with metastatic NSCLC without EGFR or ALK genomic tumor aberrations and whose tumors express PD-L1 (tumor proportion score ≥50%). Results of the study showed that the addition of ipilimumab to *Keytruda* did not improve OS or PFS but added toxicity compared with *Keytruda* monotherapy in these patients. These results were presented in the Presidential Symposium at the IASLC 2020 World Conference on Lung Cancer hosted by the International Association for the Study of Lung Cancer in January 2021 and published in the Journal of Clinical Oncology. As previously announced in November 2020, the study was discontinued due to futility based on the recommendation of an independent Data Monitoring Committee (DMC), which determined the benefit/risk profile of *Keytruda* in combination with ipilimumab did not support continuing the trial. The DMC also advised that patients in the study discontinue treatment with ipilimumab/placebo.

In February 2021, Merck's announced that the Phase 3 KEYNOTE-122 trial evaluating *Keytruda* versus standard of care treatment (capecitabine, gemcitabine, or docetaxel) for the treatment of recurrent or metastatic nasopharyngeal cancer did not meet its primary endpoint of OS. Full results will be presented at a future medical meeting.

In May 2020, Merck and Eisai presented data from analyses of two Phase 2 trials evaluating *Keytruda* plus Lenvima at the 2020 American Society of Clinical Oncology (ASCO) Annual Meeting in which the *Keytruda* plus Lenvima combination demonstrated clinically meaningful objective response rates (ORR): the KEYNOTE-524/ Study 116 trial in patients with unresectable HCC with no prior systemic therapy; and the KEYNOTE-146/Study 111 trial in patients with metastatic clear cell renal cell carcinoma (ccRCC) who progressed following immune checkpoint inhibitor therapy.

In July 2020, Merck and Eisai announced that the FDA issued a CRL regarding Merck's and Eisai's applications seeking accelerated approval for the first-line treatment of patients with unresectable HCC based on this trial, which showed clinically meaningful efficacy in the single-arm setting. These data supported a Breakthrough Therapy designation granted by the FDA in July 2019. Ahead of the PDUFA action dates of Merck's and Eisai's applications, another combination therapy was approved based on a randomized, controlled trial that demonstrated improvement in OS versus standard-of-care treatment. Consequently, the CRL stated that Merck's and Eisai's applications do not provide evidence that *Keytruda* in combination with Lenvima represents a meaningful advantage over available therapies for the treatment of unresectable or metastatic HCC with no prior systemic therapy for advanced disease. Since the applications for KEYNOTE-524/Study 116 no longer meet the criteria for accelerated approval, both companies plan to work with the FDA to take appropriate next steps, which include conducting a well-controlled clinical trial that demonstrates substantial evidence of effectiveness and the clinical benefit of the combination. As such, LEAP-002, the Phase 3 trial evaluating the *Keytruda* plus Lenvima combination as a first-line treatment for advanced HCC, is currently underway and fully enrolled. The CRL does not impact the current approved indications for *Keytruda* or for Lenvima.

In February 2021, Merck and Eisai announced the first presentation of new investigational data from the pivotal Phase 3 CLEAR study (KEYNOTE-581/Study 307) at the 2021 Genitourinary Cancers Symposium (ASCO GU) and published simultaneously in the *New England Journal of Medicine*. The trial evaluated the combinations of *Keytruda* plus Lenvima, and Lenvima plus everolimus versus sunitinib for the first-line treatment of patients with advanced RCC. *Keytruda* plus Lenvima demonstrated statistically significant and clinically meaningful improvements in PFS, OS and ORR versus sunitinib. Lenvima plus everolimus also showed significant improvements in PFS and ORR versus sunitinib. Merck and Eisai will discuss these data with regulatory authorities worldwide, with the intent to submit marketing authorization applications based on these results.

In December 2020, Merck and Eisai announced that the pivotal Phase 3 KEYNOTE-775/Study 309 trial evaluating the investigational use of *Keytruda* plus Lenvima met its dual primary endpoints of OS and PFS and its secondary efficacy endpoint of ORR in patients with advanced endometrial cancer following at least one prior platinum-based regimen. These positive results were observed in the mismatch repair proficient (pMMR) subgroup and the ITT study population, which includes both patients with endometrial carcinoma that is pMMR as well as patients whose disease is MSI-H/dMMR. Based on an analysis conducted by an independent DMC, *Keytruda* plus Lenvima demonstrated a statistically significant and clinically meaningful improvement in OS, PFS and ORR versus chemotherapy. Merck and Eisai will discuss these data with regulatory authorities worldwide, with the intent to

submit marketing authorization applications based on these results, and plan to present these results at an upcoming medical meeting. KEYNOTE-775/Study 309 is the confirmatory trial for KEYNOTE-146/Study 111, which supported accelerated approval by the FDA in 2019 of the *Keytruda* plus Lenvima combination for the treatment of patients with advanced endometrial carcinoma that is not MSI-H or dMMR, who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation.

Merck and Eisai are continuing to study the *Keytruda* plus Lenvima combination through the LEAP (LEnvatinib And Pembrolizumab) clinical program across 19 trials in 13 different tumor types (endometrial carcinoma, HCC, melanoma, NSCLC, RCC, squamous cell carcinoma of the head and neck, urothelial cancer, biliary tract cancer, colorectal cancer, gastric cancer, glioblastoma, ovarian cancer, and TNBC).

MK-6482, belzutifan, is an investigational hypoxia-inducible factor-2α (HIF-2α) inhibitor being evaluated for the treatment of patients with von Hippel-Lindau (VHL) disease-associated RCC with nonmetastatic RCC tumors less than three centimeters in size, unless immediate surgery is required. In July 2020, the FDA granted Breakthrough Therapy designation to belzutifan and has also granted orphan drug designation to belzutifan for VHL disease. These designations are based on data from a Phase 2 trial evaluating belzutifan in patients with VHL-associated ccRCC, which were presented at the 2020 ASCO Annual Meeting. Additionally, Phase 2 data showing anti-tumor responses in VHL disease patients with ccRCC and other tumors were presented at the ESMO Virtual Congress 2020.

In February 2021, Merck and Eisai began a Phase 3 trial examining Lenvima in combination with belzutifan in previously treated patients with metastatic RCC.

MK-7119, Tukysa, is a small molecule tyrosine kinase inhibitor, for the treatment of HER2-positive cancers. In September 2020, Seagen granted Merck an exclusive license and entered into a co-development agreement with Merck to accelerate the global reach of Tukysa. Merck and Seagen also announced a collaboration to globally develop and commercialize Seagen's ladiratuzumab vedotin (MK-6440), an investigational antibody-drug conjugate targeting LIV-1, which is currently in Phase 2 clinical trials for breast cancer and other solid tumors. The collaboration will pursue a broad joint development program evaluating ladiratuzumab vedotin as monotherapy and in combination with *Keytruda* in TNBC, hormone receptor-positive breast cancer and other LIV-1-expressing solid tumors.

MK-7339, Lynparza, is an oral PARP inhibitor currently approved for certain types of advanced ovarian, breast, pancreatic and prostate cancers being co-developed for multiple cancer types as part of a collaboration with AstraZeneca.

MK-7264, gefapixant, is an investigational, orally administered, selective P2X3 receptor antagonist, for the treatment of refractory or unexplained chronic cough. In September 2020, Merck announced the results from two ongoing pivotal Phase 3 trials (COUGH-1 and COUGH-2) evaluating the efficacy and safety of gefapixant. In these studies, adult patients treated with gefapixant 45 mg twice daily demonstrated a statistically significant reduction in 24-hour cough frequency versus placebo at 12 weeks (COUGH-1) and 24 weeks (COUGH-2). The gefapixant 15 mg twice daily treatment arms did not meet the primary efficacy endpoint in either Phase 3 study. These results were presented at the Virtual European Respiratory Society International Congress 2020. Merck plans to share data from COUGH-1 and COUGH-2 with regulatory authorities worldwide.

MK-7110 (also known as CD24Fc) is an investigational treatment for patients hospitalized with COVID-19. Merck obtained MK-7110 through the acquisition of OncoImmune. In September 2020, OncoImmune reported topline findings from an interim efficacy analysis of a Phase 3 study evaluating MK-7110. An interim analysis of data from 203 participants (75% of the planned enrollment) indicated that selected hospitalized patients with COVID-19 treated with a single dose of MK-7110 showed a 60% higher probability of improvement in clinical status compared to placebo, as defined by the protocol. The risk of death or respiratory failure was reduced by more than 50%. Full results from this Phase 3 study, which were consistent with the topline results, were received in February 2021 and will be submitted for publication in the future. MK-7110 is also being studied in a Phase 3 trial for the treatment of graft versus host disease.

Molnupiravir (also known as MK-4482) is an orally available antiviral candidate for the treatment of COVID-19 being developed in collaboration with Ridgeback Biotherapeutics LP. It is currently being evaluated in

Phase 2/3 clinical trials in both the hospital and outpatient settings. The primary completion date for the Phase 2/3 studies is June 2021. The Company anticipates interim efficacy data in the first quarter of 2021.

MK-8591A is a combination of islatravir, the company's investigational oral nucleoside reverse transcriptase translocation inhibitor (NRTTI), and doravirine (*Pifeltro*) being evaluated for the treatment of HIV-1 infection. In October 2020, Merck announced Week 96 data from the Phase 2b trial (NCT03272347) evaluating the efficacy and safety of MK-8591A in treatment-naïve adults with HIV-1 infection. Week 96 findings demonstrated that the combination of islatravir and doravirine maintained virologic suppression similar to *Delstrigo* (doravirine/lamivudine/tenofovir disoproxil fumarate), and the findings were consistent with Week 48 results. Additional Week 96 data from the study show low rates of participants meeting the definition of protocol-defined virologic failure in both the islatravir plus doravirine and the *Delstrigo* treatment arms, and no participants in either arm met the criteria for resistance testing. These data were presented at the virtual 2020 International Congress on Drug Therapy in HIV Infection (HIV Glasgow).

In November 2020, Merck announced a collaboration with the Bill & Melinda Gates Foundation (the foundation) where the foundation is committing to provide funding to support a pivotal Phase 3 study investigating a once-monthly oral pre-exposure prophylaxis (PrEP) option in women and adolescent girls at high risk for acquiring HIV-1 infection in sub-Saharan Africa. The study, IMPOWER 22, will evaluate the efficacy and safety of once-monthly islatravir and is anticipated to begin in early 2021. Merck will be funding the IMPOWER 22 clinical trial in the United States. Merck also plans to conduct additional studies in HIV prevention with islatravir in once-monthly oral PrEP. These studies will include IMPOWER 24, a global Phase 3 clinical trial to evaluate islatravir as a once-monthly oral agent for PrEP at sites across the world and among other key populations impacted by the epidemic, including men who have sex with men and transgender women.

In January 2021, the FDA accepted for standard review a supplemental NDA for Steglatro (ertugliflozin) to incorporate the results of the Phase 3 VERTIS cardiovascular (CV) outcomes trial in the product labeling. The VERTIS CV trial evaluated Steglatro, an oral sodium-glucose cotransporter 2 (SGLT2) inhibitor, versus placebo, added to background standard of care treatment, in patients with type 2 diabetes and atherosclerotic CV disease. The study met the primary endpoint of non-inferiority on major adverse CV events (MACE), which is a composite of CV death, nonfatal myocardial infarction or nonfatal stroke, compared to placebo. The key secondary endpoints of superiority for Steglatro versus placebo for time to the first occurrence of the composite of CV death or hospitalization for heart failure, time to CV death alone and time to the first occurrence of the composite of renal death, dialysis/transplant or doubling of serum creatinine from baseline were not met. While not a pre-specified hypothesis for statistical testing, a reduction in hospitalization for heart failure was observed with Steglatro. A supplemental application was also submitted to the EMA and is currently under review.

In January 2021, the Company announced the discontinuation of the clinical development programs for its COVID-19 vaccine candidates, V590 and V591, following Merck's review of findings from Phase 1 clinical studies for the vaccines. In these studies, both V590 and V591 were generally well tolerated, but the immune responses were inferior to those seen following natural infection and those reported for other SARS-CoV-2/COVID-19 vaccines.

The chart below reflects the Company's research pipeline as of February 22, 2021. Candidates shown in Phase 3 include specific products and the date such candidate entered into Phase 3 development. Candidates shown in Phase 2 include the most advanced compound with a specific mechanism or, if listed compounds have the same mechanism, they are each currently intended for commercialization in a given therapeutic area. Small molecules and biologics are given MK-number designations and vaccine candidates are given V-number designations. Except as otherwise noted, candidates in Phase 1, additional indications in the same therapeutic area (other than with respect to cancer) and additional claims, line extensions or formulations for in-line products are not shown.

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Phase 2	Phase 3 (Phase 3 entry date)	Under Review
Antiviral COVID-19 MK-4482 (molnupiravir)[1] **Cancer** MK-1026 Hematological Malignancies MK-1308 (quavonlimab)[2] Melanoma Non-Small-Cell Lung Solid Tumors MK-1454[2] Head and Neck MK-2140 Advanced Solid Tumors MK-3475 *Keytruda* Advanced Solid Tumors MK-4280[2] Hematological Malignancies Non-Small-Cell Lung MK-4830 Non-Small-Cell Lung MK-5890[2] Non-Small-Cell Lung MK-6440 (ladiratuzumab vedotin)[1][3] Advanced Solid Tumors Breast MK-7119 Tukysa[1] Advanced Solid Tumors Colorectal Gastric MK-7339 Lynparza[1][3] Advanced Solid Tumors MK-7684 (vibostolimab)[2] Melanoma Non-Small-Cell Lung MK-7902 Lenvima[1][2] Advanced Solid Tumors Biliary Tract Colorectal Glioblastoma V937 Breast Cutaneous Squamous Cell Head and Neck Melanoma Solid Tumors **Chikungunya virus** V184 **Cytomegalovirus** V160 **HIV-1 Prevention** MK-8591 (islatravir) **Nonalcoholic Steatohepatitis NASH** MK-3655 **Overgrowth Syndrome** MK-7075 (miransertib) **Pneumococcal Vaccine Adult** V116 **Respiratory Syncytial Virus** MK-1654 **Schizophrenia** MK-8189	**Cancer** MK-3475 *Keytruda* Biliary Tract (September 2019) Cervical (October 2018) (EU) Cutaneous Squamous Cell (August 2019) (EU) Endometrial (August 2019) (EU) Gastric (May 2015) (EU) Hepatocellular (May 2016) (EU) Mesothelioma (May 2018) Ovarian (December 2018) Prostate (May 2019) Small-Cell Lung (May 2017) (EU) MK-6482 (belzutifan) Renal Cell (February 2020) MK-7119 Tukysa[1] Breast (October 2019) MK-7339 Lynparza[1][2] Colorectal[1] (August 2020) Non-Small-Cell Lung[2] (June 2019) Small-Cell Lung[2] (December 2020) MK-7902 Lenvima[1][2] Bladder (May 2019) Endometrial (June 2018) (EU) Gastric (December 2020) Head and Neck (February 2020) Melanoma (March 2019) Non-Small-Cell Lung (March 2019) **Cough** MK-7264 (gefapixant) (March 2018) **COVID-19** MK-7110 (December 2020) **HIV-1 Infection** MK-8591A (doravirine/islatravir) (February 2020)	**New Molecular Entities/Vaccines** **Bacterial Infection** MK-7655A (relebactam+imipenem/cilastatin) (JPN) **Heart Failure** MK-1242 (vericiguat)[1] (EU) (JPN) **Pediatric Neurofibromatosis Type 1** MK-5618 (selumetinib)[1] (EU) **Pneumococcal Infection Adult** V-114 (U.S.) (EU) **Certain Supplemental Filings** **Cancer** MK-3475 *Keytruda* • Metastatic Triple-Negative Breast Cancer (KEYNOTE-355) (EU) (JPN) • Early-Stage Triple-Negative Breast Cancer (KEYNOTE-522) (U.S.) • Refractory Classical Hodgkin Lymphoma (KEYNOTE-204) (EU) • Unresectable or Metastatic MSI-H or dMMR Colorectal Cancer (KEYNOTE-177) (JPN) • Cutaneous Squamous Cell Cancer (KEYNOTE-629) (U.S.) • Advanced Unresectable Metastatic Esophageal Cancer (KEYNOTE-590) (U.S.) (EU) (JPN) • First-Line Metastatic HER2+ Gastric Cancer (KEYNOTE-811) (U.S.) MK-7902 Lenvima[1] • First-Line Metastatic Hepatocellular Carcinoma (KEYNOTE-524) (U.S.)[2][4] • Thymic Carcinoma (NCCH1508/REMORA) (JPN)

Footnotes:

[1] Being developed in a collaboration.

[2] Being developed in combination with *Keytruda*.

[3] Being developed as monotherapy and in combination with *Keytruda.*

[4] In July 2020, the FDA issued a CRL for Merck's and Eisai's applications. Merck and Eisai intend to submit additional data when available to the FDA.

Human Capital

As of December 31, 2020, the Company had approximately 74,000 employees worldwide, with approximately 27,000 employed in the United States, including Puerto Rico, and approximately 26,000 third-party contractors globally. Approximately 73,000 of the Company's employees are full time-employees. Women and individuals with ethnically diverse backgrounds comprise approximately 50% and 31% of its workforce in the United States, respectively. Women comprise 46% of the members of the Board of Directors. Additionally, the Company's executive team, which includes individuals up to two structural levels below the Chief Executive

Officer, is made up of 34% women. Approximately 30% of the Company's employees are represented by various collective bargaining groups.

The Company recognizes that its employees are critical to meet the needs of its patients and customers and that its ability to excel depends on the integrity, skill, and diversity of its employees.

Talent Acquisition

The Company uses a comprehensive approach to ensure recruiting, retention and leadership development goals are systematically executed throughout the Company and that it hires talented leaders to achieve improved gender parity and representation across all dimensions of diversity. The Company provides training to its managers and external recruiting organizations on strategies to mitigate unconscious bias in the candidate selection and hiring process. In addition, the Company utilizes a comprehensive communications strategy, marketing outreach, social media and strategic alliance partnerships to reach a broad pool of talent in its critical business areas. In 2020, the Company hired approximately 10,000 employees across the globe through various channels including the Company's external career site, diversity partnerships, employee referrals, universities and other external sources.

Global Diversity and Inclusion

Diversity and inclusion are fundamental to the Company's success and core to future innovation. The Company fosters a globally diverse and inclusive workforce for its employees by creating an environment of belonging, engagement, equity, and empowerment. The Company is proactive and intentional about diversity hiring and development programs to advance talent. The Company creates competitive advantages by leveraging diversity and inclusion to accelerate business performance. This includes fostering global supplier diversity, integrating diversity and inclusion into the Company's commercialization strategies and leveraging employee insights to improve performance. In addition to these efforts, the Company has ten Employee Business Resource Groups, that provide opportunities for employees to take an active part in contributing to the Company's inclusive culture through their work in talent acquisition and development, business and customer insights and social and community outreach.

Gender and Ethnicity Performance Data[1]	2020	2019	2018
Women in the workforce	49%	49%	49%
Women in the workforce in the U.S.	50%	50%	NR
Women on the Board of Directors	46%	33%	23%
Women in executive roles[2]	34%	36%	32%
Women in management roles[3]	43%	43%	41%
Members of underrepresented ethnic groups on the Board of Directors	23%	17%	15%
Members of underrepresented ethnic groups in executive roles (U.S.)	22%	26%	21%
Members of underrepresented ethnic groups in the workforce (U.S.)	31%	29%	27%
Members of underrepresented ethnic groups in management roles (U.S.)	29%	27%	25%
New hires that were female	50%	50%	51%
New hires that were members of underrepresented ethnic groups (U.S.)	42%	33%	36%

NR: Not reported.

[1] As of 12/31.

[2] "Executive" is defined as the chief executive officer and two structural levels below.

[3] "Management role" is defined as all managers with direct reports other than executives defined in note 2.

Compensation and Benefits

The Company provides a valuable total rewards package reflecting its commitment to attract, retain and motivate its talent, and to supporting its employees and their families in every stage of life. The Company continuously monitors and adjusts its compensation and benefit programs to ensure they are competitive, contemporary, helpful and engaging, and that they support strategic imperatives such as diversity and inclusion, equity, flexibility, quality, security and affordability. For example, in 2020, the Company added a personal health care concierge service to assist U.S. employees participating in the Company medical plan with their health care

needs. Aligned with its business and in support of its cancer care strategy, the Company also improved cancer screening benefits, added resources and provided immediate access to a leading cancer center of excellence for U.S. employees. Globally, the Company implemented a minimum standard of 12 weeks of paid parental leave, which inclusively applies to all parents. In the United States, the Company's benefits rank in the top quartile of Fortune 100 companies under the Aon Hewitt 2019 Benefits Index. The Company has been included in the Working Mother 100 Best Companies ranking for 34 consecutive years and was named a Working Mother Best Company for Dads in 2020.

Employee Wellbeing

The Company is committed to helping its employees and their families improve their own health and wellbeing. The Company's culture of wellbeing is referred to as "*Live it*", which includes programs to support preventive health, emotional and financial wellbeing, physical fitness and nutrition. It is designed to inspire all employees to pursue, enjoy, and share healthy lifestyles. *Live it* was launched in the United States in 2011 and today is available in every country in which the Company has employees. In addition, many of the Company's larger sites offer onsite health clinics that provide an array of services to help its employees stay or get well, including vaccinations, cancer and biometric screenings, travel medicine and advice, diagnosis and treatment of non-occupational illnesses or injuries, health counseling and referrals. The Company's overall employee wellbeing program was recognized for excellence in health and wellbeing by receiving the highest-level awards from the Business Group on Health (2019 and 2020), and the American Heart Association (2018-2020).

COVID-19 Response

The Company recognizes that it has a unique responsibility to help in response to the COVID-19 pandemic and is committed to supporting and protecting its employees and their families, ensuring that its supply of medicines and vaccines reaches its patients, contributing its scientific expertise to the development of antiviral approaches and supporting its health care providers and the communities in which they serve. The Company continues to provide employees with easy and regular access to information, including details regarding the Company's tracking process, guidance around hygiene measures and travel and best practices for working from home. Examples of pandemic support resources and programs available to the Company's employees include pay continuation for workers who have been sick or exposed, volunteer policy adjustment to enable employees with medical backgrounds to volunteer in SARS-CoV-2-related activities, resources to prioritize physical and mental wellness, adjustments to medical plans to cover 100% of a COVID-19-related diagnosis, testing and treatment, backup childcare and more.

Engaging Employees

The Company strives to foster employee engagement by promoting a safe, positive, diverse and inclusive work environment that provides numerous opportunities for two-way communication with employees. Some of the Company's key programs and initiatives include promoting global employee engagement surveys, ongoing pulse checks to the organization for interim feedback on specific topics, fostering professional networking and collaboration, identifying and providing opportunities for volunteering and establishing positive, cooperative business relations with designated employee representatives.

Talent Management and Development

As the Company pursues its goal of becoming the world's premier research-based biopharmaceutical company, it needs to continuously develop its diverse and talented people. The Company's current talent management system supports company-wide performance management, development, talent reviews and succession planning. Annual performance reviews help further the professional development of the Company's employees and ensure that the Company's workforce is aligned with the Company's objectives. The Company seeks to continuously build the skills and capabilities of its workforce to accelerate talent, improve performance and mitigate risk through relevant continuous learning experiences. This includes, but is not limited to, building leadership and management skills, as well as providing technical and functional training to all employees.

Environmental Matters

The Company believes that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on the Company. The Company is also remediating environmental contamination resulting from past industrial activity at certain of its sites. Expenditures for

remediation and environmental liabilities were $11 million in 2020 and are estimated at $46 million in the aggregate for the years 2021 through 2025. These amounts do not consider potential recoveries from other parties. The Company has taken an active role in identifying and accruing for these costs and, in management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $67 million at both December 31, 2020 and 2019. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed approximately $65 million in the aggregate. Management also does not believe that these expenditures should have a material adverse effect on the Company's financial condition, results of operations, liquidity or capital resources for any year.

Merck believes that climate change could present risks to its business. Some of the potential impacts of climate change to its business include increased operating costs due to additional regulatory requirements, physical risks to the Company's facilities, water limitations and disruptions to its supply chain. These potential risks are integrated into the Company's business planning including investment in reducing energy usage, water use and greenhouse gas emissions. The Company does not believe these risks are material to its business at this time.

Geographic Area Information

The Company's operations outside the United States are conducted primarily through subsidiaries. Sales worldwide by subsidiaries outside the United States as a percentage of total Company sales were 56% in both 2020 and 2019 and were 57% in 2018.

The Company's worldwide business is subject to risks of currency fluctuations, governmental actions and other governmental proceedings abroad. The Company does not regard these risks as a deterrent to further expansion of its operations abroad. However, the Company closely reviews its methods of operations and adopts strategies responsive to changing economic and political conditions.

Merck has operations in countries located in Latin America, the Middle East, Africa, Eastern Europe and Asia Pacific. Business in these developing areas, while sometimes less stable, offers important opportunities for growth over time.

Available Information

The Company's Internet website address is *www.merck.com*. The Company will make available, free of charge at the "Investors" portion of its website, its Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after such reports are electronically filed with, or furnished to, the U.S. Securities and Exchange Commission (SEC). The address of that website is www.sec.gov. In addition, the Company will provide without charge a copy of its Annual Report on Form 10-K, including financial statements and schedules, upon the written request of any shareholder to the Office of the Secretary, Merck & Co., Inc., 2000 Galloping Hill Road, K1-4157, Kenilworth, NJ 07033 U.S.A.

The Company's corporate governance guidelines and the charters of the Board of Directors' four standing committees are available on the Company's website at *www.merck.com/company-overview/leadership* and all such information is available in print to any shareholder who requests it from the Company.

Item 1A. Risk Factors.

Summary Risk Factors

The Company is subject to a number of risks that if realized could materially adversely affect its business, results of operations, cash flow, financial condition or prospects. The following is a summary of the principal risk factors facing the Company:

- The Company is dependent on its patent rights, and if its patent rights are invalidated or circumvented, its business could be materially adversely affected.
- As the Company's products lose market exclusivity, the Company generally experiences a significant and rapid loss of sales from those products.

- Key products generate a significant amount of the Company's profits and cash flows, and any events that adversely affect the markets for its leading products could have a material adverse effect on the Company's results of operations and financial condition.
- The Company's research and development efforts may not succeed in developing commercially successful products and the Company may not be able to acquire commercially successful products in other ways; in consequence, the Company may not be able to replace sales of successful products that lose patent protection.
- The Company's success is dependent on the successful development and marketing of new products, which are subject to substantial risks.
- The Company faces continued pricing pressure with respect to its products.
- The uncertainty in global economic conditions together with cost-reduction measures being taken by certain governments could negatively affect the Company's operating results.
- The Company faces intense competition from lower cost generic products.
- The Company faces intense competition from competitors' products.
- The global COVID-19 pandemic is having an adverse impact on the Company's business, operations and financial performance. The Company is unable to predict the full extent to which the COVID-19 pandemic or any future pandemic, epidemic or similar public health threat will adversely impact its business, operations, financial performance, results of operations, and financial condition.
- The Company has significant global operations, which expose it to additional risks, and any adverse event could have a material adverse effect on the Company's results of operations and financial condition.
- Failure to attract and retain highly qualified personnel could affect the Company's ability to successfully develop and commercialize products.
- In the past, the Company has experienced difficulties and delays in manufacturing certain of its products, including vaccines.
- The Company may not be able to realize the expected benefits of its investments in emerging markets.
- The Company is exposed to market risk from fluctuations in currency exchange rates and interest rates.
- Pharmaceutical products can develop unexpected safety or efficacy concerns.
- Reliance on third-party relationships and outsourcing arrangements could materially adversely affect the Company's business.
- Negative events in the animal health industry could have a material adverse effect on future results of operations and financial condition.
- Biologics and vaccines carry unique risks and uncertainties, which could have a material adverse effect on the Company's future results of operations and financial condition.
- The health care industry in the United States has been, and will continue to be, subject to increasing regulation and political action.
- The Company's products, including products in development, cannot be marketed unless the Company obtains and maintains regulatory approval.
- Developments following regulatory approval may adversely affect sales of the Company's products.
- The Company is subject to a variety of U.S. and international laws and regulations.

- The Company is subject to evolving and complex tax laws, which may result in additional liabilities that may affect results of operations and financial condition.
- Product liability insurance for products may be limited, cost prohibitive or unavailable.
- The Company is increasingly dependent on sophisticated software applications, computing infrastructure and cloud service providers. In 2017, the Company experienced a network cyber-attack that led to a disruption of its worldwide operations, including manufacturing, research and sales operations. The Company could be a target of future cyber-attacks.
- Social media platforms present risks and challenges.
- The proposed Spin-Off of Organon may not be completed on the terms or timeline currently contemplated, if at all, and may not achieve the expected results.
- The costs to complete the proposed Spin-Off will be significant. In addition, the Company may be unable to achieve some or all of the strategic and financial benefits that it expects to achieve from the Spin-Off of Organon.
- Following the Spin-Off, the price of shares of the Company's common stock may fluctuate significantly.
- There could be significant income tax liability if the Spin-Off or certain related transactions are determined to be taxable for U.S. federal income tax purposes.

The above list is not exhaustive, and the Company faces additional challenges and risks. Investors should carefully consider all of the information set forth in this Form 10-K, including the following risk factors, before deciding to invest in any of the Company's securities.

Risk Factors

The risks below are not the only ones the Company faces. Additional risks not currently known to the Company or that the Company presently deems immaterial may also impair its business operations. The Company's business, financial condition, results of operations, cash flow or prospects could be materially adversely affected by any of these risks. This Form 10-K also contains forward-looking statements that involve risks and uncertainties. The Company's results could materially differ from those anticipated in these forward-looking statements as a result of certain factors, including the risks it faces described below and elsewhere. See "Cautionary Factors that May Affect Future Results" below.

Risks Related to the Company's Business

The Company is dependent on its patent rights, and if its patent rights are invalidated or circumvented, its business could be materially adversely affected.

Patent protection is considered, in the aggregate, to be of material importance to the Company's marketing of human health and animal health products in the United States and in most major foreign markets. Patents covering products that it has introduced normally provide market exclusivity, which is important for the successful marketing and sale of its products. The Company seeks patents covering each of its products in each of the markets where it intends to sell the products and where meaningful patent protection is available.

Even if the Company succeeds in obtaining patents covering its products, third parties or government authorities may challenge or seek to invalidate or circumvent its patents and patent applications. It is important for the Company's business to defend successfully the patent rights that provide market exclusivity for its products. The Company is often involved in patent disputes relating to challenges to its patents or claims by third parties of infringement against the Company. The Company defends its patents both within and outside the United States, including by filing claims of infringement against other parties. See Item 8. "Financial Statements and Supplementary Data," Note 10. "Contingencies and Environmental Liabilities" below. In particular, manufacturers of generic pharmaceutical products from time to time file abbreviated NDAs with the FDA seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned or licensed by the Company. The Company normally responds by defending its patent, including by filing lawsuits alleging patent

infringement. Patent litigation and other challenges to the Company's patents are costly and unpredictable and may deprive the Company of market exclusivity for a patented product or, in some cases, third-party patents may prevent the Company from marketing and selling a product in a particular geographic area.

Additionally, certain foreign governments have indicated that compulsory licenses to patents may be granted in the case of national emergencies or in other circumstances, which could diminish or eliminate sales and profits from those regions and negatively affect the Company's results of operations. Further, court decisions relating to other companies' patents, potential legislation in both the United States and certain foreign markets relating to patents, as well as regulatory initiatives may result in a more general weakening of intellectual property protection.

If one or more important products lose patent protection in profitable markets, sales of those products are likely to decline significantly as a result of generic versions of those products becoming available. The Company's results of operations may be adversely affected by the lost sales unless and until the Company has launched commercially successful products that replace the lost sales. In addition, if products that were measured at fair value and capitalized in connection with acquisitions experience difficulties in the market that negatively affect product cash flows, the Company may recognize material non-cash impairment charges with respect to the value of those products.

A chart listing the patent protection for certain of the Company's marketed products, and U.S. patent protection for candidates in Phase 3 clinical development is set forth above in Item 1. "Business — Patents, Trademarks and Licenses."

As the Company's products lose market exclusivity, the Company generally experiences a significant and rapid loss of sales from those products.

The Company depends upon patents to provide it with exclusive marketing rights for its products for some period of time. Loss of patent protection for one of the Company's products typically leads to a significant and rapid loss of sales for that product as lower priced generic versions of that drug become available. In the case of products that contribute significantly to the Company's sales, the loss of market exclusivity can have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects. For example, the patent that provided U.S. market exclusivity for *NuvaRing* expired in April 2018 and generic competition began in December 2019. The Company experienced a rapid and substantial decline in U.S. *NuvaRing* sales in 2020 as a result of this generic competition. In addition, *Januvia* and *Janumet* will lose market exclusivity in the United States in January 2023. *Januvia* will lose market exclusivity in the EU in September 2022. Finally, the SPC that provides market exclusivity for *Janumet* in the EU expires in April 2023. The Company anticipates sales of *Januvia* and *Janumet* in these markets will decline substantially after the loss of market exclusivity.

Key products generate a significant amount of the Company's profits and cash flows, and any events that adversely affect the markets for its leading products could have a material adverse effect on the Company's results of operations and financial condition.

The Company's ability to generate profits and operating cash flow depends largely upon the continued profitability of the Company's key products, such as *Keytruda, Gardasil/Gardasil* 9, *Januvia*, *Janumet*, and *Bridion*. In particular, in 2020, the Company's oncology portfolio, led by *Keytruda,* represented the vast majority of the Company's revenue growth. As a result of the Company's dependence on key products, any event that adversely affects any of these products or the markets for any of these products could have a significant adverse impact on results of operations and cash flows. These events could include loss of patent protection, increased costs associated with manufacturing, generic or over-the-counter availability of the Company's product or a competitive product, the discovery of previously unknown side effects, results of post-approval trials, increased competition from the introduction of new, more effective treatments and discontinuation or removal from the market of the product for any reason. Such events could have a material adverse effect on the sales of any such products.

The Company's research and development efforts may not succeed in developing commercially successful products and the Company may not be able to acquire commercially successful products in other ways; in consequence, the Company may not be able to replace sales of successful products that lose patent protection.

In order to remain competitive, the Company, like other major pharmaceutical companies, must continue to launch new products. Expected declines in sales of products after the loss of market exclusivity mean that the Company's future success is dependent on its pipeline of new products, including new products that it may develop through collaborations and joint ventures and products that it is able to obtain through license or acquisition. To accomplish this, the Company commits substantial effort, funds and other resources to research and development, both through its own dedicated resources and through various collaborations with third parties. There is a high rate of failure inherent in the research and development process for new drugs and vaccines. As a result, there is a high risk that funds invested by the Company in research programs will not generate financial returns. This risk profile is compounded by the fact that this research has a long investment cycle. To bring a pharmaceutical compound from the discovery phase to market may take a decade or more and failure can occur at any point in the process, including later in the process after significant funds have been invested.

For a description of the research and development process, see Item 1. "Business — Research and Development" above. Each phase of testing is highly regulated and during each phase there is a substantial risk that the Company will encounter serious obstacles or will not achieve its goals. Therefore, the Company may abandon a product in which it has invested substantial amounts of time and resources. Some of the risks encountered in the research and development process include the following: pre-clinical testing of a new compound may yield disappointing results; competing products from other manufacturers may reach the market first; clinical trials of a new drug may not be successful; a new drug may not be effective or may have harmful side effects; a new drug may not be approved by the regulators for its intended use; it may not be possible to obtain a patent for a new drug; payers may refuse to cover or reimburse the new product; or sales of a new product may be disappointing.

The Company cannot state with certainty when or whether any of its products now under development will be approved or launched; whether it will be able to develop, license or otherwise acquire compounds, product candidates or products; or whether any products, once launched, will be commercially successful. The Company must maintain a continuous flow of successful new products and successful new indications for existing products sufficient both to cover its substantial research and development costs and to replace sales that are lost as profitable products lose market exclusivity or are displaced by competing products or therapies. Failure to do so in the short term or long term would have a material adverse effect on the Company's business, results of operations, cash flow, financial condition and prospects.

The Company's success is dependent on the successful development and marketing of new products, which are subject to substantial risks.

Products that appear promising in development may fail to reach the market or fail to succeed for numerous reasons, including the following:

- findings of ineffectiveness, superior safety or efficacy of competing products, or harmful side effects in clinical or pre-clinical testing;
- failure to receive the necessary regulatory approvals, including delays in the approval of new products and new indications, or the anticipated labeling, and uncertainties about the time required to obtain regulatory approvals and the benefit/risk standards applied by regulatory agencies in determining whether to grant approvals;
- failure in certain markets to obtain reimbursement commensurate with the level of innovation and clinical benefit presented by the product;
- lack of economic feasibility due to manufacturing costs or other factors; and
- preclusion from commercialization by the proprietary rights of others.

In the future, if certain pipeline programs are cancelled or if the Company believes that their commercial prospects have been reduced, the Company may recognize material non-cash impairment charges for those programs that were measured at fair value and capitalized in connection with acquisitions or certain collaborations.

Failure to successfully develop and market new products in the short term or long term would have a material adverse effect on the Company's business, results of operations, cash flow, financial condition and prospects.

The Company faces continued pricing pressure with respect to its products.

The Company faces continued pricing pressure globally and, particularly in mature markets, from managed care organizations, government agencies and programs that could negatively affect the Company's sales and profit margins. In the United States, these include (i) practices of managed care groups and institutional and governmental purchasers, (ii) U.S. federal laws and regulations related to Medicare and Medicaid, including the Medicare Prescription Drug Improvement and Modernization Act of 2003 and the ACA, and (iii) state activities aimed at increasing price transparency, including new laws as noted above in Item 1. "Competition and the Health Care Environment." Changes to the health care system enacted as part of health care reform in the United States, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, could result in further pricing pressures. In addition, in the United States, larger customers have received higher rebates on drugs in certain highly competitive categories. The Company must also compete to be placed on formularies of managed care organizations. Exclusion of a product from a formulary can lead to reduced usage in the managed care organization.

In order to provide information about the Company's pricing practices, the Company annually posts on its website its Pricing Transparency Report for the United States. The report provides the Company's average annual list price and net price increases across the Company's U.S. portfolio dating back to 2010. In 2020, the Company's gross U.S. sales were reduced by 45.5% as a result of rebates, discounts and returns.

Outside the United States, numerous major markets, including the EU, Japan and China have pervasive government involvement in funding health care and, in that regard, fix the pricing and reimbursement of pharmaceutical and vaccine products. Consequently, in those markets, the Company is subject to government decision making and budgetary actions with respect to its products. In Japan, the pharmaceutical industry is subject to government-mandated biennial price reductions of pharmaceutical products and certain vaccines. Furthermore, the government can order re-pricing for specific products if it determines that use of such product will exceed certain thresholds defined under applicable re-pricing rules. The next government-mandated price reduction will occur in April 2021 and is expected to impact many Company products.

The Company expects pricing pressures to continue in the future.

The uncertainty in global economic conditions together with cost-reduction measures being taken by certain governments could negatively affect the Company's operating results.

Uncertainty in global economic and geopolitical conditions may result in a slowdown to the global economy that could affect the Company's business by reducing the prices that drug wholesalers and retailers, hospitals, government agencies and managed health care providers may be able or willing to pay for the Company's products or by reducing the demand for the Company's products, which could in turn negatively impact the Company's sales and result in a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects.

As discussed above in "Competition and the Health Care Environment," global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. Changes to the U.S. health care system as part of health care reform, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, have contributed to pricing pressure. In several international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. In addition, the Company's revenue performance in 2020 was negatively affected by other cost-reduction measures taken by governments and other third-parties to lower health care costs. The Company anticipates all of these actions, and additional actions in the future, will continue to negatively affect revenue performance.

If credit and economic conditions worsen, the resulting economic and currency impacts in the affected markets and globally could have a material adverse effect on the Company's results.

The Company faces intense competition from lower cost generic products.

In general, the Company faces increasing competition from lower-cost generic products. The patent rights that protect its products are of varying strengths and durations. In addition, in some countries, patent protection is significantly weaker than in the United States or in the EU. In the United States and the EU, political pressure to reduce spending on prescription drugs has led to legislation and other measures that encourage the use of generic and biosimilar products. Although it is the Company's policy to actively protect its patent rights, generic challenges to the Company's products can arise at any time, and the Company's patents may not prevent the emergence of generic competition for its products.

Loss of patent protection for a product typically is followed promptly by generic substitutes, reducing the Company's sales of that product. Availability of generic substitutes for the Company's drugs may adversely affect its results of operations and cash flow. In addition, proposals emerge from time to time in the United States and other countries for legislation to further encourage the early and rapid approval of generic drugs. Any such proposal that is enacted into law could worsen this substantial negative effect on the Company's sales and, potentially, its business, cash flow, results of operations, financial condition and prospects.

The Company faces intense competition from competitors' products.

The Company's products face intense competition from competitors' products. This competition may increase as new products enter the market. In such an event, the competitors' products may be safer or more effective, more convenient to use, have better insurance coverage or reimbursement levels or be more effectively marketed and sold than the Company's products. Alternatively, in the case of generic competition, including the generic availability of competitors' branded products, they may be equally safe and effective products that are sold at a substantially lower price than the Company's products. As a result, if the Company fails to maintain its competitive position, this could have a material adverse effect on its business, cash flow, results of operations, financial condition and prospects. In addition, if products that were measured at fair value and capitalized in connection with acquisitions experience difficulties in the market that negatively impact product cash flows, the Company may recognize material non-cash impairment charges with respect to the value of those products.

The global COVID-19 pandemic is having an adverse impact on the Company's business, operations and financial performance. The Company is unable to predict the full extent to which the COVID-19 pandemic or any future pandemic, epidemic or similar public health threat will adversely impact its business, operations, financial performance, results of operations, and financial condition.

The Company's business and financial results were negatively impacted by the outbreak of COVID-19 in 2020. The continued duration and severity of the COVID-19 pandemic is uncertain, rapidly changing and difficult to predict. The degree to which COVID-19 impacts the Company's results in 2021 will depend on future developments, beyond the Company's knowledge or control, including, but not limited to, the duration of the outbreak, its severity, the success of actions taken to contain or prevent the virus or treat its impact, and how quickly and to what extent normal economic and operating conditions can resume.

In 2020, the COVID-19 pandemic impacted the Company's business in numerous ways. As expected, within the Company's human health business, revenue was negatively impacted by reduced access to health care providers given social distancing measures, which negatively affected vaccine and oncology sales in particular. The estimated overall negative impact of the COVID-19 pandemic to Merck's revenue for the full year 2020 was approximately $2.5 billion, largely attributable to the Pharmaceutical segment, with approximately $50 million attributable to the Animal Health segment.

Roughly two-thirds of Merck's Pharmaceutical segment revenue is comprised of physician-administered products, which, despite strong underlying demand, have been affected by social distancing measures, fewer well visits and delays in elective surgeries due to the COVID-19 pandemic. These impacts, as well as the prioritization of COVID-19 patients at health care providers, have resulted in reduced administration of many of the Company's human health products, in particular for its vaccines, including *Gardasil* 9, as well as for *Keytruda* and *Implanon/*

Nexplanon. In addition, declines in elective surgeries negatively affected the demand for *Bridion*. However, sales of *Pneumovax* 23 have increased due to heightened awareness of pneumococcal vaccination.

Merck believes that global health systems and patients have largely adapted to the impacts of COVID-19, but the Company's assumption is that ongoing residual negative impacts will persist, particularly during the first half of 2021 and most notably with respect to vaccine sales, with the impact expected to be more acute in the United States. For the full year of 2021, Merck assumes an unfavorable impact to revenue of approximately 2% due to the COVID-19 pandemic, all of which relates to Pharmaceutical segment sales. In addition, for the full year of 2021, with respect to the COVID-19 pandemic, Merck expects a net negative impact to operating expenses, as spending on the development of its COVID-19 antiviral programs is expected to exceed the favorable impact of lower spending in other areas due to the COVID-19 pandemic. Despite the Company's efforts to manage these impacts, their ultimate impact will also depend on factors beyond the Company's knowledge or control, including the duration of the COVID-19 virus as well as governmental and third-party actions taken to contain or prevent its spread, treat the virus and mitigate its public health and economic effects. In addition, any future pandemic, epidemic or similar public health threat could present similar risks to the Company's business, cash flow, results of operations, financial condition and prospects.

The Company has significant global operations, which expose it to additional risks, and any adverse event could have a material adverse effect on the Company's results of operations and financial condition.

The extent of the Company's operations outside the United States is significant. Risks inherent in conducting a global business include:

- changes in medical reimbursement policies and programs and pricing restrictions in key markets;
- multiple regulatory requirements that could restrict the Company's ability to manufacture and sell its products in key markets;
- trade protection measures and import or export licensing requirements, including the imposition of trade sanctions or similar restrictions by the United States or other governments;
- foreign exchange fluctuations;
- diminished protection of intellectual property in some countries; and
- possible nationalization and expropriation.

In addition, there may be changes to the Company's business and political position if there is instability, disruption or destruction in a significant geographic region, regardless of cause, including war, terrorism, riot, civil insurrection or social unrest; and natural or man-made disasters, including famine, flood, fire, earthquake, storm or disease.

Failure to attract and retain highly qualified personnel could affect the Company's ability to successfully develop and commercialize products.

The Company's success is largely dependent on its continued ability to attract and retain highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical research and development, governmental regulation and commercialization. Competition for qualified personnel in the pharmaceutical industry is intense. The Company cannot be sure that it will be able to attract and retain quality personnel or that the costs of doing so will not materially increase.

In the past, the Company has experienced difficulties and delays in manufacturing certain of its products, including vaccines.

Merck has, in the past, experienced difficulties in manufacturing certain of its products, including vaccines. For example, in 2020 the Company issued a product recall for *Zerbaxa* following the identification of product sterility issues. The Company may, in the future, experience other difficulties and delays in manufacturing its products, such as (i) failure of the Company or any of its vendors or suppliers to comply with Current Good Manufacturing Practices and other applicable regulations and quality assurance guidelines that could lead to

manufacturing shutdowns, product shortages and delays in product manufacturing; (ii) delays related to the construction of new facilities or the expansion of existing facilities, including those intended to support future demand for the Company's products; and (iii) other manufacturing or distribution problems including changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, changes in types of products produced, or physical limitations that could impact continuous supply. In addition, the Company could experience difficulties or delays in manufacturing its products caused by natural disasters, such as hurricanes. Manufacturing difficulties can result in product shortages, leading to lost sales and reputational harm to the Company.

The Company may not be able to realize the expected benefits of its investments in emerging markets.

The Company has been taking steps to increase its sales in emerging markets. However, there is no guarantee that the Company's efforts to expand sales in these markets will succeed. Some countries within emerging markets may be especially vulnerable to periods of global financial instability or may have very limited resources to spend on health care. In order for the Company to successfully implement its emerging markets strategy, it must attract and retain qualified personnel. The Company may also be required to increase its reliance on third-party agents within less developed markets. In addition, many of these countries have currencies that fluctuate substantially and, if such currencies devalue and the Company cannot offset the devaluations, the Company's financial performance within such countries could be adversely affected.

The Company's business in China has grown rapidly in the past few years, and the importance of China to the Company's overall pharmaceutical and vaccines business outside the United States has increased accordingly. Continued growth of the Company's business in China is dependent upon ongoing development of a favorable environment for innovative pharmaceutical products and vaccines, sustained access for the Company's currently marketed products, and the absence of trade impediments or adverse pricing controls. As noted above in "Competition and the Health Care Environment," pricing pressure in China has increased as the Chinese government has been taking steps to reduce costs, including implementing health care reform that has led to the acceleration of generic substitution, where available. In 2017, the Chinese government updated the NRDL for the first time in eight years. While the mechanism for drugs being added to the list evolves, inclusion may require a price negotiation which could impact the outlook in the market for selected brands. In 2020, drugs were added to the NRDL through double-digit price reductions. While pricing pressure has always existed in China, health care reform has increased this pressure in part due to the acceleration of generic substitution through the government's VBP program. In 2019, the government implemented the VBP program through a tendering process for mature products which have generic substitutes with a Generic Quality Consistency Evaluation approval. Mature products that have entered into the first three rounds of VBP had, on average, a price reduction of 50%. The Company expects VBP to be a semi-annual process that will have a significant impact on mature products moving forward. In addition, the Company anticipates that the reported inquiries made by various governmental authorities involving multinational pharmaceutical companies in China may continue.

For all these reasons, sales within emerging markets carry significant risks. However, at the same time macro-economic growth of selected emerging markets is expected to outpace Europe and even the United States, leading to significant increased headcount spending in those countries and access to innovative medicines for patients. A failure to maintain the Company's presence in emerging markets could therefore have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects.

The Company is exposed to market risk from fluctuations in currency exchange rates and interest rates.

The Company operates in multiple jurisdictions and virtually all sales are denominated in currencies of the local jurisdiction. Additionally, the Company has entered and will enter into business development transactions, borrowings or other financial transactions that may give rise to currency and interest rate exposure.

Since the Company cannot, with certainty, foresee and mitigate against such adverse fluctuations, fluctuations in currency exchange rates, interest rates and inflation could negatively affect the Company's business, cash flow, results of operations, financial condition and prospects.

In order to mitigate against the adverse impact of these market fluctuations, the Company will from time to time enter into hedging agreements. While hedging agreements, such as currency options and forwards and interest rate swaps, may limit some of the exposure to exchange rate and interest rate fluctuations, such attempts to mitigate these risks may be costly and not always successful.

Certain of the Company's interest rate derivatives and investments are based on the London Interbank Offered Rate (LIBOR), and a portion of Merck's indebtedness bears interest at variable interest rates, primarily based on LIBOR. LIBOR is the subject of recent national, international and other regulatory guidance and proposals for reform, which will cause LIBOR to cease to exist entirely in the future. While the Company expects that reasonable alternatives to LIBOR will be implemented prior to its termination, the Company cannot predict the consequences and timing of these developments, which could include an increase in interest expense and may also require the amendment of contracts that reference LIBOR.

Pharmaceutical products can develop unexpected safety or efficacy concerns.

Unexpected safety or efficacy concerns can arise with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals, or declining sales, as well as product liability, consumer fraud and/or other claims, including potential civil or criminal governmental actions.

Reliance on third-party relationships and outsourcing arrangements could materially adversely affect the Company's business.

The Company depends on third parties, including suppliers, alliances with other pharmaceutical and biotechnology companies, and third-party service providers, for key aspects of its business including development, manufacture and commercialization of its products and support for its information technology (IT) systems. Failure of these third parties to meet their contractual, regulatory and other obligations to the Company or the development of factors that materially disrupt the relationships between the Company and these third parties could have a material adverse effect on the Company's business.

Negative events in the animal health industry could have a material adverse effect on future results of operations and financial condition.

Future sales of key animal health products could be adversely affected by a number of risk factors including certain risks that are specific to the animal health business. For example, the outbreak of disease carried by animals, such as African Swine Fever, could lead to their widespread death and precautionary destruction as well as the reduced consumption and demand for animals, which could adversely affect the Company's results of operations. Also, the outbreak of any highly contagious diseases near the Company's main production sites could require the Company to immediately halt the manufacture of its animal health products at such sites or force the Company to incur substantial expenses in procuring raw materials or products elsewhere. Other risks specific to animal health include epidemics and pandemics, government procurement and pricing practices, weather and global agribusiness economic events. As the Animal Health segment of the Company's business becomes more significant, the impact of any such events on future results of operations would also become more significant.

Biologics and vaccines carry unique risks and uncertainties, which could have a material adverse effect on the Company's future results of operations and financial condition.

The successful development, testing, manufacturing and commercialization of biologics and vaccines, particularly human and animal health vaccines, is a long, complex, expensive and uncertain process. There are unique risks and uncertainties related to biologics and vaccines, including:

- There may be limited access to, and supply of, normal and diseased tissue samples, cell lines, pathogens, bacteria, viral strains and other biological materials. In addition, government regulations in multiple jurisdictions, such as the United States and the EU, could result in restricted access to, or transport or use of, such materials. If the Company loses access to sufficient sources of such materials, or if tighter restrictions are imposed on the use of such materials, the Company may not be able to conduct research activities as planned and may incur additional development costs.

- The development, manufacturing and marketing of biologics and vaccines are subject to regulation by the FDA, the EMA and other regulatory bodies. These regulations are often more complex and extensive than the regulations applicable to other pharmaceutical products. For example, in the United States, a BLA, including both pre-clinical and clinical trial data and extensive data regarding the manufacturing procedures, is required for human vaccine candidates, and FDA approval is generally required for the release of each manufactured commercial lot.
- Manufacturing biologics and vaccines, especially in large quantities, is often complex and may require the use of innovative technologies to handle living micro-organisms. Each lot of an approved biologic and vaccine must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, the Company may be required to provide pre-clinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes.
- Biologics and vaccines are frequently costly to manufacture because production ingredients are derived from living animal or plant material, and most biologics and vaccines cannot be made synthetically. In particular, keeping up with the demand for vaccines may be difficult due to the complexity of producing vaccines.
- The use of biologically derived ingredients can lead to variability in the manufacturing process and could lead to allegations of harm, including infections or allergic reactions, which allegations would be reviewed through a standard investigation process that could lead to closure of product facilities due to possible contamination. Any of these events could result in substantial costs.

Risks Relating to Government Regulation and Legal Proceedings

The health care industry in the United States has been, and will continue to be, subject to increasing regulation and political action.

As discussed above "Competition and the Health Care Environment," the Company believes that the health care industry will continue to be subject to increasing regulation as well as political and legal action, as future proposals to reform the health care system are considered by the Executive branch, Congress and state legislatures.

In 2010, the United States enacted major health care reform legislation in the form of the ACA. Various insurance market reforms have advanced and state and federal insurance exchanges were launched in 2014. The ACA increased the mandated Medicaid rebate from 15.1% to 23.1%, expanded the rebate to Medicaid managed care utilization, and increased the types of entities eligible for the federal 340B drug discount program.

The ACA also requires pharmaceutical manufacturers to pay 70% of the cost of medicine, including biosimilar products, when Medicare Part D beneficiaries are in the Medicare Part D coverage gap (i.e., the so-called "donut hole"). In 2020, the Company's revenue was reduced by approximately $700 million due to this requirement. Also, pharmaceutical manufacturers are required to pay an annual non-tax deductible health care reform fee. In 2020, the Company recorded $85 million of costs for this annual fee.

In February 2016, the Centers for Medicare & Medicaid Services (CMS) issued the Medicaid rebate final rule that implemented provisions of the ACA effective April 1, 2016. The rule provides comprehensive guidance on the calculation of Average Manufacturer Price and Best Price; two metrics utilized to determine the rebates drug manufacturers are required to pay to state Medicaid programs. More recently, although CMS previously declined to define what constitutes a product "line extension" (beyond the statutory definition), CMS issued a new rule on December 21, 2020 that will significantly expand the definition of the term "line extension" as of January 1, 2022 to include a broad range of products, including products reflecting new strengths, dosage forms, release mechanisms, and routes of administration. This expanded definition will increase the number of drugs subject to a higher Medicaid rebate. Effective January 1, 2023, this final rule also changes the way that manufacturers must calculate Best Price, in relation to certain patient support programs, including coupons, which also may result in an increase in

the Company's Medicaid rebates. The impact of these and other provisions in this final rule could adversely impact the Company's business, cash flow, results of operations, financial condition and prospects.

As discussed above in "Competition and the Health Care Environment," in November 2020, the Department of Health and Human Services Office of Inspector General (OIG) issued a Final Rule that would, effective January 1, 2023, eliminate the Anti-Kickback Statute safe harbor for rebates paid to Medicare Part D plans or to PBMs on behalf of such plans. While the Company cannot anticipate the effects of this change to the way it currently contracts, this new framework could significantly alter the way it does business with Part D Plan Sponsors and PBMs on behalf of such plans.

On November 20, 2020, CMS also issued the MFN Rule, which was intended to be effective January 1, 2021, to institute a new pricing system for certain prescription drugs and biologic products covered by Medicare Part B in which Medicare would reimburse no more than the "most favored nation price," meaning the lowest price after adjusting for volume and differences in gross domestic product, for the top fifty Part B reimbursed products, which includes *Keytruda*, sold in 22 member countries of the OECD, rather than use the current Average Sales Price ("ASP")-based payment framework for certain physician-administered drugs. Implementation of the MFN Rule could have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects.

The FDA also recently issued rulemaking allowing the commercial importation of certain prescription drugs from Canada through FDA-authorized, time-limited programs sponsored by states or Native American tribes recognized under the rule, and, in certain future circumstances, pharmacists and wholesalers. The FDA also recently released a final guidance for industry detailing procedures for drug manufacturers to import FDA-approved prescription drug, biological, and combination products that were manufactured abroad and authorized and intended for sale in a foreign country. These changes, if they become effective, could have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects.

Several organizations, including two trade groups of which Merck is a member, have filed suit challenging the MFN Rule. Those lawsuits remain pending with a preliminary injunction having been entered in one of the cases. A trade organization in which Merck is a member brought suit, which is pending, in federal district court challenging the commercial importation rule.

The Company cannot predict the likelihood of these regulations becoming effective or what additional future changes in the health care industry in general, or the pharmaceutical industry in particular, will occur, however, these changes could have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects.

The Company's products, including products in development, cannot be marketed unless the Company obtains and maintains regulatory approval.

The Company's activities, including research, pre-clinical testing, clinical trials and the manufacturing and marketing of its products, are subject to extensive regulation by numerous federal, state and local governmental authorities in the United States, including the FDA, and by foreign regulatory authorities, including in the EU, Japan and China. In the United States, the FDA administers requirements covering the testing, approval, safety, effectiveness, manufacturing, labeling and marketing of prescription pharmaceuticals. In many cases, the FDA requirements have increased the amount of time and money necessary to develop new products and bring them to market in the United States. Regulation outside the United States also is primarily focused on drug safety and effectiveness and, in many cases, reduction in the cost of drugs. The FDA and foreign regulatory authorities, including in Japan and China, have substantial discretion to require additional testing, to delay or withhold registration and marketing approval and to otherwise preclude distribution and sale of a product.

Even if the Company is successful in developing new products, it will not be able to market any of those products unless and until it has obtained all required regulatory approvals in each jurisdiction where it proposes to market the new products. Once obtained, the Company must maintain approval as long as it plans to market its new products in each jurisdiction where approval is required. The Company's failure to obtain approval, significant delays in the approval process, or its failure to maintain approval in any jurisdiction will prevent it from selling the products in that jurisdiction. The Company would not be able to realize revenues for those new products in any jurisdiction where it does not have approval.

Developments following regulatory approval may adversely affect sales of the Company's products.

Even after a product reaches the market, certain developments following regulatory approval may decrease demand for the Company's products, including the following:

- results in post-approval Phase 4 trials or other studies;
- the re-review of products that are already marketed;
- the recall or loss of marketing approval of products that are already marketed;
- changing government standards or public expectations regarding safety, efficacy, quality or labeling changes; and
- scrutiny of advertising and promotion.

In the past, clinical trials and post-marketing surveillance of certain marketed drugs of the Company and of competitors within the industry have raised concerns that have led to recalls, withdrawals or adverse labeling of marketed products. Clinical trials and post-marketing surveillance of certain marketed drugs also have raised concerns among some prescribers and patients relating to the safety or efficacy of pharmaceutical products in general that have negatively affected the sales of such products. In addition, increased scrutiny of the outcomes of clinical trials has led to increased volatility in market reaction. Further, these matters often attract litigation and, even where the basis for the litigation is groundless, considerable resources may be needed to respond.

In addition, following in the wake of product withdrawals and other significant safety issues, health authorities such as the FDA, the EMA, Japan's PMDA and China's NMPA have increased their focus on safety when assessing the benefit/risk balance of drugs. Some health authorities appear to have become more cautious when making decisions about approvability of new products or indications.

If previously unknown side effects are discovered or if there is an increase in negative publicity regarding known side effects of any of the Company's products, it could significantly reduce demand for the product or require the Company to take actions that could negatively affect sales, including removing the product from the market, restricting its distribution or applying for labeling changes. Further, in the current environment in which all pharmaceutical companies operate, the Company is at risk for product liability and consumer protection claims and civil and criminal governmental actions related to its products, research and/or marketing activities. In addition, dissemination of promotional materials through evolving digital channels serves to increase visibility and scrutiny in the marketplace.

The Company is subject to a variety of U.S. and international laws and regulations.

The Company is currently subject to a number of government laws and regulations and, in the future, could become subject to new government laws and regulations. The costs of compliance with such laws and regulations, or the negative results of non-compliance, could adversely affect the business, cash flow, results of operations, financial condition and prospects of the Company; these laws and regulations include (i) additional health care reform initiatives in the United States or in other countries, including additional mandatory discounts or fees; (ii) the U.S. Foreign Corrupt Practices Act or other anti-bribery and corruption laws; (iii) new laws, regulations and judicial or other governmental decisions affecting pricing, drug reimbursement, and access or marketing within or across jurisdictions; (iv) changes in intellectual property laws; (v) changes in accounting standards; (vi) new and increasing data privacy regulations and enforcement, particularly in the EU and the United States; (vii) legislative mandates or preferences for local manufacturing of pharmaceutical or vaccine products; (viii) emerging and new global regulatory requirements for reporting payments and other value transfers to health care professionals; (ix) environmental regulations; and (x) the potential impact of importation restrictions, embargoes, trade sanctions and legislative and/or other regulatory changes.

The Company is subject to evolving and complex tax laws, which may result in additional liabilities that may affect results of operations and financial condition.

The Company is subject to evolving and complex tax laws in the jurisdictions in which it operates. Significant judgment is required for determining the Company's tax liabilities, and the Company's tax returns are periodically examined by various tax authorities. The Company believes that its accrual for tax contingencies is adequate for all open years based on past experience, interpretations of tax law, and judgments about potential actions by tax authorities; however, due to the complexity of tax contingencies, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued. In addition, the Company may be negatively affected by changes in tax laws, or new tax laws, affecting, for example, tax rates, and/or revised tax law interpretations in domestic or foreign jurisdictions.

Product liability insurance for products may be limited, cost prohibitive or unavailable.

As a result of a number of factors, product liability insurance has become less available while the cost of such insurance has increased significantly. The Company is subject to a substantial number of product liability claims. See Item 8. "Financial Statements and Supplementary Data," Note 10. "Contingencies and Environmental Liabilities" below for more information on the Company's current product liability litigation. With respect to product liability, the Company self-insures substantially all of its risk, as the availability of commercial insurance has become more restrictive. The Company has evaluated its risks and has determined that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and, as such, has no insurance for most product liabilities. The Company will continually assess the most efficient means to address its risk; however, there can be no guarantee that insurance coverage will be obtained or, if obtained, will be sufficient to fully cover product liabilities that may arise.

Risks Related to Technology

The Company is increasingly dependent on sophisticated software applications and computing infrastructure. In 2017, the Company experienced a network cyber-attack that led to a disruption of its worldwide operations, including manufacturing, research and sales operations. The Company could be a target of future cyber-attacks.

The Company is increasingly dependent on sophisticated software applications, complex information technology systems, computing infrastructure, and cloud service providers (collectively, IT systems) to conduct critical operations. Certain of these systems are managed, hosted, provided or used by third parties to assist in conducting the Company's business. Disruption, degradation, or manipulation of these IT systems through intentional or accidental means by the Company's employees, third parties with authorized access or unauthorized third parties could adversely affect key business processes. Cyber-attacks against the Company's IT systems or third-party providers' IT systems, such as cloud-based systems, could result in exposure of confidential information, the modification of critical data, and/or the failure of critical operations. Misuse of any of these IT systems could result in the disclosure of sensitive personal information or the theft of trade secrets, intellectual property, or other confidential business information. The Company continues to leverage new and innovative technologies across the enterprise to improve the efficacy and efficiency of its business processes; the use of which can create new risks.

In 2017, the Company experienced a network cyber-attack that led to a disruption of its worldwide operations, including manufacturing, research and sales operations, and resulting losses.

The Company has implemented a variety of measures to further enhance and modernize its systems to guard against similar attacks in the future, and also is pursuing an enterprise-wide effort to enhance the Company's resiliency against future cyber-attacks, including incidents similar to the 2017 attack. The objective of these efforts is not only to protect against future cyber-attacks, but also to improve the speed of the Company's recovery from such attacks and enable continued business operations to the greatest extent possible during any recovery period.

Although the aggregate impact of cyber-attacks and network disruptions, including the 2017 cyber-attack, on the Company's operations and financial condition has not been material to date, the Company continues to be a target of events of this nature and expects them to continue. The Company monitors its data, information technology and personnel usage of Company IT systems to reduce these risks and continues to do so on an ongoing

basis for any current or potential threats. There can be no assurance that the Company's efforts to protect its data and IT systems or the efforts of third-party providers to protect their IT systems will be successful in preventing disruptions to the Company's operations, including its manufacturing, research and sales operations. Such disruptions have in the past and could in the future result in loss of revenue, or the loss of critical or sensitive information from the Company's or the Company's third-party providers' databases or IT systems and have in the past and could in the future also result in financial, legal, business or reputational harm to the Company and substantial remediation costs.

Social media platforms present risks and challenges.

The inappropriate and/or unauthorized use of certain social media channels could cause brand damage or information leakage or could lead to legal implications, including from the improper collection and/or dissemination of personally identifiable information. In addition, negative or inaccurate posts or comments about the Company or its products on any social networking platforms could damage the Company's reputation, brand image and goodwill. Further, the disclosure of non-public Company-sensitive information by the Company's workforce or others through external media channels could lead to information loss. Although there is an internal Company Social Media Policy that guides employees on appropriate personal and professional use of social media about the Company, the processes in place may not completely secure and protect information. Identifying new points of entry as social media continues to expand also presents new challenges.

Risks Related to the Proposed Spin-Off of Organon

The proposed Spin-Off of Organon may not be completed on the terms or timeline currently contemplated, if at all, and may not achieve the expected results.

In February 2020, the Company announced its intention to Spin-Off products from its women's health, biosimilars and established brands businesses into a new, independent, publicly traded company, which has been named Organon & Co. (Organon) through a distribution of Organon's publicly traded stock to Company shareholders. The distribution is expected to qualify as tax-free to the Company and its shareholders for U.S. federal income tax purposes. The transaction is expected to be completed late in the second quarter of 2021. Completion of the Spin-Off will be subject to a number of factors and conditions, and there can be no assurances that the Company will be able to complete the Spin-Off on the terms or on the timeline that was announced, if at all. Unanticipated developments could delay, prevent or otherwise adversely affect the proposed Spin-Off, including but not limited to disruptions in general or financial market conditions or potential problems or delays in obtaining various regulatory and tax approvals or clearances. In addition, consummation of the proposed Spin-Off will require final approval from the Company's Board of Directors.

The costs to complete the proposed Spin-Off will be significant. In addition, the Company may be unable to achieve some or all of the strategic and financial benefits that it expects to achieve from the Spin-Off of Organon.

The Company will incur significant expenses in connection with the Spin-Off. In addition, the Company may not be able to achieve the full strategic and financial benefits that are expected to result from the Spin-Off. The anticipated benefits of the Spin-Off are based on a number of assumptions, some of which may prove incorrect.

Following the Spin-Off, the price of shares of the Company's common stock may fluctuate significantly.

The Company cannot predict the effect of the Spin-Off on the trading price of shares of its common stock, and the market value of shares of its common stock may be less than, equal to or greater than the market value of shares of its common stock prior to the Spin-Off. In addition, the price of Merck's common stock may be more volatile around the time of the Spin-Off.

There could be significant income tax liability if the Spin-Off or certain related transactions are determined to be taxable for U.S. federal income tax purposes.

The Company expects that prior to completion of the Spin-Off it will receive an opinion from its U.S. tax counsel that concludes, among other things, that the Spin-Off of all of the outstanding Organon shares to Merck

shareholders and certain related transactions will qualify as tax-free to Merck and its shareholders under Sections 355 and 368 of the U.S. Internal Revenue Code, except to the extent of any cash received in lieu of fractional shares of Organon common stock. Any such opinion is not binding on the Internal Revenue Service (IRS). Accordingly, while the Company believes the risk is low, the IRS may reach conclusions with respect to the Spin-Off that are different from the conclusions reached in the opinion. The opinion will rely on certain facts, assumptions, representations and undertakings from Merck and Organon regarding the past and future conduct of the companies' respective businesses and other matters, which, if incomplete, incorrect or not satisfied, could alter the conclusions of the party giving such opinion.

If the proposed Spin-Off ultimately is determined to be taxable, which the Company believes is unlikely, the Spin-Off could be treated as a taxable dividend to Merck's shareholders for U.S. federal income tax purposes, and Merck's shareholders could incur significant U.S. federal income tax liabilities. In addition, Merck would recognize a taxable gain to the extent that the fair market value of Organon common stock exceeds Merck's tax basis in such stock on the date of the Spin-Off.

Cautionary Factors that May Affect Future Results

(Cautionary Statements Under the Private Securities Litigation Reform Act of 1995)

This report and other written reports and oral statements made from time to time by the Company may contain so-called "forward-looking statements," all of which are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially from those set forth in the statements. One can identify these forward-looking statements by their use of words such as "anticipates," "expects," "plans," "will," "estimates," "forecasts," "projects" and other words of similar meaning, or negative variations of any of the foregoing. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address the Company's growth strategy, financial results, product approvals, product potential, development programs and include statements related to the expected impact of the COVID-19 pandemic. One must carefully consider any such statement and should understand that many factors could cause actual results to differ materially from the Company's forward-looking statements. These factors include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. No forward-looking statement can be guaranteed and actual future results may vary materially. The Company does not assume the obligation to update any forward-looking statement. The Company cautions you not to place undue reliance on these forward-looking statements. Although it is not possible to predict or identify all such factors, they may include the following:

- Competition from generic and/or biosimilar products as the Company's products lose patent protection.

- Increased "brand" competition in therapeutic areas important to the Company's long-term business performance.

- The difficulties and uncertainties inherent in new product development. The outcome of the lengthy and complex process of new product development is inherently uncertain. A drug candidate can fail at any stage of the process and one or more late-stage product candidates could fail to receive regulatory approval. New product candidates may appear promising in development but fail to reach the market because of efficacy or safety concerns, the inability to obtain necessary regulatory approvals, the difficulty or excessive cost to manufacture and/or the infringement of patents or intellectual property rights of others. Furthermore, the sales of new products may prove to be disappointing and fail to reach anticipated levels.

- Pricing pressures, both in the United States and abroad, including rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and health care reform, pharmaceutical reimbursement and pricing in general.

- The impact of the global COVID-19 pandemic and any future pandemic, epidemic, or similar public health threat, on the Company's business, operations and financial performance.

- Changes in government laws and regulations, including laws governing intellectual property, and the enforcement thereof affecting the Company's business.

- Efficacy or safety concerns with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales.
- Significant changes in customer relationships or changes in the behavior and spending patterns of purchasers of health care products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing health care insurance coverage.
- Legal factors, including product liability claims, antitrust litigation and governmental investigations, including tax disputes, environmental concerns and patent disputes with branded and generic competitors, any of which could preclude commercialization of products or negatively affect the profitability of existing products.
- Cyber-attacks on the Company's or third-party providers' information technology systems, which could disrupt the Company's operations.
- Lost market opportunity resulting from delays and uncertainties in the approval process of the FDA and foreign regulatory authorities.
- Increased focus on privacy issues in countries around the world, including the United States and the EU. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect directly the Company's business, including recently enacted laws in a majority of states in the United States requiring security breach notification.
- Changes in tax laws including changes related to the taxation of foreign earnings.
- Changes in accounting pronouncements promulgated by standard-setting or regulatory bodies, including the Financial Accounting Standards Board and the SEC, that are adverse to the Company.
- Economic factors over which the Company has no control, including changes in inflation, interest rates and foreign currency exchange rates.
- The proposed Spin-Off might be delayed or the costs to complete the Spin-Off might be more significant than expected.

This list should not be considered an exhaustive statement of all potential risks and uncertainties. See "Risk Factors" above.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

The Company's corporate headquarters is currently located in Kenilworth, New Jersey. The Company has previously announced that it intends to consolidate its New Jersey campuses into a single corporate headquarters location in Rahway, New Jersey by the end of 2023. The Company also maintains operational or divisional headquarters in Kenilworth, New Jersey; Madison, New Jersey and Upper Gwynedd, Pennsylvania. Principal U.S. research facilities are located in Rahway and Kenilworth, New Jersey; West Point, Pennsylvania; Boston, Massachusetts; South San Francisco, California; and Elkhorn, Nebraska (Animal Health). Principal research facilities outside the United States are located in the United Kingdom, Switzerland and China. Merck's manufacturing operations are currently headquartered in Whitehouse Station, New Jersey. The Company also has production facilities for human health products at nine locations in the United States and Puerto Rico. Outside the United States, through subsidiaries, the Company owns or has an interest in manufacturing plants or other properties in Japan, Singapore, South Africa, and other countries in Western Europe, Central and South America, and Asia. A number of properties will be transferred to Organon in the Spin-Off.

Capital expenditures were $4.7 billion in 2020, $3.5 billion in 2019 and $2.6 billion in 2018. In the United States, these amounted to $2.7 billion in 2020, $1.9 billion in 2019 and $1.5 billion in 2018. Abroad, such expenditures amounted to $2.0 billion in 2020, $1.6 billion in 2019, and $1.1 billion in 2018.

The Company and its subsidiaries own their principal facilities and manufacturing plants under titles that they consider to be satisfactory. The Company believes that its properties are in good operating condition and that its machinery and equipment have been well maintained. The Company believes that its plants for the manufacture of products are suitable for their intended purposes and have capacities and projected capacities, including previously-disclosed capital expansion projects, that will be adequate for current and projected needs for existing Company products. Some capacity of the plants is being converted, with any needed modification, to the requirements of newly introduced and future products.

Item 3. Legal Proceedings.

The information called for by this Item is incorporated herein by reference to Item 8. “Financial Statements and Supplementary Data,” Note 10. “Contingencies and Environmental Liabilities”.

Item 4. Mine Safety Disclosures.

Not Applicable.

Executive Officers of the Registrant (ages as of February 1, 2021)

All officers listed below serve at the pleasure of the Board of Directors. None of these officers was elected pursuant to any arrangement or understanding between the officer and any other person(s).

Name	Age
Kenneth C. Frazier	66
Sanat Chattopadhyay	61
Frank Clyburn	56
Robert M. Davis	54
Richard R. DeLuca, Jr.	58
Michael W. Fleming	62
Julie L. Gerberding	65
Rita A. Karachun	57
Dean Li	58
Steven C. Mizell	60
Michael T. Nally	45
Jennifer Zachary	43

In February 2021, Merck announced that Kenneth C. Frazier, chairman and chief executive officer, will retire as chief executive officer, effective June 30, 2021. Mr. Frazier will continue to serve on Merck's Board of Directors as executive chairman, for a transition period to be determined by the board. The Merck Board of Directors has unanimously elected Robert M. Davis, Merck's current executive vice president, global services and chief financial officer, as chief executive officer, as well as a member of the board, effective July 1, 2021. Mr. Davis will become president of Merck, effective April 1, 2021, at which time the Company's operating divisions—Human Health, Animal Health, Manufacturing, and Merck Research Laboratories—will begin reporting to Mr. Davis.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

The principal market for trading of the Company's Common Stock is the New York Stock Exchange (NYSE) under the symbol MRK.

As of January 31, 2021, there were approximately 104,900 shareholders of record of the Company's Common Stock.

Issuer purchases of equity securities for the three months ended December 31, 2020 were as follows:

Issuer Purchases of Equity Securities

Period	Total Number of Shares Purchased[1]	Average Price Paid Per Share	($ in millions) Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs[1]
October 1 — October 31	—	$0.00	$5,888
November 1 — November 30	—	$0.00	$5,888
December 1 — December 31	—	$0.00	$5,888
Total	—	$0.00	$5,888

[1] *The Company did not purchase any shares during the three months ended December 31, 2020 under the plan approved by the Board of Directors in October 2018 to purchase up to $10 billion in Merck shares for its treasury.*

Performance Graph

The following graph assumes a $100 investment on December 31, 2015, and reinvestment of all dividends, in each of the Company's Common Shares, the S&P 500 Index, and a composite peer group of major U.S. and European-based pharmaceutical companies, which are: AbbVie Inc., Amgen Inc., AstraZeneca plc, Bristol-Myers Squibb Company, Johnson & Johnson, Eli Lilly and Company, GlaxoSmithKline plc, Novartis AG, Pfizer Inc., Roche Holding AG, and Sanofi SA.

Comparison of Five-Year Cumulative Total Return*

Merck & Co., Inc., Composite Peer Group and S&P 500 Index

	End of Period Value	2020/2015 CAGR*
MERCK	$180	12%
PEER GRP.**	157	9%
S&P 500	203	15%

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	2015	2016	2017	2018	2019
MERCK	100.0	115.1	113.4	158.9	194.3
PEER GRP.	100.0	96.9	116.1	124.1	147.2
S&P 500	100.0	112.0	136.4	130.4	171.4

* *Compound Annual Growth Rate*

** *Peer group average was calculated on a market cap weighted basis.*

This Performance Graph will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that the Company specifically incorporates it by reference. In addition, the Performance Graph will not be deemed to be "soliciting material" or to be "filed" with the SEC or subject to Regulation 14A or 14C, other than as provided in Regulation S-K, or to the liabilities of section 18 of the Securities Exchange Act of 1934, except to the extent that the Company specifically requests that such information be treated as soliciting material or specifically incorporates it by reference into a filing under the Securities Act or the Exchange Act.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following section of this Form 10-K generally discusses 2020 and 2019 results and year-to-year comparisons between 2020 and 2019. Discussion of 2018 results and year-to-year comparisons between 2019 and 2018 that are not included in this Form 10-K can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 filed on February 26, 2020.

Description of Merck's Business

Merck & Co., Inc. (Merck or the Company) is a global health care company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies and animal health products. The Company's operations are principally managed on a products basis and include two operating segments, which are the Pharmaceutical and Animal Health segments, both of which are reportable segments.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities.

The Animal Health segment discovers, develops, manufactures and markets a wide range of veterinary pharmaceutical and vaccine products, as well as health management solutions and services, for the prevention, treatment and control of disease in all major livestock and companion animal species. The Company also offers an extensive suite of digitally connected identification, traceability and monitoring products. The Company sells its products to veterinarians, distributors and animal producers.

The Company previously had a Healthcare Services segment that provided services and solutions focused on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company divested the remaining businesses in this segment in the first quarter of 2020.

The Company previously had an Alliances segment that primarily included activity from the Company's relationship with AstraZeneca LP related to sales of Nexium and Prilosec, which concluded in 2018.

Planned Spin-Off of Women's Health, Biosimilars and Established Brands into a New Company

In February 2020, Merck announced its intention to spin-off products from its women's health, biosimilars and established brands businesses into a new, independent, publicly traded company named Organon & Co. (Organon) through a distribution of Organon's publicly traded stock to Company shareholders. The distribution is expected to qualify as tax-free to the Company and its shareholders for U.S. federal income tax purposes. The established brands included in the transaction consist of dermatology, non-opioid pain management, respiratory, and select cardiovascular products including *Zetia* and *Vytorin*, as well as the rest of Merck's diversified brands franchise. Merck's existing research pipeline programs will continue to be owned and developed within Merck as planned. Organon will have development capabilities initially focused on late-stage development and life-cycle management and is expected over time to develop research capabilities in selected therapeutic areas. The spin-off is expected to be completed late in the second quarter of 2021, subject to market and certain other conditions.

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Overview

Financial Highlights

($ in millions)	2020	% Change	% Change Excluding Foreign Exchange	2019
Sales	**$ 47,994**	**2 %**	**4 %**	$ 46,840
Net Income Attributable to Merck & Co., Inc.	**7,067**	**(28)%**	**(25)%**	9,843
Non-GAAP Net Income Attributable to Merck & Co., Inc. [(1)]	**15,082**	**13 %**	**16 %**	13,382
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	**$2.78**	**(27)%**	**(24)%**	$3.81
Non-GAAP Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders [(1)]	**$5.94**	**14 %**	**17 %**	$5.19

[(1)] *Non-GAAP net income and non-GAAP earnings per share (EPS) exclude acquisition and divestiture-related costs, restructuring costs and certain other items. For further discussion and a reconciliation of GAAP to non-GAAP net income and EPS (see "Non-GAAP Income and Non-GAAP EPS" below).*

Executive Summary

Worldwide sales were $48.0 billion in 2020, an increase of 2% compared with 2019, or 4% excluding the unfavorable effect from foreign exchange. The sales increase was driven primarily by oncology, certain hospital acute care products and animal health. Growth in these areas was largely offset by the negative effects of the coronavirus disease 2019 (COVID-19) pandemic as discussed below, the effects of generic competition, particularly in the diversified brands and women's health franchises, competitive pressure in the virology franchise and pricing pressure in the diabetes franchise.

During 2020, Merck continued executing on its strategic priorities reporting year-over-year sales growth despite the business challenges posed by the COVID-19 pandemic. Roughly two-thirds of Merck's Pharmaceutical segment revenue is comprised of physician-administered products, sales of which were negatively affected in 2020 by patients' inability to access health care providers, fewer well visits, and social distancing measures. However, in the latter part of the year, the Company experienced a partial recovery in the underlying demand for products across its key growth pillars. Despite the pandemic, Merck employees across the organization continued their important work, enrolling and maintaining clinical studies, progressing the pipeline and ensuring the supply of and patient access to the Company's portfolio of medically important medicines and vaccines. The Company also executed on Merck's capital allocation priorities by completing business development transactions and investing in its pipeline. Additionally, the Company remains on track to complete the spin-off of Organon late in the second quarter of 2021 thereby creating two companies, each focused on their strengths and portfolios allowing them to pursue their respective market opportunities and business strategies. In 2020, the products that will comprise Organon had total sales of $6.5 billion.

Merck actively monitors the business development landscape for growth opportunities that meet the Company's strategic criteria. To expand its oncology presence, Merck completed the acquisitions of ArQule, Inc. (ArQule), a biopharmaceutical company focused on kinase inhibitor discovery and development for the treatment of cancer and other diseases; and VelosBio Inc. (VelosBio), a clinical-stage biopharmaceutical company committed to developing first-in-class cancer therapies targeting receptor tyrosine kinase-like orphan receptor 1 (ROR1) currently being evaluated for the treatment of patients with hematologic malignancies and solid tumors. Additionally, Merck entered into strategic collaboration agreements with Seagen to gain access to ladiratuzumab vedotin, an investigational antibody-drug conjugate targeting LIV-1, and Tukysa (tucatinib), a small molecule tyrosine kinase inhibitor for the treatment of human epidermal growth factor receptor 2 (HER2)-positive cancers. To augment Merck's animal health business, the Company acquired the U.S. rights to Sentinel Flavor Tabs and Sentinel Spectrum Chews.

As part of industry-wide efforts to develop solutions to the pandemic, the Company acquired OncoImmune, a company developing a therapeutic candidate for the treatment of patients hospitalized with COVID-19; and Themis Bioscience GmbH (Themis), a company focused on vaccines and immune-modulation therapies for infectious diseases, including a COVID-19 vaccine candidate. Additionally, Merck entered into

strategic collaborations with Ridgeback Biotherapeutics LP (Ridgeback Bio) to develop an orally available antiviral candidate in clinical development for the treatment of patients with COVID-19; and with the International AIDS Vaccine Initiative, Inc. (IAVI) to develop an investigational vaccine against SARS-CoV-2 being studied for the prevention of COVID-19. In January 2021, the Company announced it was discontinuing development of the COVID-19 vaccine candidates (see Note 3 to the consolidated financial statements).

During 2020, the Company received numerous regulatory approvals within oncology. *Keytruda* received approval in the United States as monotherapy in the therapeutic areas of cutaneous squamous cell carcinoma (cSCC), metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer, non-muscle invasive bladder cancer (NMIBC) and tumor mutational burden-high (TMB-H) solid tumors, as well as in combination with chemotherapy for the treatment of triple-negative breast cancer (TNBC). Merck also received approval in the United States for an every six weeks (Q6W) dosing regimen across all adult indications. Additionally, *Keytruda* received approval in China for the treatment of certain patients with head and neck squamous cell carcinoma (HNSCC) and in both China and Japan for the treatment of certain patients with esophageal squamous cell carcinoma (ESCC). Lynparza, which is being developed in collaboration with AstraZeneca PLC (AstraZeneca), received approval in the United States: in combination with bevacizumab as a first-line maintenance treatment of certain adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy; and for the treatment of certain adult patients with metastatic castration-resistant prostate cancer (mCRPC) following progression on prior treatment. Additionally, Lynparza was approved in the European Union (EU): as monotherapy for the treatment of adult patients with mCRPC and *BRCA*1/2 mutations who have progressed following a prior therapy; and for the maintenance treatment of certain adult patients with metastatic adenocarcinoma of the pancreas. Lynparza was also approved in Japan for the treatment of three types of advanced cancer: ovarian, prostate and pancreatic cancer. Lenvima, which is being developed in collaboration with Eisai Co., Ltd. (Eisai), received approval in China as monotherapy for the treatment of differentiated thyroid cancer.

Also in 2020, *Gardasil* 9 was approved for use in women and girls in Japan where it is marketed as *Silgard* 9. Additionally, in 2020, the U.S. Food and Drug and Administration (FDA) granted accelerated approval for an expanded indication for *Gardasil* 9 for the prevention of oropharyngeal and other head and neck cancers caused by certain HPV types. In January 2021, the Company received FDA approval for Verquvo (vericiguat), to reduce the risk of cardiovascular death and heart failure hospitalization following a hospitalization for heart failure or need for outpatient intravenous diuretics in adults. Verquvo is being jointly developed with Bayer AG (Bayer).

In addition to the recent regulatory approvals discussed above, the Company advanced its late-stage pipeline with several regulatory submissions. *Keytruda* is under review in United States and/or internationally for the treatment of certain patients with TNBC, classical Hodgkin Lymphoma (cHL), colorectal cancer, cSCC, esophageal and gastric cancer. Lenvima is under review in Japan as monotherapy for the treatment of thymic cancer. V114, an investigational 15-valent pneumococcal conjugate vaccine, is under priority review by the FDA for the prevention of invasive pneumococcal disease in adults 18 years of age and older. The European Medicines Agency (EMA) is also reviewing an application for licensure of V114 in adults. The Company is involved in litigation challenging the validity of several Pfizer Inc. patents that relate to pneumococcal vaccine technology in the United States and several foreign jurisdictions.

The Company's Phase 3 oncology programs include *Keytruda* in the therapeutic areas of biliary tract, cervical, cutaneous squamous cell, endometrial, gastric, hepatocellular, mesothelioma, ovarian, prostate and small-cell lung cancers; Lynparza as monotherapy for colorectal cancer and in combination with *Keytruda* for non-small-cell lung and small-cell lung cancers; and Lenvima in combination with *Keytruda* for bladder, endometrial, gastric, head and neck, melanoma and non-small-cell lung cancers. Also within oncology, MK-6482, belzutifan, an investigational hypoxia-inducible factor-2 alpha (HIF-2α) inhibitor being evaluated for the treatment of patients with von Hippel-Lindau disease-associated renal cell carcinoma (RCC), received Breakthrough Therapy designation from the FDA. Additionally, the Company has candidates in Phase 3 clinical development in several other therapeutic areas, including MK-7264, gefapixant, a selective, non-narcotic, orally-administered, investigational P2X3-receptor antagonist being developed for the treatment of refractory, chronic cough; MK-7110, an investigational treatment for patients hospitalized with COVID-19; MK-8591A, islatravir, an investigational nucleoside reverse transcriptase translocation inhibitor (NRTTI) in combination with doravirine for the treatment of HIV-1 infection; and V114, which is being evaluated for the prevention of pneumococcal disease in pediatric patients.

The Company is allocating resources to support its commercial opportunities in the near term while making the necessary investments to support long-term growth. Research and development expenses in 2020 reflect higher costs related to business development activity, higher clinical development spending and increased investment in discovery research and early drug development.

In November 2020, Merck's Board of Directors approved an increase to the Company's quarterly dividend, raising it to $0.65 per share from $0.61 per share on the Company's outstanding common stock. During 2020, the Company returned $7.5 billion to shareholders through dividends and share repurchases.

Management

In February 2021, Merck announced that Kenneth C. Frazier, chairman and chief executive officer, will retire as chief executive officer, effective June 30, 2021. Mr. Frazier will continue to serve on Merck's Board of Directors as executive chairman, for a transition period to be determined by the board. The Merck Board of Directors has unanimously elected Robert M. Davis, Merck's current executive vice president, global services and chief financial officer, as chief executive officer, as well as a member of the board, effective July 1, 2021. Mr. Davis will become president of Merck, effective April 1, 2021, at which time the Company's operating divisions—Human Health, Animal Health, Manufacturing, and Merck Research Laboratories (MRL)—will begin reporting to Mr. Davis.

COVID-19

Overall, in response to the COVID-19 pandemic, Merck remains focused on protecting the safety of its employees, ensuring that its supply of medicines and vaccines reaches its patients, contributing its scientific expertise to the development of antiviral approaches, and supporting health care providers and Merck's communities. Although COVID-19-related disruptions to patients' ability to access health care providers negatively affected results in 2020, Merck remains confident in the fundamental underlying demand for its products and its prospects for long-term growth.

In 2020, the estimated negative impact of the COVID-19 pandemic to Merck's sales was approximately $2.5 billion, largely attributable to the Pharmaceutical segment, with approximately $50 million attributable to the Animal Health segment. Roughly two-thirds of Merck's Pharmaceutical segment revenue is comprised of physician-administered products, which, despite strong underlying demand, have been affected by social distancing measures, fewer well visits and delays in elective surgeries due to the COVID-19 pandemic. These impacts, as well as the prioritization of COVID-19 patients at health care providers, have resulted in reduced administration of many of the Company's human health products, in particular for its vaccines, including *Gardasil* 9, as well as for *Keytruda* and *Implanon/Nexplanon*. In addition, declines in elective surgeries negatively affected the demand for *Bridion*. However, sales of *Pneumovax* 23 increased due to heightened awareness of pneumococcal vaccination.

Operating expenses were positively affected in 2020 by approximately $600 million primarily due to lower promotional and selling costs, as well as lower research and development expenses, net of investments in COVID-19-related antiviral and vaccine research programs.

Merck believes that global health systems and patients have largely adapted to the impacts of COVID-19, but the Company's assumption is that ongoing residual negative impacts will persist, particularly during the first half of 2021 and most notably with respect to vaccine sales, with the impact expected to be more acute in the United States. For the full year of 2021, Merck assumes an unfavorable impact to revenue of approximately 2% due to the COVID-19 pandemic, all of which relates to Pharmaceutical segment sales. In addition, for the full year of 2021, with respect to the COVID-19 pandemic, Merck expects a net negative impact to operating expenses, as spending on the development of its COVID-19 antiviral programs is expected to exceed the favorable impact of lower spending in other areas due to the COVID-19 pandemic.

Pricing

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. Changes to the U.S. health care system as part of health care reform, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, have contributed to pricing pressure. In several international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. In addition, the Company's revenue performance in 2020 was negatively

affected by other cost-reduction measures taken by governments and other third-parties to lower health care costs. The Company anticipates all of these actions and additional actions in the future will continue to negatively affect revenue performance.

Operating Results

Sales

($ in millions)	**2020**	**% Change**	**% Change Excluding Foreign Exchange**	2019	% Change	% Change Excluding Foreign Exchange	2018
United States	**$ 21,027**	**2 %**	**2 %**	$ 20,519	12 %	12 %	$ 18,346
International	**26,967**	**2 %**	**5 %**	26,321	10 %	13 %	23,949
Total	**$ 47,994**	**2 %**	**4 %**	$ 46,840	11 %	13 %	$ 42,294

U.S. plus international may not equal total due to rounding.

Worldwide sales grew 2% in 2020 due to higher sales in the oncology franchise reflecting strong growth of *Keytruda*, as well as increased alliance revenue from Lynparza and Lenvima. Also contributing to revenue growth were higher sales of certain vaccines, including *Gardasil/Gardasil* 9 and *Pneumovax* 23, as well as increased sales of certain hospital acute care products, including *Prevymis* and *Bridion.* Higher sales of animal health products also drove revenue growth in 2020.

Sales growth in 2020 was partially offset by the effects of generic competition for certain products including women's health product *NuvaRing*, hospital acute care products *Noxafil* and *Cubicin*, oncology products *Emend*/*Emend* for Injection, cardiovascular products *Zetia* and *Vytorin*, and products within the diversified brands franchise, particularly *Singulair.* The diversified brands franchise includes certain products that are approaching the expiration of their marketing exclusivity or that are no longer protected by patents in developed markets. Lower sales of pediatric vaccines, including *ProQuad*, *M-M-R* II, and *Varivax*, as well as lower sales of diabetes products *Januvia* and *Janumet*, and virology products *Zepatier* and *Isentress/Isentress HD* also partially offset revenue growth in 2020. As discussed above, the COVID-19 pandemic negatively affected sales in 2020.

Sales in the United States grew 2% in 2020 primarily driven by higher sales of *Keytruda*, increased alliance revenue from Lynparza and Lenvima, and higher sales of animal health products. Revenue growth was largely offset by lower sales of *NuvaRing*, *Januvia*, *Noxafil*, *Emend/Emend* for Injection, *M-M-R* II, *Janumet*, *Varivax* and *Implanon/Nexplanon*.

International sales grew 2% in 2020. The increase in international sales primarily reflects growth in *Keytruda*, *Gardasil/Gardasil* 9, increased alliance revenue from Lynparza, as well as higher sales of *Pneumovax* 23, *Prevymis*, *Januvia* and animal health products. Sales growth was partially offset by lower sales of *Zepatier*, *Vytorin*, *Noxafil*, *Zetia*, *Remicade*, *Emend/Emend* for Injection and products within the diversified brands franchise, particularly *Singulair* and *Nasonex*. International sales represented 56% of total sales in both 2020 and 2019.

See Note 18 to the consolidated financial statements for details on sales of the Company's products. A discussion of performance for select products in the franchises follows.

Pharmaceutical Segment

Oncology

($ in millions)	**2020**	**% Change**	**% Change Excluding Foreign Exchange**	2019	% Change	% Change Excluding Foreign Exchange	2018
Keytruda	**$ 14,380**	**30 %**	**30 %**	$ 11,084	55 %	58 %	$ 7,171
Alliance Revenue - Lynparza [(1)]	**725**	**63 %**	**62 %**	444	137 %	141 %	187
Alliance Revenue - Lenvima [(1)]	**580**	**44 %**	**43 %**	404	171 %	173 %	149
Emend	**145**	**(63)%**	**(62)%**	388	(26)%	(24)%	522

[(1)] *Alliance revenue represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs (see Note 4 to the consolidated financial statements).*

Keytruda is an anti-PD-1 (programmed death receptor-1) therapy that has been approved as monotherapy for the treatment of certain patients with cervical cancer, cHL, cSCC, ESCC, gastric or gastroesophageal junction adenocarcinoma, HNSCC, hepatocellular carcinoma (HCC), non-small-cell lung cancer (NSCLC), small-cell lung cancer (SCLC), melanoma, Merkel cell carcinoma, MSI-H or dMMR cancer including MSI-H/dMMR colorectal cancer, primary mediastinal large B-cell lymphoma (PMBCL), TMB-H cancer, and urothelial carcinoma including NMIBC. *Keytruda* is also approved for the treatment of certain patients: in combination with chemotherapy for metastatic squamous and nonsquamous NSCLC, in combination with chemotherapy for HNSCC, in combination with chemotherapy for TNBC, in combination with axitinib for RCC, and in combination with Lenvima for endometrial carcinoma. The *Keytruda* clinical development program includes studies across a broad range of cancer types.

Global sales of *Keytruda* grew 30% in 2020 driven by higher demand as the Company continues to launch *Keytruda* with multiple new indications globally, although the COVID-19 pandemic had a dampening effect on growing demand. Sales in the United States continue to build across the multiple approved indications, in particular for the treatment of advanced NSCLC as monotherapy, and in combination with chemotherapy for both nonsquamous and squamous metastatic NSCLC, along with uptake in the RCC, adjuvant melanoma, HNSCC, bladder cancer and endometrial carcinoma indications. Uptake of the every six weeks (Q6W) adult dosing regimen in the United States benefited sales in 2020. *Keytruda* sales growth in international markets was driven by continued uptake in approved indications, particularly in the EU. Sales growth was partially offset by declines in Japan due to pricing. Pursuant to a re-pricing rule, the Japanese government reduced the price of *Keytruda* by 17.5% effective February 2020. Additionally, *Keytruda* was subject to another price reduction of 20.9% in April 2020 under a provision of the Japanese pricing rules.

In January 2020, the FDA approved *Keytruda* as monotherapy for the treatment of certain patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, NMIBC based on the results of the KEYNOTE-057 trial.

In April 2020, the FDA granted accelerated approval for an additional recommended dosage of 400 mg every six weeks (Q6W) for *Keytruda* across all adult indications, including monotherapy and combination therapy. This new dosage option is available in addition to the current dose of 200 mg every three weeks (Q3W).

In June 2020, the FDA granted accelerated approval for *Keytruda* as monotherapy for the treatment of adult and pediatric patients with unresectable or metastatic TMB-H solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options based in part on the results of the KEYNOTE-158 trial.

Also in June 2020, the FDA approved *Keytruda* as monotherapy for the treatment of patients with recurrent or metastatic cSCC that is not curable by surgery or radiation based on data from the KEYNOTE-629 trial.

Additionally in June 2020, the FDA approved *Keytruda* as monotherapy for the first-line treatment of patients with unresectable or metastatic MSI-H or dMMR colorectal cancer based on results from the KEYNOTE-177 trial.

In October 2020, the FDA approved an expanded label for *Keytruda* as monotherapy for the treatment of adult patients with relapsed or refractory cHL based on results from the KEYNOTE-204 trial. The FDA also approved an updated pediatric indication for *Keytruda* for the treatment of pediatric patients with refractory cHL or cHL that has relapsed after two or more lines of therapy. *Keytruda* was previously approved under the FDA's accelerated approval process for the treatment of adult and pediatric patients with refractory cHL, or who have relapsed after three or more prior lines of therapy based on data from the KEYNOTE-087 trial. In accordance with accelerated approval regulations, continued approval was contingent upon verification and description of clinical benefit; these accelerated approval requirements have been fulfilled with the data from KEYNOTE-204.

In November 2020, the FDA granted accelerated approval for *Keytruda* in combination with chemotherapy for the treatment of patients with locally recurrent unresectable or metastatic TNBC whose tumors express PD-L1 (Combined Positive Score [CPS] ≥10) as determined by an FDA-approved test. The approval is based on results from the KEYNOTE-355 trial.

In June 2020, *Keytruda* was approved by the National Medical Products Administration (NMPA) in China as monotherapy for the second-line treatment of patients with locally advanced or metastatic ESCC whose

tumors express PD-L1 (CPS ≥10). This indication was granted based on the KEYNOTE-181 trial, including data from an extension of the global study in Chinese patients. In December 2020, China's NMPA approved *Keytruda* as monotherapy for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC whose tumors express PD-L1 (CPS ≥20) as determined by a fully validated test.

In August 2020, *Keytruda* was approved by Japan's Pharmaceuticals and Medical Devices Agency (PMDA) as monotherapy for the treatment of patients whose tumors are PD-L1-positive, and have radically unresectable, advanced or recurrent ESCC who have progressed after chemotherapy. The approval was based on results from the KEYNOTE-181 trial. Additionally, *Keytruda* was approved by Japan's PMDA for use at an additional recommended dosage of 400 mg Q6W, including monotherapy and combination therapy. This new dosage option is available in addition to the current dose of 200 mg Q3W.

In January 2021, *Keytruda* was approved by the European Commission (EC) as a first-line treatment in adult patients with MSI-H or dMMR colorectal cancer based on the results of the KEYNOTE-177 study.

The Company is a party to certain third-party license agreements pursuant to which the Company pays royalties on sales of *Keytruda*. Under the terms of the more significant of these agreements, Merck pays a royalty of 6.5% on worldwide sales of *Keytruda* through 2023 to one third party; this royalty will decline to 2.5% for 2024 through 2026 and will terminate thereafter. The Company pays an additional 2% royalty on worldwide sales of *Keytruda* to another third party, the termination date of which varies by country; this royalty will expire in the United States in 2024 and in major European markets in 2025. The royalties are included in *Cost of sales*.

Lynparza, an oral poly (ADP-ribose) polymerase (PARP) inhibitor being developed as part of a collaboration with AstraZeneca (see Note 4 to the consolidated financial statements), is approved for the treatment of certain types of advanced ovarian, breast, pancreatic and prostate cancers. Alliance revenue related to Lynparza grew 63% in 2020 due to continued uptake across the multiple approved indications in the United States, the EU, China and Japan.

In May 2020, the FDA approved Lynparza in combination with bevacizumab as a first-line maintenance treatment of certain adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. In November 2020, Lynparza was approved in the EU for the maintenance treatment of adult patients with advanced high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response following completion of first-line platinum-based chemotherapy in combination with bevacizumab and whose cancer is associated with homologous recombination deficiency (HRD)-positive status. These approvals were based on the results from the PAOLA-1 trial.

Also in May 2020, the FDA approved Lynparza for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated mCRPC who have progressed following prior treatment. In November 2020, Lynparza was approved in the EU as monotherapy for the treatment of adult patients with mCRPC and *BRCA*1/2 mutations (germline and/or somatic) who have progressed following a prior therapy. These approvals were based on the results from the PROfound trial.

In July 2020, Lynparza was approved in the EU as a monotherapy for the maintenance treatment of adult patients with germline *BRCA*1/2 mutations who have metastatic adenocarcinoma of the pancreas and have not progressed after a first-line chemotherapy regimen. This approval was based on the results from the POLO trial.

In December 2020, Lynparza was approved in Japan for the treatment of three types of advanced cancer: ovarian, prostate and pancreatic cancer. The three approvals authorize Lynparza for use as maintenance treatment after first-line chemotherapy containing bevacizumab (genetical recombination) in patients with HRD ovarian cancer; the treatment of patients with *BRCA* gene-mutated (*BRCA*m) mCRPC; and maintenance treatment after platinum-based chemotherapy for patients with *BRCA*m curatively unresectable pancreas cancer. The concurrent approvals by the Japanese Ministry of Health, Labor, and Welfare are based on results from the PAOLA-1, PROfound and POLO trials.

Lenvima, an oral receptor tyrosine kinase inhibitor being developed as part of a collaboration with Eisai (see Note 4 to the consolidated financial statements), is approved for the treatment of certain types of thyroid cancer, HCC, in combination with everolimus for certain patients with RCC, and in combination with *Keytruda* for the

treatment of certain patients with endometrial carcinoma. Alliance revenue related to Lenvima grew 44% in 2020 due to higher demand in the United States, China and the EU.

In November 2020, China's NMPA approved Lenvima as a monotherapy for the treatment of differentiated thyroid cancer.

Global sales of *Emend*, for the prevention of certain chemotherapy-induced nausea and vomiting, declined 63% in 2020 primarily due to lower demand and pricing in the United States due to generic competition for *Emend* for Injection following U.S. patent expiry in September 2019. Also contributing to the *Emend* sales decline was lower demand in the EU and Japan as a result of generic competition for the oral formulation of *Emend* following loss of market exclusivity in May 2019 and December 2019, respectively. U.S. market exclusivity for the oral formulation of *Emend* previously expired in 2015.

In April 2020, the FDA approved Koselugo (selumetinib) for the treatment of pediatric patients two years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN). The FDA approval is based on positive results from the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP)-sponsored Phase 2 SPRINT Stratum 1 trial coordinated by the NCI's Center for Cancer Research, Pediatric Oncology Branch. This is the first regulatory approval of a medicine for the treatment of NF1 PN, a rare and debilitating genetic condition. Koselugo is being jointly developed and commercialized with AstraZeneca globally (see Note 4 to the consolidated financial statements).

Vaccines

($ in millions)	**2020**	**% Change**	**% Change Excluding Foreign Exchange**	2019	% Change	% Change Excluding Foreign Exchange	2018
Gardasil/Gardasil 9	**$ 3,938**	**5 %**	**6 %**	$ 3,737	19 %	21 %	$ 3,151
ProQuad	**678**	**(10)%**	**(10)%**	756	27 %	29 %	593
M-M-R II	**378**	**(31)%**	**(31)%**	549	28 %	29 %	430
Varivax	**823**	**(15)%**	**(15)%**	970	25 %	28 %	774
Pneumovax 23	**1,087**	**17 %**	**18 %**	926	2 %	3 %	907

Worldwide sales of *Gardasil/Gardasil* 9, vaccines to help prevent certain cancers and other diseases caused by certain types of HPV, grew 5% in 2020 primarily due to higher volumes in China and the replenishment in 2020 of doses borrowed from the U.S. Centers for Disease Control and Prevention (CDC) Pediatric Vaccine Stockpile in 2019. The replenishment resulted in the recognition of sales of $120 million in 2020, which, when combined with the reduction of sales of $120 million in 2019 due to the borrowing, resulted in a favorable impact to sales of $240 million in 2020. Lower demand in the United States and Hong Kong, SAR, PRC attributable to the COVID-19 pandemic partially offset the increase in sales of *Gardasil/Gardasil* 9.

In June 2020, the FDA approved an expanded indication for *Gardasil* 9 for the prevention of oropharyngeal and other head and neck cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58. The oropharyngeal and head and neck cancer indication was approved under accelerated approval based on effectiveness in preventing HPV-related anogenital disease.

In July 2020, *Gardasil* 9 was approved by the PMDA in Japan for use in women and girls nine years and older for the prevention of cervical cancer, certain cervical, vaginal and vulvar precancers, and genital warts caused by the HPV types covered by the vaccine. In December 2020, *Silgard* 9 was also approved in Japan for the prevention of anal cancer and precursor lesions caused by HPV types 6, 11, 16 and 18 for individuals nine years and older and for genital warts for men nine years and older. *Gardasil* 9 is marketed in Japan as *Silgard* 9.

The Company is a party to certain third-party license agreements pursuant to which the Company pays royalties on sales of *Gardasil/Gardasil* 9. Under the terms of the more significant of these agreements, Merck pays a 7% royalty on worldwide sales of *Gardasil/Gardasil* 9 to one third party (royalty obligations under this agreement expire in December 2023) and an additional 7% royalty on sales of *Gardasil/Gardasil* 9 in the United States to another third party (these royalty obligations expire in December 2028). The royalties are included in *Cost of sales*.

Global sales of *ProQuad*, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, declined 10% in 2020 driven primarily by lower demand in the United States resulting from fewer measles outbreaks in 2020 compared with 2019, coupled with the unfavorable impact of the COVID-19 pandemic, partially offset by higher pricing.

Worldwide sales of *M-M-R* II, a vaccine to help protect against measles, mumps and rubella, declined 31% in 2020 driven primarily by lower demand in the United States resulting from fewer measles outbreaks in 2020 compared with 2019, coupled with the unfavorable impact of the COVID-19 pandemic. Lower demand in Brazil also contributed to the *M-M-R* II sales decline in 2020.

Global sales of *Varivax,* a vaccine to help prevent chickenpox (varicella), declined 15% in 2020 driven primarily by lower demand in the United States resulting from the COVID-19 pandemic, partially offset by higher pricing. The *Varivax* sales decline was also attributable to lower government tenders in Brazil.

Worldwide sales of *Pneumovax* 23, a vaccine to help prevent pneumococcal disease, grew 17% in 2020 primarily due to higher volumes in the EU and in the United States attributable in part to heightened awareness of pneumococcal vaccination. Higher pricing in the United States also contributed to *Pneumovax* 23 sales growth in 2020.

Hospital Acute Care

($ in millions)	**2020**	**% Change**	**% Change Excluding Foreign Exchange**	2019	% Change	% Change Excluding Foreign Exchange	2018
Bridion	**$ 1,198**	**6 %**	**7 %**	$ 1,131	23 %	26 %	$ 917
Noxafil	**329**	**(50)%**	**(50)%**	662	(11)%	(7)%	742
Prevymis	**281**	**70 %**	**69 %**	165	128 %	131 %	72
Cubicin	**152**	**(41)%**	**(40)%**	257	(30)%	(28)%	367
Zerbaxa	**130**	**8 %**	**10 %**	121	39 %	42 %	87

Global sales of *Bridion*, for the reversal of two types of neuromuscular blocking agents used during surgery, grew 6% in 2020 due to higher demand globally, particularly in the United States. However, fewer elective surgeries as a result of the COVID-19 pandemic unfavorably affected demand in 2020.

Worldwide sales of *Noxafil*, an antifungal agent for the prevention of certain invasive fungal infections, declined 50% in 2020 due to generic competition in the United States and in the EU. The patent that provided U.S. market exclusivity for certain forms of *Noxafil* representing the majority of U.S. *Noxafil* sales expired in July 2019. Additionally, the patent for *Noxafil* expired in a number of major European markets in December 2019. As a result, the Company is experiencing volume and pricing declines in *Noxafil* sales in these markets as a result of generic competition and expects the declines to continue.

Worldwide sales of *Prevymis*, a medicine for prophylaxis (prevention) of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients of an allogenic hematopoietic stem cell transplant, grew 70% in 2020 due to continued uptake since launch in the EU and in the United States. *Prevymis* was approved by the EC in January 2018 and by the FDA in November 2017.

Global sales of *Cubicin* for injection, an antibiotic for the treatment of certain bacterial infections, declined 41% in 2020 primarily due to ongoing generic competition in the EU and in the United States.

In December 2020, the Company temporarily suspended sales of *Zerbaxa*, a combination antibacterial and beta-lactamase inhibitor for the treatment of certain bacterial infections, and subsequently issued a product recall, following the identification of product sterility issues. As a result, the Company recorded an intangible asset impairment charge related to *Zerbaxa* (see Note 8 to the consolidated financial statements). The Company does not anticipate that *Zerbaxa* will return to the market before 2022.

In June 2020, the FDA approved a supplemental New Drug Application (NDA) for *Recarbrio* (imipenem, cilastatin, and relebactam) for the treatment of patients 18 years of age and older with hospital-acquired

bacterial pneumonia and ventilator-associated bacterial pneumonia caused by certain susceptible Gram-negative microorganisms.

Immunology

($ in millions)	2020	% Change	% Change Excluding Foreign Exchange	2019	% Change	% Change Excluding Foreign Exchange	2018
Simponi	$ 838	1 %	1 %	$ 830	(7)%	(2)%	$ 893
Remicade	330	(20)%	(20)%	411	(29)%	(25)%	582

Sales of *Simponi*, a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were nearly flat in 2020. Sales of *Simponi* are being unfavorably affected by the launch of biosimilars for a competing product. The Company expects this competition will continue to unfavorably affect sales of *Simponi*.

Sales of *Remicade,* a treatment for inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), declined 20% in 2020 driven by ongoing biosimilar competition in the Company's marketing territories in Europe. The Company lost market exclusivity for *Remicade* in major European markets in 2015 and no longer has market exclusivity in any of its marketing territories. The Company is experiencing pricing and volume declines in these markets as a result of biosimilar competition and expects the declines to continue.

The Company's marketing rights with respect to these products will revert to Janssen Pharmaceuticals, Inc. in the second half of 2024.

Virology

($ in millions)	2020	% Change	% Change Excluding Foreign Exchange	2019	% Change	% Change Excluding Foreign Exchange	2018
Isentress/Isentress HD	$ 857	(12)%	(11)%	$ 975	(15)%	(10)%	$ 1,140
Zepatier	167	(55)%	(54)%	370	(19)%	(16)%	455

Worldwide sales of *Isentress/Isentress HD*, an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, declined 12% in 2020 primarily due to competitive pressure in the United States and in the EU. The Company expects competitive pressures for *Isentress/Isentress HD* to continue.

Global sales of *Zepatier*, a treatment for adult patients with chronic hepatitis C virus genotype (GT) 1 or GT4 infection, declined 55% in 2020 driven by lower demand globally due to competition and declining patient volumes, coupled with the impact of the COVID-19 pandemic.

Cardiovascular

($ in millions)	2020	% Change	% Change Excluding Foreign Exchange	2019	% Change	% Change Excluding Foreign Exchange	2018
Zetia/Vytorin	$ 664	(24)%	(24)%	$ 874	(35)%	(34)%	$ 1,355
Atozet	453	16 %	16 %	391	13 %	18 %	347
Rosuzet	130	8 %	9 %	120	107 %	115 %	58
Alliance revenue - Adempas *(1)*	281	38 %	38 %	204	47 %	47 %	139
Adempas	220	3 %	2 %	215	13 %	17 %	190

[1] *Alliance revenue represents Merck's share of profits from sales in Bayer's marketing territories, which are product sales net of cost of sales and commercialization costs (see Note 4 to the consolidated financial statements).*

Combined global sales of *Zetia* (marketed in most countries outside the United States as *Ezetrol*) and *Vytorin* (marketed outside the United States as *Inegy*), medicines for lowering LDL cholesterol, declined 24% in 2020 driven primarily by lower sales of *Ezetrol* in Japan and *Ezetrol* and *Inegy* in the EU. The patent that provided market exclusivity for *Ezetrol* in Japan expired in September 2019 and generic competition began in June 2020. The

EU patents for *Ezetrol* and *Inegy* expired in April 2018 and April 2019, respectively. Accordingly, the Company is experiencing sales declines in these markets as a result of generic competition and expects the declines to continue. The sales decline in 2020 was also attributable to lower pricing following loss of exclusivity in Australia. Higher demand for *Ezetrol* in China partially offset the sales decline in 2020. Merck lost market exclusivity in the United States for *Zetia* in 2016 and *Vytorin* in 2017 and subsequently lost nearly all U.S. sales of these products as a result of generic competition.

Sales of *Atozet* (marketed outside of the United States), a medicine for lowering LDL cholesterol, grew 16% in 2020, primarily driven by higher demand in most markets, particularly in the EU, Japan and other countries in the Asia Pacific region.

Zetia, *Vytorin*, *Atozet* and *Rosuzet* will be contributed to Organon in connection with the spin-off (see Note 1 to the consolidated financial statements).

Adempas, a cardiovascular drug for the treatment of pulmonary arterial hypertension, is part of a worldwide collaboration with Bayer to market and develop soluble guanylate cyclase (sGC) modulators including Adempas (see Note 4 to the consolidated financial statements). Revenue from Adempas includes Merck's share of profits from the sale of Adempas in Bayer's marketing territories, which grew 38% in 2020, as well as sales in Merck's marketing territories, which grew 3% in 2020.

In January 2021, the FDA approved Verquvo (vericiguat), an sGC stimulator, to reduce the risk of cardiovascular death and heart failure hospitalization following a hospitalization for heart failure or need for outpatient intravenous diuretics in adults with symptomatic chronic heart failure and reduced ejection fraction. The approval was based on the results of the pivotal Phase 3 VICTORIA trial and follows a priority regulatory review. Verquvo is part of the same worldwide clinical development collaboration with Bayer that includes Adempas referenced above.

Diabetes

($ in millions)	**2020**	**% Change**	**% Change Excluding Foreign Exchange**	2019	% Change	% Change Excluding Foreign Exchange	2018
Januvia/Janumet	**$ 5,276**	**(4)%**	**(4)%**	$ 5,524	(7)%	(4)%	$ 5,914

Worldwide combined sales of *Januvia* and *Janumet*, medicines that help lower blood sugar levels in adults with type 2 diabetes, declined 4% in 2020 as a result of continued pricing pressure in the United States, partially offset by higher demand in certain international markets, particularly in China. The Company expects U.S. pricing pressure to continue. *Januvia* and *Janumet* will lose market exclusivity in the United States in January 2023. The supplementary patent certificates that provide market exclusivity for *Januvia* and *Janumet* in the EU expire in September 2022 and April 2023, respectively. The Company anticipates sales of *Januvia* and *Janumet* in these markets will decline substantially after loss of market exclusivity.

Women's Health

($ in millions)	**2020**	**% Change**	**% Change Excluding Foreign Exchange**	2019	% Change	% Change Excluding Foreign Exchange	2018
Implanon/Nexplanon	**680**	**(14)%**	**(13)%**	787	12 %	14 %	703
NuvaRing	**236**	**(73)%**	**(73)%**	879	(3)%	(2)%	902

Worldwide sales of *Implanon/Nexplanon*, a single-rod subdermal contraceptive implant, declined 14% in 2020, primarily driven by lower demand in the United States and in the EU resulting from the COVID-19 pandemic.

Worldwide sales of *NuvaRing*, a vaginal contraceptive product, declined 73% in 2020 due to generic competition in the United States. The patent that provided U.S. market exclusivity for *NuvaRing* expired in April

2018 and generic competition began in December 2019. Accordingly, the Company is experiencing a rapid and substantial decline in U.S. *NuvaRing* sales and expects the decline to continue.

Implanon/Nexplanon and *NuvaRing* will be contributed to Organon in connection with the spin-off (see Note 1 to the consolidated financial statements).

Biosimilars

($ in millions)	**2020**	**% Change**	**% Change Excluding Foreign Exchange**	2019	% Change	% Change Excluding Foreign Exchange	2018
Biosimilars	**$ 330**	**31 %**	**31 %**	$ 252	*	*	$ 64

** Calculation not meaningful.*

Biosimilar products are marketed by the Company pursuant to an agreement with Samsung Bioepis Co., Ltd. (Samsung) to develop and commercialize multiple pre-specified biosimilar candidates. Currently, the Company markets Renflexis (infliximab-abda), a biosimilar to Remicade (infliximab) for the treatment of certain inflammatory diseases; Ontruzant (trastuzumab-dttb), a biosimilar to Herceptin (trastuzumab) for the treatment of HER2-positive breast cancer and HER2 overexpressing gastric cancer; Brenzys (etanercept biosimilar), a biosimilar to Enbrel for the treatment of certain inflammatory diseases; and Aybintio (bevacizumab) for the treatment of certain types of cancer. Merck's commercialization territories under the agreement vary by product. Sales growth of biosimilars in 2020 was primarily due to continued post-launch uptake of Renflexis in the United States and Canada and the launch of Ontruzant in Brazil in 2020.

In August 2020, the EC granted marketing authorization for Aybintio for the treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer, NSCLC, advanced and/or metastatic RCC, epithelial ovarian, fallopian tube and primary peritoneal cancer and cervical cancer. An application seeking approval of Aybintio in the United States was filed in September 2019.

The above biosimilar products will be contributed to Organon in connection with the spin-off (see Note 1 to the consolidated financial statements).

Animal Health Segment

($ in millions)	**2020**	**% Change**	**% Change Excluding Foreign Exchange**	2019	% Change	% Change Excluding Foreign Exchange	2018
Livestock	**$ 2,939**	**6 %**	**9 %**	$ 2,784	6 %	11 %	$ 2,630
Companion Animal	**1,764**	**10 %**	**11 %**	1,609	2 %	5 %	1,582

Sales of livestock products grew 6% in 2020 predominantly due to an additional five months of sales in 2020 related to the April 2019 acquisition of Antelliq, a leader in digital animal identification, traceability and monitoring solutions (see Note 3 to the consolidated financial statements). Sales of companion animal products grew 10% in 2020 driven primarily by higher demand for the *Bravecto* line of products for parasitic control, as well as higher demand for companion animal vaccines.

Costs, Expenses and Other

($ in millions)	**2020**	**% Change**	2019	% Change	2018
Cost of sales	**$ 15,485**	**10 %**	$ 14,112	4 %	$ 13,509
Selling, general and administrative	**10,468**	**(1)%**	10,615	5 %	10,102
Research and development	**13,558**	**37 %**	9,872	1 %	9,752
Restructuring costs	**578**	**(9)%**	638	1 %	632
Other (income) expense, net	**(886)**	*****	139	*	(402)
	$ 39,203	**11 %**	$ 35,376	5 %	$ 33,593

** Calculation not meaningful.*

Cost of Sales

Cost of sales was $15.5 billion in 2020 compared with $14.1 billion in 2019. Cost of sales includes the amortization of intangible assets recorded in connection with acquisitions, collaborations, and licensing arrangements, which totaled $1.8 billion in 2020 compared with $2.0 billion in 2019, respectively. Additionally, costs in 2020 and 2019 include intangible asset impairment charges of $1.6 billion and $705 million related to marketed products and other intangibles (see Note 8 to the consolidated financial statements). The Company may recognize additional impairment charges in the future related to intangible assets that were measured at fair value and capitalized in connection with business acquisitions and such charges could be material. Costs in 2020 also include a charge of $260 million in connection with the discontinuation of COVID-19 vaccine development programs (see Note 3 to the consolidated financial statements) and inventory write-offs of $120 million related to a recall for *Zerbaxa* (see Note 8 to the consolidated financial statements). Also included in cost of sales are expenses associated with restructuring activities which amounted to $175 million in 2020 compared with $251 million in 2019, primarily reflecting accelerated depreciation and asset write-offs related to the planned sale or closure of manufacturing facilities. Separation costs associated with manufacturing-related headcount reductions have been incurred and are reflected in *Restructuring costs* as discussed below.

Gross margin was 67.7% in 2020 compared with 69.9% in 2019. The gross margin decline in 2020 reflects the unfavorable effects of higher impairment charges (noted above), pricing pressure, a charge related to the discontinuation of COVID-19 vaccine development programs, and higher inventory write-offs related to the recall of *Zerbaxa* (noted above), partially offset by the favorable effects of product mix, lower amortization of intangible assets and lower restructuring costs.

Selling, General and Administrative

Selling, general and administrative (SG&A) expenses were $10.5 billion in 2020, a decline of 1% compared with 2019. The decline was driven primarily by lower administrative, selling and promotional costs, including lower travel and meeting expenses, due in part to the COVID-19 pandemic, and the favorable effect of foreign exchange, partially offset by higher costs related to the spin-off of Organon and a contribution to the Merck Foundation. SG&A expenses in 2020 include $710 million of costs related to the spin-off of Organon. SG&A expenses in 2020 and 2019 include restructuring costs of $47 million and $34 million, respectively, related primarily to accelerated depreciation for facilities to be closed or divested. Separation costs associated with sales force reductions have been incurred and are reflected in *Restructuring costs* as discussed below.

Research and Development

Research and development (R&D) expenses were $13.6 billion in 2020, an increase of 37% compared with 2019. The increase was driven primarily by higher upfront payments related to acquisitions and collaborations, including a $2.7 billion charge in 2020 related to the acquisition of VelosBio (see Note 3 to the consolidated financial statements), as well as higher expenses related to clinical development and increased investment in discovery research and early drug development. Higher restructuring costs also contributed to the increase in R&D expenses in 2020. The increase in R&D expenses in 2020 was partially offset by lower in-process research and development (IPR&D) impairment charges and lower costs resulting from the COVID-19 pandemic, net of spending on COVID-19-related vaccine and antiviral research programs.

R&D expenses are comprised of the costs directly incurred by MRL, the Company's research and development division that focuses on human health-related activities, which were $6.6 billion in 2020 compared with $6.1 billion in 2019. Also included in R&D expenses are Animal Health research costs, licensing costs and costs incurred by other divisions in support of R&D activities, including depreciation, production and general and administrative, which in the aggregate were $2.7 billion in 2020 and $2.6 billion in 2019. Additionally, R&D expenses in 2020 include a $2.7 billion charge for the acquisition of VelosBio (noted above), a $462 million charge for the acquisition of OncoImmune and charges of $826 million related to transactions with Seagen. R&D expenses in 2019 include a $993 million charge for the acquisition of Peloton. See Note 3 to the consolidated financial statements for more information on these transactions. R&D expenses also include IPR&D impairment charges of $90 million and $172 million in 2020 and 2019, respectively (see Note 8 to the consolidated financial statements). The Company may recognize additional impairment charges in the future related to the cancellation or delay of other pipeline programs that were measured at fair value and capitalized in connection with business acquisitions and such

charges could be material. In addition, R&D expenses in 2020 include $83 million of costs associated with restructuring activities, primarily relating to accelerated depreciation. R&D expenses also include expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration recorded in connection with business acquisitions. During 2020 and 2019, the Company recorded a net reduction in expenses of $95 million and $39 million, respectively, related to changes in these estimates.

Restructuring Costs

In early 2019, Merck approved a new global restructuring program (Restructuring Program) as part of a worldwide initiative focused on further optimizing the Company's manufacturing and supply network, as well as reducing its global real estate footprint. This program is a continuation of the Company's plant rationalization, builds on prior restructuring programs and does not include any actions associated with the planned spin-off of Organon. As the Company continues to evaluate its global footprint and overall operating model, it subsequently identified additional actions under the Restructuring Program, and could identify further actions over time. The actions currently contemplated under the Restructuring Program are expected to be substantially completed by the end of 2023, with the cumulative pretax costs to be incurred by the Company to implement the program now estimated to be approximately $3.0 billion. The Company expects to record charges of approximately $700 million in 2021 related to the Restructuring Program. The Company anticipates the actions under the Restructuring Program to result in annual net cost savings of approximately $900 million by the end of 2023. Actions under previous global restructuring programs have been substantially completed.

Restructuring costs, primarily representing separation and other related costs associated with these restructuring activities, were $578 million in 2020 and $638 million in 2019. Separation costs incurred were associated with actual headcount reductions, as well as estimated expenses under existing severance programs for headcount reductions that were probable and could be reasonably estimated. Also included in restructuring costs are asset abandonment, facility shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation plan costs. For segment reporting, restructuring costs are unallocated expenses.

Additional costs associated with the Company's restructuring activities are included in *Cost of sales*, *Selling, general and administrative* expenses and *Research and development* costs. The Company recorded aggregate pretax costs of $883 million in 2020 and $927 million in 2019 related to restructuring program activities (see Note 5 to the consolidated financial statements).

Other (Income) Expense, Net

Other (income) expense, net, was $886 million of income in 2020 compared with $139 million of expense in 2019, primarily due to higher income from investments in equity securities, net, largely related to Moderna, Inc. For details on the components of Other (income) expense, net, see Note 14 to the consolidated financial statements.

Segment Profits

($ in millions)	**2020**	2019	2018
Pharmaceutical segment profits	**$ 29,722**	$ 28,324	$ 24,871
Animal Health segment profits	**1,650**	1,609	1,659
Other non-reportable segment profits	**1**	(7)	103
Other	**(22,582)**	(18,462)	(17,932)
Income Before Taxes	**$ 8,791**	$ 11,464	$ 8,701

Pharmaceutical segment profits are comprised of segment sales less standard costs, as well as SG&A expenses directly incurred by the segment. Animal Health segment profits are comprised of segment sales, less all cost of sales, as well as SG&A and R&D expenses directly incurred by the segment. For internal management reporting presented to the chief operating decision maker, Merck does not allocate the remaining cost of sales not included in segment profits as described above, research and development expenses incurred by MRL, or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for

monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. Also excluded from the determination of segment profits are costs related to restructuring activities and acquisition and divestiture-related costs, including the amortization of purchase accounting adjustments, intangible asset impairment charges, and changes in the estimated fair value measurement of liabilities for contingent consideration. Additionally, segment profits do not reflect other expenses from corporate and manufacturing cost centers and other miscellaneous income or expense. These unallocated items are reflected in "Other" in the above table. Also included in "Other" are miscellaneous corporate profits (losses), as well as operating profits (losses) related to third-party manufacturing sales.

Pharmaceutical segment profits grew 5% in 2020 compared with 2019 driven primarily by higher sales, as well as lower selling and promotional costs. Animal Health segment profits grew 3% in 2020 driven primarily by higher sales and lower promotional and selling costs, partially offset by higher R&D costs and the unfavorable effect of foreign exchange.

Taxes on Income

The effective income tax rates of 19.4% in 2020 and 14.7% in 2019 reflect the impacts of acquisition and divestiture-related costs and restructuring costs, partially offset by the beneficial impact of foreign earnings, including product mix. The effective income tax rate in 2020 reflects the unfavorable impact of a charge for the acquisition of VelosBio for which no tax benefit was recognized. The effective income tax rate in 2019 reflects the favorable impact of a $364 million net tax benefit related to the settlement of certain federal income tax matters (see Note 15 to the consolidated financial statements) and the reversal of tax reserves established in connection with the 2014 divestiture of Merck's Consumer Care (MCC) business due to the lapse in the statute of limitations. In addition, the effective income tax rate in 2019 reflects the unfavorable impacts of a charge for the acquisition of Peloton for which no tax benefit was recognized and charges of $117 million related to the finalization of treasury regulations for the transition tax associated with the 2017 enactment of U.S. tax legislation known as the Tax Cuts and Jobs Act (TCJA) (see Note 15 to the consolidated financial statements).

Net Income (Loss) Attributable to Noncontrolling Interests

Net income (loss) attributable to noncontrolling interests was $15 million in 2020 compared with $(66) million in 2019. The loss in 2019 was driven primarily by the portion of goodwill impairment charges related to certain businesses in the Healthcare Services segment that were attributable to noncontrolling interests.

Net Income and Earnings per Common Share

Net income attributable to Merck & Co., Inc. was $7.1 billion in 2020 and $9.8 billion in 2019. EPS was $2.78 in 2020 and $3.81 in 2019.

Non-GAAP Income and Non-GAAP EPS

Non-GAAP income and non-GAAP EPS are alternative views of the Company's performance that Merck is providing because management believes this information enhances investors' understanding of the Company's results as it permits investors to understand how management assesses performance. Non-GAAP income and non-GAAP EPS exclude certain items because of the nature of these items and the impact that they have on the analysis of underlying business performance and trends. The excluded items (which should not be considered non-recurring) consist of acquisition and divestiture-related costs, restructuring costs and certain other items. These excluded items are significant components in understanding and assessing financial performance.

Non-GAAP income and non-GAAP EPS are important internal measures for the Company. Senior management receives a monthly analysis of operating results that includes non-GAAP EPS. Management uses these measures internally for planning and forecasting purposes and to measure the performance of the Company along with other metrics. In addition, senior management's annual compensation is derived in part using non-GAAP pretax income. Since non-GAAP income and non-GAAP EPS are not measures determined in accordance with GAAP, they have no standardized meaning prescribed by GAAP and, therefore, may not be comparable to the calculation of similar measures of other companies. The information on non-GAAP income and non-GAAP EPS should be considered in addition to, but not as a substitute for or superior to, net income and EPS prepared in accordance with generally accepted accounting principles in the United States (GAAP).

A reconciliation between GAAP financial measures and non-GAAP financial measures is as follows:

($ in millions except per share amounts)	**2020**	2019	2018
Income before taxes as reported under GAAP	**$ 8,791**	$ 11,464	$ 8,701
Increase (decrease) for excluded items:			
Acquisition and divestiture-related costs [1]	**3,704**	2,681	3,066
Restructuring costs	**883**	927	658
Other items:			
Charge for the acquisition of VelosBio	**2,660**	—	—
Charges for the formation of collaborations [2]	**1,076**	—	1,400
Charge for the acquisition of OncoImmune	**462**	—	—
Charge for the discontinuation of COVID-19 vaccine development programs	**305**	—	—
Charge for the acquisition of Peloton	**—**	993	—
Charge related to the termination of a collaboration with Samsung	**—**	—	423
Charge for the acquisition of Viralytics Limited	**—**	—	344
Other	**(20)**	55	(57)
Non-GAAP income before taxes	**17,861**	16,120	14,535
Taxes on income as reported under GAAP	**1,709**	1,687	2,508
Estimated tax benefit on excluded items [3]	**1,122**	695	535
Adjustment to tax benefits recorded in conjunction with the 2015 Cubist Pharmaceuticals, Inc. acquisition	**(67)**	—	—
Net tax benefit from the settlement of certain federal income tax matters	**—**	364	—
Tax benefit from the reversal of tax reserves related to the divestiture of MCC	**—**	86	—
Net tax charge related to the finalization of treasury regulations related to the enactment of the TCJA	**—**	(117)	(160)
Non-GAAP taxes on income	**2,764**	2,715	2,883
Non-GAAP net income	**15,097**	13,405	11,652
Less: Net income (loss) attributable to noncontrolling interests as reported under GAAP	**15**	(66)	(27)
Acquisition and divestiture-related costs attributable to noncontrolling interests	**—**	(89)	(58)
Non-GAAP net income attributable to noncontrolling interests	**15**	23	31
Non-GAAP net income attributable to Merck & Co., Inc.	**$ 15,082**	$ 13,382	$ 11,621
EPS assuming dilution as reported under GAAP	**$ 2.78**	$ 3.81	$ 2.32
EPS difference	**3.16**	1.38	2.02
Non-GAAP EPS assuming dilution	**$ 5.94**	$ 5.19	$ 4.34

[1] *Amount in 2020 includes a $1.6 billion intangible asset impairment charge related to* Zerbaxa. *Amount in 2019 includes a $612 million intangible asset impairment charge related to* Sivextro. *See Note 8 to the consolidated financial statements.*

[2] *Amount in 2020 includes $826 million related to transactions with Seagen (see Note 3 to the consolidated financial statements). Amount in 2018 represents charge for the formation of a collaboration with Eisai (see Note 4 to the consolidated financial statements).*

[3] *The estimated tax impact on the excluded items is determined by applying the statutory rate of the originating territory of the non-GAAP adjustments.*

Acquisition and Divestiture-Related Costs

Non-GAAP income and non-GAAP EPS exclude the impact of certain amounts recorded in connection with business acquisitions and divestitures. These amounts include the amortization of intangible assets and amortization of purchase accounting adjustments to inventories, as well as intangible asset impairment charges and expense or income related to changes in the estimated fair value measurement of liabilities for contingent

consideration. Also excluded are integration, transaction, and certain other costs associated with business acquisitions and divestitures.

Restructuring Costs

Non-GAAP income and non-GAAP EPS exclude costs related to restructuring actions (see Note 5 to the consolidated financial statements). These amounts include employee separation costs and accelerated depreciation

associated with facilities to be closed or divested. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the asset, based upon the anticipated date the site will be closed or divested or the equipment disposed of, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. Restructuring costs also include asset abandonment, facility shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation costs.

Certain Other Items

These items are adjusted for after evaluating them on an individual basis considering their quantitative and qualitative aspects. Typically, these consist of items that are unusual in nature, significant to the results of a particular period or not indicative of future operating results. Excluded from non-GAAP income and non-GAAP EPS in 2020 are charges for the acquisitions of VelosBio and OncoImmune, charges related to collaborations, including transactions with Seagen (see Note 3 to the consolidated financial statements), a charge for the discontinuation of COVID-19 vaccine development programs, and an adjustment to tax benefits recorded in conjunction with the 2015 Cubist Pharmaceuticals, Inc. acquisition. Excluded from non-GAAP income and non-GAAP EPS in 2019 is a charge for the acquisition of Peloton (see Note 3 to the consolidated financial statements), tax charges related to the finalization of U.S. treasury regulations related to the TCJA, a net tax benefit related to the settlement of certain federal income tax matters, and a tax benefit related to the reversal of tax reserves established in connection with the 2014 divestiture of MCC (see Note 15 to the consolidated financial statements). Excluded from non-GAAP income and non-GAAP EPS in 2018 is a charge related to the formation of a collaboration with Eisai (see Note 4 to the consolidated financial statements), a charge related to the termination of a collaboration agreement with Samsung for insulin glargine (see Note 3 to the consolidated financial statements), a charge for the acquisition of Viralytics (see Note 3 to the consolidated financial statements), and measurement-period adjustments related to the provisional amounts recorded for the TCJA (see Note 15 to the consolidated financial statements).

Beginning in 2021, the Company will be changing the treatment of certain items for the purposes of its non-GAAP reporting. Historically, Merck's non-GAAP results excluded the amortization of intangible assets recognized in connection with business acquisitions (reflected as part of acquisition and divestiture-related costs) but did not exclude the amortization of intangibles originating from collaborations, asset acquisitions or licensing arrangements. Beginning in 2021, Merck's non-GAAP results will no longer differentiate between the nature of the intangible assets being amortized and will exclude all amortization of intangible assets. Also, beginning in 2021, Merck's non-GAAP results will exclude gains and losses on investments in equity securities. Prior period amounts will be recast to conform to the new presentation.

Research and Development

Research Pipeline

The Company currently has several candidates under regulatory review in the United States and internationally, as well as in late-stage clinical development. A chart reflecting the Company's current research pipeline as of February 22, 2021 and related discussion is set forth in Item 1. "Business — Research and Development" above.

Acquired In-Process Research and Development

In connection with business acquisitions, the Company has recorded the fair value of in-process research projects which, at the time of acquisition, had not yet reached technological feasibility. At December 31, 2020, the balance of IPR&D was $3.2 billion (see Note 8 to the consolidated financial statements).

The IPR&D projects that remain in development are subject to the inherent risks and uncertainties in drug development and it is possible that the Company will not be able to successfully develop and complete the IPR&D programs and profitably commercialize the underlying product candidates. The time periods to receive approvals from the FDA and other regulatory agencies are subject to uncertainty. Significant delays in the approval process, or the Company's failure to obtain approval at all, would delay or prevent the Company from realizing revenues from these products. Additionally, if certain of the IPR&D programs fail or are abandoned during development, then the Company will not realize the future cash flows it has estimated and recorded as IPR&D as of

the acquisition date. If such circumstances were to occur, the Company's future operating results could be adversely affected and the Company may recognize impairment charges and such charges could be material.

In 2020, 2019, and 2018 the Company recorded IPR&D impairment charges within *Research and development* expenses of $90 million, $172 million and $152 million, respectively (see Note 8 to the consolidated financial statements).

Additional research and development will be required before any of the remaining programs reach technological feasibility. The costs to complete the research projects will depend on whether the projects are brought to their final stages of development and are ultimately submitted to the FDA or other regulatory agencies for approval.

Acquisitions, Research Collaborations and License Agreements

Merck continues to remain focused on pursuing opportunities that have the potential to drive both near- and long-term growth. Certain recent transactions are summarized below; additional details are included in Note 3 to the consolidated financial statements. Merck is actively monitoring the landscape for growth opportunities that meet the Company's strategic criteria.

In January 2020, Merck acquired ArQule, a publicly traded biopharmaceutical company focused on kinase inhibitor discovery and development for the treatment of patients with cancer and other diseases for $2.7 billion. ArQule's lead investigational candidate, MK-1026 (formerly ARQ 531), is a novel, oral Bruton's tyrosine kinase (BTK) inhibitor currently being evaluated for the treatment of B-cell malignancies. The transaction was accounted for as an acquisition of a business. The Company recorded IPR&D of $2.3 billion (related to MK-1026), goodwill of $512 million and other net liabilities of $102 million.

In July 2020, Merck and Ridgeback Bio, a closely held biotechnology company, closed a collaboration agreement to develop molnupiravir (MK-4482, also known as EIDD-2801), an orally available antiviral candidate in clinical development for the treatment of patients with COVID-19. Merck gained exclusive worldwide rights to develop and commercialize molnupiravir and related molecules. Under the terms of the agreement, Ridgeback Bio received an upfront payment and also is eligible to receive future contingent payments dependent upon the achievement of certain developmental and regulatory approval milestones, as well as a share of the net profits of molnupiravir and related molecules, if approved. Molnupiravir is currently being evaluated in Phase 2/3 clinical trials in both the hospital and outpatient settings. The primary completion date for the Phase 2/3 studies is June 2021. The Company anticipates interim efficacy data in the first quarter of 2021.

In September 2020, Merck and Seagen announced an oncology collaboration to globally develop and commercialize Seagen's ladiratuzumab vedotin (MK-6440), an investigational antibody-drug conjugate targeting LIV-1, which is currently in Phase 2 clinical trials for breast cancer and other solid tumors. Under the terms of the agreement, Merck made an upfront payment of $600 million and a $1.0 billion equity investment in 5 million shares of Seagen common stock at a price of $200 per share. Merck recorded $616 million in *Research and development* expenses in 2020 related to this transaction. Seagen is also eligible to receive future contingent milestone payments dependent upon the achievement of certain developmental and sales-based milestones.

Concurrent with the above transaction, Seagen granted Merck an exclusive license to commercialize Tukysa (tucatinib), a small molecule tyrosine kinase inhibitor, for the treatment of HER2-positive cancers, in Asia, the Middle East and Latin America and other regions outside of the United States, Canada and Europe. Under the terms of the agreement, Merck made upfront payments aggregating $210 million, which were recorded as *Research and development* expenses in 2020. Seagen is also eligible to receive future contingent regulatory approval milestones and tiered royalties based on annual sales levels of Tukysa in Merck's territories.

In December 2020, Merck acquired OncoImmune, a privately held, clinical-stage biopharmaceutical company, for an upfront payment of $423 million. In addition, OncoImmune shareholders will be eligible to receive future contingent regulatory approval milestone payments and tiered royalties. OncoImmune's lead therapeutic candidate MK-7110 (also known as CD24Fc) is being evaluated for the treatment of patients hospitalized with COVID-19. Topline results from a pre-planned interim efficacy analysis from a Phase 3 study of MK-7110 were released in September 2020. Full results from this Phase 3 study, which were consistent with the topline results, were received in February 2021 and will be submitted for publication in the future. The transaction was accounted

for as an acquisition of an asset. Under the agreement, prior to the completion of the acquisition, OncoImmune spun-out certain rights and assets unrelated to the MK-7110 program to a new entity owned by the existing shareholders of OncoImmune. In connection with the closing of the acquisition, Merck invested $50 million for a 20% ownership interest in the new entity, which was valued at $33 million resulting in a $17 million premium. Merck also recognized other net liabilities of $22 million. The Company recorded *Research and development* expenses of $462 million in 2020 related to this transaction.

In December 2020, Merck announced it had entered into an agreement with the U.S. Government to support the development, manufacture and initial distribution of MK-7110 upon approval or Emergency Use Authorization (EUA) from the FDA by June 30, 2021. Under the agreement, Merck was to receive up to approximately $356 million for manufacturing and supply of approximately 60,000-100,000 doses of MK-7110 to the U.S. government by June 30, 2021 to help meet the government's pandemic response goals. Following the execution of this agreement, Merck received feedback from the FDA that additional data, beyond the study conducted by OncoImmune, would be needed to support a potential EUA application. Based on this FDA feedback, Merck no longer expects to supply the U.S. government with MK-7110 in the first half of 2021. Merck is actively working with FDA to address the agency's comments.

In December 2020, Merck acquired VelosBio, a privately held clinical-stage biopharmaceutical company, for $2.8 billion. VelosBio's lead investigational candidate is MK-2140 (formerly known as VLS-101), an antibody-drug conjugate targeting receptor tyrosine kinase-like orphan receptor 1 (ROR1) that is currently being evaluated for the treatment of patients with hematologic malignancies and solid tumors. The transaction was accounted for as an acquisition of an asset. Merck recorded net assets of $180 million (primarily cash) and *Research and development* expenses of $2.7 billion in 2020 related to the transaction.

In February 2021, Merck and Pandion Therapeutics, Inc. (Pandion) entered into a definitive agreement under which Merck will acquire Pandion, a clinical-stage biotechnology company developing novel therapeutics designed to address the unmet needs of patients living with autoimmune diseases, for $60 per share in cash representing an approximate total equity value of $1.85 billion. Pandion is advancing a pipeline of precision immune modulators targeting critical immune control nodes. Under the terms of the acquisition agreement, Merck, through a subsidiary, will initiate a tender offer to acquire all outstanding shares of Pandion. The closing of the tender offer is subject to certain conditions, including the tender of shares representing at least a majority of the total number of Pandion's shares of fully-diluted common stock, the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and other customary conditions. The transaction is expected to close in the first half of 2021.

Capital Expenditures

Capital expenditures were $4.7 billion in 2020, $3.5 billion in 2019 and $2.6 billion in 2018. Expenditures in the United States were $2.7 billion in 2020, $1.9 billion in 2019 and $1.5 billion in 2018. The increased capital expenditures in 2020 and 2019 reflect investment in new capital projects focused primarily on increasing manufacturing capacity for Merck's key products. The increased capital expenditures in 2020 also reflect the purchase of a manufacturing facility in Dunboyne, Ireland to support upcoming product launches (see Note 3 to the consolidated financial statements). The Company plans to invest more than $20 billion in new capital projects from 2020-2024.

Depreciation expense was $1.7 billion in 2020, $1.7 billion in 2019 and $1.4 billion in 2018, of which $1.2 billion in 2020, $1.2 billion in 2019 and $1.0 billion in 2018, related to locations in the United States. Total depreciation expense in 2020 and 2019 included accelerated depreciation of $268 million and $233 million, respectively, associated with restructuring activities (see Note 5 to the consolidated financial statements).

Analysis of Liquidity and Capital Resources

Merck's strong financial profile enables it to fund research and development, focus on external alliances, support in-line products and maximize upcoming launches while providing significant cash returns to shareholders.

Selected Data

($ in millions)	**2020**	2019	2018
Working capital	**$ 437**	$ 5,263	$ 3,669
Total debt to total liabilities and equity	**34.7 %**	31.2 %	30.4 %
Cash provided by operations to total debt	**0.3:1**	0.5:1	0.4:1

The decline in working capital in 2020 compared with 2019 is primarily related to increased short-term debt supporting the funding of business development activities and capital expenditures.

Cash provided by operating activities was $10.3 billion in 2020 compared with $13.4 billion in 2019, reflecting higher payments related to collaborations which were $2.9 billion in 2020 compared with $805 million in 2019. Cash provided by operating activities continues to be the Company's primary source of funds to finance operating needs, capital expenditures, treasury stock purchases and dividends paid to shareholders.

Cash used in investing activities was $9.4 billion in 2020 compared with $2.6 billion in 2019. The increase was driven primarily by lower proceeds from the sales of securities and other investments, higher use of cash for acquisitions and higher capital expenditures, partially offset by lower purchases of securities and other investments.

Cash used in financing activities was $2.8 billion in 2020 compared with $8.9 billion in 2019. The lower use of cash in financing activities was driven primarily by a net increase in short-term borrowings in 2020 compared with a net decrease in short-term borrowing in 2019, as well as lower purchases of treasury stock, partially offset by higher payments on debt (see below), lower proceeds from the issuance of debt (see below), higher dividends paid to shareholders and lower proceeds from the exercise of stock options.

The Company has accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable (see Note 6 to the consolidated financial statements). The Company factored $2.3 billion and $2.7 billion of accounts receivable in the fourth quarter of 2020 and 2019, respectively, under these factoring arrangements, which reduced outstanding accounts receivable. The cash received from the financial institutions is reported within operating activities in the Consolidated Statement of Cash Flows. In certain of these factoring arrangements, for ease of administration, the Company will collect customer payments related to the factored receivables, which it then remits to the financial institutions. At December 31, 2020 and 2019 the Company had collected $102 million and $256 million, respectively, on behalf of the financial institutions, which was remitted to them in January 2021 and 2020, respectively. The net cash flows from these collections are reported as financing activities in the Consolidated Statement of Cash Flows.

The Company's contractual obligations as of December 31, 2020 are as follows:

Payments Due by Period

($ in millions)	Total	2021	2022—2023	2024—2025	Thereafter
Purchase obligations [1]	$ 3,458	$ 977	$ 1,232	$ 668	$ 581
Loans payable and current portion of long-term debt	6,432	6,432	—	—	—
Long-term debt	25,437	—	4,000	3,863	17,574
Interest related to debt obligations	10,779	759	1,431	1,254	7,335
Unrecognized tax benefits [2]	305	305	—	—	—
Transition tax related to the enactment of the TCJA [3]	3,006	390	736	1,880	—
Milestone payments related to collaborations [4]	200	200	—	—	—
Leases [5]	1,778	335	521	342	580
	$ 51,395	$ 9,398	$ 7,920	$ 8,007	$ 26,070

[1] *Includes future inventory purchases the Company has committed to in connection with certain divestitures.*

[2] *As of December 31, 2020, the Company's Consolidated Balance Sheet reflects liabilities for unrecognized tax benefits, including interest and penalties, of $1.8 billion, including $305 million reflected as a current liability. Due to the high degree of uncertainty regarding the timing of future cash outflows of liabilities for unrecognized tax benefits beyond one year, a reasonable estimate of the period of cash settlement for years beyond 2021 cannot be made.*

[3] *In connection with the enactment of the TCJA, the Company is required to pay a one-time transition tax, which the Company has elected to pay over a period of eight years through 2025 as permitted under the TCJA (see Note 15 to the consolidated financial statements).*

[4] *Reflects payments under collaborative agreements for sales-based milestones that were achieved in 2020 (and therefore deemed to be contractual obligations) but not paid until 2021 (see Note 4 to the consolidated financial statements).*

[5] *Amounts exclude reasonably certain lease renewals that have not yet been executed (see Note 9 to the consolidated financial statements).*

Purchase obligations are enforceable and legally binding obligations for purchases of goods and services including minimum inventory contracts, research and development and advertising. Amounts do not include contingent milestone payments related to collaborative arrangements or acquisitions as they are not considered contractual obligations until the successful achievement of developmental, regulatory approval or commercial milestones. At December 31, 2020, the Company has recognized liabilities for contingent sales-based milestone payments related to collaborations with AstraZeneca and Eisai where payment remains subject to the achievement of the related sales milestone aggregating $1.0 billion (see Note 4 to the consolidated financial statements). Excluded from research and development obligations are potential future funding commitments of up to approximately $52 million for investments in research venture capital funds. Loans payable and current portion of long-term debt reflects $73 million of long-dated notes that are subject to repayment at the option of the holders. Required funding obligations for 2021 relating to the Company's pension and other postretirement benefit plans are not expected to be material. However, the Company currently anticipates contributing approximately $300 million to its U.S. pension plans, $170 million to its international pension plans and $35 million to its other postretirement benefit plans during 2021.

In June 2020, the Company issued $4.5 billion principal amount of senior unsecured notes consisting of $1.0 billion of 0.75% notes due 2026, $1.25 billion of 1.45% notes due 2030, $1.0 billion of 2.35% notes due 2040 and $1.25 billion of 2.45% notes due 2050. Merck used the net proceeds from the offering for general corporate purposes, including without limitation the repayment of outstanding commercial paper borrowings and other indebtedness with upcoming maturities.

In March 2019, the Company issued $5.0 billion principal amount of senior unsecured notes consisting of $750 million of 2.90% notes due 2024, $1.75 billion of 3.40% notes due 2029, $1.0 billion of 3.90% notes due 2039, and $1.5 billion of 4.00% notes due 2049. The Company used the net proceeds from the offering for general corporate purposes, including the repayment of outstanding commercial paper borrowings.

The Company has a $6.0 billion credit facility that matures in June 2024. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

In March 2018, the Company filed a securities registration statement with the U.S. Securities and Exchange Commission (SEC) under the automatic shelf registration process available to "well-known seasoned issuers" which is effective for three years.

Effective as of November 3, 2009, the Company executed a full and unconditional guarantee of the then existing debt of its subsidiary Merck Sharp & Dohme Corp. (MSD) and MSD executed a full and unconditional guarantee of the then existing debt of the Company (excluding commercial paper), including for payments of principal and interest. These guarantees do not extend to debt issued subsequent to that date.

The Company continues to maintain a conservative financial profile. The Company places its cash and investments in instruments that meet high credit quality standards, as specified in its investment policy guidelines. These guidelines also limit the amount of credit exposure to any one issuer. The Company does not participate in any off-balance sheet arrangements involving unconsolidated subsidiaries that provide financing or potentially expose the Company to unrecorded financial obligations.

In November 2020, Merck's Board of Directors declared a quarterly dividend of $0.65 per share on the Company's outstanding common stock that was paid in January 2021. In January 2021, the Board of Directors declared a quarterly dividend of $0.65 per share on the Company's common stock for the second quarter of 2021 payable in April 2021.

In October 2018, Merck's Board of Directors authorized purchases of up to $10 billion of Merck's common stock for its treasury. The treasury stock purchase authorization has no time limit and will be made over time in open-market transactions, block transactions, on or off an exchange, or in privately negotiated transactions. The Company spent $1.3 billion to purchase 16 million shares of its common stock for its treasury during 2020 under this program. In March 2020, the Company temporarily suspended its share repurchase program. As of December 31, 2020, the Company's remaining share repurchase authorization was $5.9 billion. The Company purchased $4.8 billion and $9.1 billion of its common stock during 2019 and 2018, respectively, under authorized share repurchase programs.

In 2018, the Company entered into accelerated share repurchase (ASR) agreements with two third-party financial institutions (the Dealers). Under the ASR agreements, Merck agreed to purchase $5 billion of Merck's common stock, in total, with an initial delivery of 56.7 million shares of Merck's common stock, based on the then-current market price, made by the Dealers to Merck, and payments of $5 billion made by Merck to the Dealers in 2018, which were funded with existing cash and investments, as well as short-term borrowings. Upon settlement of the ASR agreements in 2019, Merck received an additional 7.7 million shares as determined by the average daily volume weighted-average price of Merck's common stock during the term of the ASR program, less a negotiated discount, bringing the total shares received by Merck under this program to 64.4 million.

Financial Instruments Market Risk Disclosures

The Company manages the impact of foreign exchange rate movements and interest rate movements on its earnings, cash flows and fair values of assets and liabilities through operational means and through the use of various financial instruments, including derivative instruments.

A significant portion of the Company's revenues and earnings in foreign affiliates is exposed to changes in foreign exchange rates. The objectives of the Company's foreign currency risk management program, as well as its interest rate risk management activities are discussed below.

Foreign Currency Risk Management

The Company has established revenue hedging, balance sheet risk management, and net investment hedging programs to protect against volatility of future foreign currency cash flows and changes in fair value caused by changes in foreign exchange rates.

The objective of the revenue hedging program is to reduce the variability caused by changes in foreign exchange rates that would affect the U.S. dollar value of future cash flows derived from foreign currency denominated sales, primarily the euro, Japanese yen and Chinese renminbi. To achieve this objective, the Company will hedge a portion of its forecasted foreign currency denominated third-party and intercompany distributor entity sales (forecasted sales) that are expected to occur over its planning cycle, typically no more than two years into the

future. The Company will layer in hedges over time, increasing the portion of forecasted sales hedged as it gets closer to the expected date of the forecasted sales. The portion of forecasted sales hedged is based on assessments of cost-benefit profiles that consider natural offsetting exposures, revenue and exchange rate volatilities and correlations, and the cost of hedging instruments. The Company manages its anticipated transaction exposure principally with purchased local currency put options, forward contracts, and purchased collar options.

The fair values of these derivative contracts are recorded as either assets (gain positions) or liabilities (loss positions) in the Consolidated Balance Sheet. Changes in the fair value of derivative contracts are recorded each period in either current earnings or *Other Comprehensive Income (Loss)* (*OCI)*, depending on whether the derivative is designated as part of a hedge transaction and, if so, the type of hedge transaction. For derivatives that are designated as cash flow hedges, the unrealized gains or losses on these contracts are recorded in *Accumulated Other Comprehensive Income (Loss)* (*AOCI)* and reclassified into *Sales* when the hedged anticipated revenue is recognized. For those derivatives which are not designated as cash flow hedges, but serve as economic hedges of forecasted sales, unrealized gains or losses are recorded in *Sales* each period. The cash flows from both designated and non-designated contracts are reported as operating activities in the Consolidated Statement of Cash Flows. The Company does not enter into derivatives for trading or speculative purposes.

Because Merck principally sells foreign currency in its revenue hedging program, a uniform weakening of the U.S. dollar would yield the largest overall potential loss in the market value of these hedge instruments. The market value of Merck's hedges would have declined by an estimated $593 million and $456 million at December 31, 2020 and 2019, respectively, from a uniform 10% weakening of the U.S. dollar. The market value was determined using a foreign exchange option pricing model and holding all factors except exchange rates constant. Although not predictive in nature, the Company believes that a 10% threshold reflects reasonably possible near-term changes in Merck's major foreign currency exposures relative to the U.S. dollar.

The Company manages operating activities and net asset positions at each local subsidiary in order to mitigate the effects of exchange on monetary assets and liabilities. The Company also uses a balance sheet risk management program to mitigate the exposure of net monetary assets that are denominated in a currency other than a subsidiary's functional currency from the effects of volatility in foreign exchange. In these instances, Merck principally utilizes forward exchange contracts to offset the effects of exchange on exposures denominated in developed country currencies, primarily the euro and Japanese yen. For exposures in developing country currencies, the Company will enter into forward contracts to partially offset the effects of exchange on exposures when it is deemed economical to do so based on a cost-benefit analysis that considers the magnitude of the exposure, the volatility of the exchange rate and the cost of the hedging instrument. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

A sensitivity analysis to changes in the value of the U.S. dollar on foreign currency denominated derivatives, investments and monetary assets and liabilities indicated that if the U.S. dollar uniformly weakened by 10% against all currency exposures of the Company at December 31, 2020 and 2019, *Income before taxes* would have declined by approximately $99 million and $110 million in 2020 and 2019, respectively. Because the Company was in a net short (payable) position relative to its major foreign currencies after consideration of forward contracts, a uniform weakening of the U.S. dollar will yield the largest overall potential net loss in earnings due to exchange. This measurement assumes that a change in one foreign currency relative to the U.S. dollar would not affect other foreign currencies relative to the U.S. dollar. Although not predictive in nature, the Company believes that a 10% threshold reflects reasonably possible near-term changes in Merck's major foreign currency exposures relative to the U.S. dollar. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

The economy of Argentina was determined to be hyperinflationary in 2018; consequently, in accordance with U.S. GAAP, the Company began remeasuring its monetary assets and liabilities for those operations in earnings. The impact to the Company's results was immaterial.

The Company also uses forward exchange contracts to hedge a portion of its net investment in foreign operations against movements in exchange rates. The forward contracts are designated as hedges of the net investment in a foreign operation. The unrealized gains or losses on these contracts are recorded in foreign currency translation adjustment within *OCI*, and remain in *AOCI* until either the sale or complete or substantially complete liquidation of the subsidiary. The Company excludes certain portions of the change in fair value of its derivative

instruments from the assessment of hedge effectiveness (excluded components). Changes in fair value of the excluded components are recognized in *OCI*. The Company recognizes in earnings the initial value of the excluded components on a straight-line basis over the life of the derivative instrument, rather than using the mark-to-market approach. The cash flows from these contracts are reported as investing activities in the Consolidated Statement of Cash Flows.

Foreign exchange risk is also managed through the use of foreign currency debt. The Company's senior unsecured euro-denominated notes have been designated as, and are effective as, economic hedges of the net investment in a foreign operation. Accordingly, foreign currency transaction gains or losses due to spot rate fluctuations on the euro-denominated debt instruments are included in foreign currency translation adjustment within *OCI*.

Interest Rate Risk Management

The Company may use interest rate swap contracts on certain investing and borrowing transactions to manage its net exposure to interest rate changes and to reduce its overall cost of borrowing. The Company does not use leveraged swaps and, in general, does not leverage any of its investment activities that would put principal capital at risk.

At December 31, 2020, the Company was a party to 14 pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes as detailed in the table below.

($ in millions)	**2020**		
Debt Instrument	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
3.875% notes due 2021 [(1)]	$ 1,150	5	$ 1,150
2.40% notes due 2022	1,000	4	1,000
2.35% notes due 2022	1,250	5	1,250

[(1)] *These interest rate swaps matured in January 2021.*

The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in the benchmark London Interbank Offered Rate (LIBOR) swap rate. The fair value changes in the notes attributable to changes in the LIBOR swap rate are recorded in interest expense along with the offsetting fair value changes in the swap contracts. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

The Company's investment portfolio includes cash equivalents and short-term investments, the market values of which are not significantly affected by changes in interest rates. The market value of the Company's medium- to long-term fixed-rate investments is modestly affected by changes in U.S. interest rates. Changes in medium- to long-term U.S. interest rates have a more significant impact on the market value of the Company's fixed-rate borrowings, which generally have longer maturities. A sensitivity analysis to measure potential changes in the market value of Merck's investments and debt from a change in interest rates indicated that a one percentage point increase in interest rates at December 31, 2020 and 2019 would have positively affected the net aggregate market value of these instruments by $2.6 billion and $2.0 billion, respectively. A one percentage point decrease at December 31, 2020 and 2019 would have negatively affected the net aggregate market value by $3.1 billion and $2.2 billion, respectively. The fair value of Merck's debt was determined using pricing models reflecting one percentage point shifts in the appropriate yield curves. The fair values of Merck's investments were determined using a combination of pricing and duration models.

Critical Accounting Estimates

The Company's consolidated financial statements are prepared in conformity with GAAP and, accordingly, include certain amounts that are based on management's best estimates and judgments. Estimates are used when accounting for amounts recorded in connection with acquisitions, including initial fair value determinations of assets and liabilities (primarily IPR&D, other intangible assets and contingent consideration), as

well as subsequent fair value measurements. Additionally, estimates are used in determining such items as provisions for sales discounts and returns, depreciable and amortizable lives, recoverability of inventories, including

those produced in preparation for product launches, amounts recorded for contingencies, environmental liabilities, accruals for contingent sales-based milestone payments and other reserves, pension and other postretirement benefit plan assumptions, share-based compensation assumptions, restructuring costs, impairments of long-lived assets (including intangible assets and goodwill) and investments, and taxes on income. Because of the uncertainty inherent in such estimates, actual results may differ from these estimates. Application of the following accounting policies result in accounting estimates having the potential for the most significant impact on the financial statements.

Acquisitions and Dispositions

To determine whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses, the Company makes certain judgments, which include assessment of the inputs, processes, and outputs associated with the acquired set of activities. If the Company determines that substantially all of the fair value of gross assets included in a transaction is concentrated in a single asset (or a group of similar assets), the assets would not represent a business. To be considered a business, the assets in a transaction need to include an input and a substantive process that together significantly contribute to the ability to create outputs.

In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the acquisition at their respective fair values with limited exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are generally recognized at fair value. If fair value cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Accordingly, the Company may be required to value assets at fair value measures that do not reflect the Company's intended use of those assets. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in the Company's consolidated financial statements after the date of the acquisition. The fair values of intangible assets, including acquired IPR&D, are determined utilizing information available near the acquisition date based on expectations and assumptions that are deemed reasonable by management. Given the considerable judgment involved in determining fair values, the Company typically obtains assistance from third-party valuation specialists for significant items. Amounts allocated to acquired IPR&D are capitalized and accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, Merck will make a determination as to the then-useful life of the intangible asset, generally determined by the period in which the substantial majority of the cash flows are expected to be generated, and begin amortization. Certain of the Company's business acquisitions involve the potential for future payment of consideration that is contingent upon the achievement of performance milestones, including product development milestones and royalty payments on future product sales. The fair value of contingent consideration liabilities is determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date, at each reporting period until the contingency is resolved, the contingent consideration liability is remeasured at current fair value with changes (either expense or income) recorded in earnings. Changes in any of the inputs may result in a significantly different fair value adjustment.

The judgments made in determining estimated fair values assigned to assets acquired and liabilities assumed in a business combination, as well as asset lives, can materially affect the Company's results of operations.

The fair values of identifiable intangible assets related to currently marketed products and product rights are primarily determined by using an income approach through which fair value is estimated based on each asset's discounted projected net cash flows. The Company's estimates of market participant net cash flows consider historical and projected pricing, margins and expense levels; the performance of competing products where applicable; relevant industry and therapeutic area growth drivers and factors; current and expected trends in technology and product life cycles; the time and investment that will be required to develop products and technologies; the ability to obtain marketing and regulatory approvals; the ability to manufacture and commercialize

the products; the extent and timing of potential new product introductions by the Company's competitors; and the life of each asset's underlying patent, if any. The net cash flows are then probability-adjusted where appropriate to consider the uncertainties associated with the underlying assumptions, as well as the risk profile of the net cash flows utilized in the valuation. The probability-adjusted future net cash flows of each product are then discounted to present value utilizing an appropriate discount rate.

The fair values of identifiable intangible assets related to IPR&D are also determined using an income approach, through which fair value is estimated based on each asset's probability-adjusted future net cash flows, which reflect the different stages of development of each product and the associated probability of successful completion. The net cash flows are then discounted to present value using an appropriate discount rate.

If the Company determines the transaction will not be accounted for as an acquisition of a business, the transaction will be accounted for as an asset acquisition rather than a business combination and, therefore, no goodwill will be recorded. In an asset acquisition, acquired IPR&D with no alternative future use is charged to expense and contingent consideration is not recognized at the acquisition date. In these instances, product development milestones are recognized upon achievement and sales-based milestones are recognized when the milestone is deemed probable by the Company of being achieved.

Revenue Recognition

Recognition of revenue requires evidence of a contract, probable collection of sales proceeds and completion of substantially all performance obligations. Merck acts as the principal in substantially all of its customer arrangements and therefore records revenue on a gross basis. The majority of the Company's contracts related to the Pharmaceutical and Animal Health segments have a single performance obligation - the promise to transfer goods. Shipping is considered immaterial in the context of the overall customer arrangement and damages or loss of goods in transit are rare. Therefore, shipping is not deemed a separately recognized performance obligation.

The vast majority of revenues from sales of products are recognized at a point in time when control of the goods is transferred to the customer, which the Company has determined is when title and risks and rewards of ownership transfer to the customer and the Company is entitled to payment. For certain services in the Animal Health segment, revenue is recognized over time, generally ratably over the contract term as services are provided. These service revenues are not material.

The nature of the Company's business gives rise to several types of variable consideration including discounts and returns, which are estimated at the time of sale generally using the expected value method, although the most likely amount method is used for prompt pay discounts.

In the United States, sales discounts are issued to customers at the point-of-sale, through an intermediary wholesaler (known as chargebacks), or in the form of rebates. Additionally, sales are generally made with a limited right of return under certain conditions. Revenues are recorded net of provisions for sales discounts and returns, which are established at the time of sale. In addition, revenues are recorded net of time value of money discounts if collection of accounts receivable is expected to be in excess of one year.

The U.S. provision for aggregate customer discounts covers chargebacks and rebates. Chargebacks are discounts that occur when a contracted customer purchases through an intermediary wholesaler. The contracted customer generally purchases product from the wholesaler at its contracted price plus a mark-up. The wholesaler, in turn, charges the Company back for the difference between the price initially paid by the wholesaler and the contract price paid to the wholesaler by the customer. The provision for chargebacks is based on expected sell-through levels by the Company's wholesale customers to contracted customers, as well as estimated wholesaler inventory levels. Rebates are amounts owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. The Company uses historical customer segment utilization mix, sales forecasts, changes to product mix and price, inventory levels in the distribution channel, government pricing calculations and prior payment history in order to estimate the expected provision. Amounts accrued for aggregate customer discounts are evaluated on a quarterly

basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal and state agencies, and other customers to the amounts accrued.

The Company continually monitors its provision for aggregate customer discounts. There were no material adjustments to estimates associated with the aggregate customer discount provision in 2020, 2019 or 2018.

Summarized information about changes in the aggregate customer discount accrual related to U.S. sales is as follows:

($ in millions)	**2020**	2019
Balance January 1	**$ 2,436**	$ 2,630
Current provision	**13,144**	11,999
Adjustments to prior years	**(16)**	(230)
Payments	**(12,454)**	(11,963)
Balance December 31	**$ 3,110**	$ 2,436

Accruals for chargebacks are reflected as a direct reduction to accounts receivable and accruals for rebates as current liabilities. The accrued balances relative to these provisions included in *Accounts receivable* and *Accrued and other current liabilities* were $249 million and $2.9 billion, respectively, at December 31, 2020 and were $233 million and $2.2 billion, respectively, at December 31, 2019.

Outside of the United States, variable consideration in the form of discounts and rebates are a combination of commercially-driven discounts in highly competitive product classes, discounts required to gain or maintain reimbursement, or legislatively mandated rebates. In certain European countries, legislatively mandated rebates are calculated based on an estimate of the government's total unbudgeted spending and the Company's specific payback obligation. Rebates may also be required based on specific product sales thresholds. The Company applies an estimated factor against its actual invoiced sales to represent the expected level of future discount or rebate obligations associated with the sale.

The Company maintains a returns policy that allows its U.S. pharmaceutical customers to return product within a specified period prior to and subsequent to the expiration date (generally, three to six months before and 12 months after product expiration). The estimate of the provision for returns is based upon historical experience with actual returns. Additionally, the Company considers factors such as levels of inventory in the distribution channel, product dating and expiration period, whether products have been discontinued, entrance in the market of generic competition, changes in formularies or launch of over-the-counter products, among others. The product returns provision for U.S. pharmaceutical sales as a percentage of U.S. net pharmaceutical sales was 0.6% in 2020, 1.1% in 2019 and 1.6% in 2018. Outside of the United States, returns are only allowed in certain countries on a limited basis.

Merck's payment terms for U.S. pharmaceutical customers are typically 36 days from receipt of invoice and for U.S. animal health customers are typically 30 days from receipt of invoice; however, certain products, including *Keytruda*, have longer payment terms, some of which are up to 90 days. Outside of the United States, payment terms are typically 30 days to 90 days, although certain markets have longer payment terms.

Through its distribution programs with U.S. wholesalers, the Company encourages wholesalers to align purchases with underlying demand and maintain inventories below specified levels. The terms of the programs allow the wholesalers to earn fees upon providing visibility into their inventory levels, as well as by achieving certain performance parameters such as inventory management, customer service levels, reducing shortage claims and reducing product returns. Information provided through the wholesaler distribution programs includes items such as sales trends, inventory on-hand, on-order quantity and product returns.

Wholesalers generally provide only the above-mentioned data to the Company, as there is no regulatory requirement to report lot level information to manufacturers, which is the level of information needed to determine the remaining shelf life and original sale date of inventory. Given current wholesaler inventory levels, which are generally less than a month, the Company believes that collection of order lot information across all wholesale customers would have limited use in estimating sales discounts and returns.

Inventories Produced in Preparation for Product Launches

The Company capitalizes inventories produced in preparation for product launches sufficient to support estimated initial market demand. Typically, capitalization of such inventory does not begin until the related product candidates are in Phase 3 clinical trials and are considered to have a high probability of regulatory approval. The Company monitors the status of each respective product within the regulatory approval process; however, the Company generally does not disclose specific timing for regulatory approval. If the Company is aware of any specific risks or contingencies other than the normal regulatory approval process or if there are any specific issues identified during the research process relating to safety, efficacy, manufacturing, marketing or labeling, the related inventory would generally not be capitalized. Expiry dates of the inventory are affected by the stage of completion. The Company manages the levels of inventory at each stage to optimize the shelf life of the inventory in relation to anticipated market demand in order to avoid product expiry issues. For inventories that are capitalized, anticipated future sales and shelf lives support the realization of the inventory value as the inventory shelf life is sufficient to meet initial product launch requirements. Inventories produced in preparation for product launches capitalized at December 31, 2020 and 2019 were $279 million and $168 million, respectively.

Contingencies and Environmental Liabilities

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property and commercial litigation, as well as certain additional matters including governmental and environmental matters (see Note 10 to the consolidated financial statements). The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. For product liability claims, a portion of the overall accrual is actuarially determined and considers such factors as past experience, number of claims reported and estimates of claims incurred but not yet reported. Individually significant contingent losses are accrued when probable and reasonably estimable.

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of December 31, 2020 and 2019 of approximately $250 million and $240 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

The Company and its subsidiaries are parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund, and other federal and state equivalents. When a legitimate claim for contribution is asserted, a liability is initially accrued based upon the estimated transaction costs to manage the site. Accruals are adjusted as site investigations, feasibility studies and related cost assessments of remedial techniques are completed, and as the extent to which other potentially responsible parties who may be jointly and severally liable can be expected to contribute is determined.

The Company is also remediating environmental contamination resulting from past industrial activity at certain of its sites and takes an active role in identifying and accruing for these costs. In the past, Merck performed a worldwide survey to assess all sites for potential contamination resulting from past industrial activities. Where assessment indicated that physical investigation was warranted, such investigation was performed, providing a better evaluation of the need for remedial action. Where such need was identified, remedial action was then initiated. As definitive information became available during the course of investigations and/or remedial efforts at each site, estimates were refined and accruals were established or adjusted accordingly. These estimates and related accruals continue to be refined annually.

The Company believes that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on the Company. Expenditures for remediation and environmental liabilities were $11 million in 2020 and are estimated at $46 million in the aggregate for the years 2021 through 2025. In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $67 million at both December 31, 2020 and 2019. These liabilities are undiscounted, do not consider potential recoveries from other parties and will be paid out over the periods of remediation for the applicable sites, which are expected to occur primarily over the next 15 years. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed approximately $65 million in the aggregate. Management also does not believe that these expenditures should result in a material adverse effect on the Company's financial condition, results of operations or liquidity for any year.

Share-Based Compensation

The Company expenses all share-based payment awards to employees, including grants of stock options, over the requisite service period based on the grant date fair value of the awards. The Company determines the fair value of certain share-based awards using the Black-Scholes option-pricing model which uses both historical and current market data to estimate the fair value. This method incorporates various assumptions such as the risk-free interest rate, expected volatility, expected dividend yield and expected life of the options. Total pretax share-based compensation expense was $475 million in 2020, $417 million in 2019 and $348 million in 2018. At December 31, 2020, there was $678 million of total pretax unrecognized compensation expense related to nonvested stock option, restricted stock unit and performance share unit awards which will be recognized over a weighted-average period of 1.9 years. For segment reporting, share-based compensation costs are unallocated expenses.

Pensions and Other Postretirement Benefit Plans

Net periodic benefit cost for pension plans totaled $454 million in 2020, $137 million in 2019 and $195 million in 2018. Net periodic benefit (credit) for other postretirement benefit plans was $(59) million in 2020, $(49) million in 2019 and $(45) million in 2018. Pension and other postretirement benefit plan information for financial reporting purposes is calculated using actuarial assumptions including a discount rate for plan benefit obligations and an expected rate of return on plan assets. The changes in net periodic benefit cost year over year for pension plans are largely attributable to changes in the discount rate affecting net loss amortization.

The Company reassesses its benefit plan assumptions on a regular basis. For both the pension and other postretirement benefit plans, the discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due. The discount rates for the Company's U.S. pension and other postretirement benefit plans ranged from 2.10% to 2.80% at December 31, 2020, compared with a range of 3.20% to 3.50% at December 31, 2019.

The expected rate of return for both the pension and other postretirement benefit plans represents the average rate of return to be earned on plan assets over the period the benefits included in the benefit obligation are to be paid. In developing the expected rate of return, the Company considers long-term compound annualized returns of historical market data, current market conditions and actual returns on the Company's plan assets. Using this reference information, the Company develops forward-looking return expectations for each asset category and a weighted-average expected long-term rate of return for a target portfolio allocated across these investment categories. The expected portfolio performance reflects the contribution of active management as appropriate. For 2021, the expected rate of return for the Company's U.S. pension and other postretirement benefit plans will range from 6.50% to 6.70%, compared to a range of 7.00% to 7.30% in 2020.

The Company has established investment guidelines for its U.S. pension and other postretirement plans to create an asset allocation that is expected to deliver a rate of return sufficient to meet the long-term obligation of each plan, given an acceptable level of risk. The target investment portfolio of the Company's U.S. pension and other postretirement benefit plans is allocated 30% to 45% in U.S. equities, 15% to 30% in international equities, 35% to 45% in fixed-income investments, and up to 5% in cash and other investments. The portfolio's equity weighting is consistent with the long-term nature of the plans' benefit obligations. The expected annual standard

deviation of returns of the target portfolio, which approximates 11%, reflects both the equity allocation and the diversification benefits among the asset classes in which the portfolio invests. For non-U.S. pension plans, the targeted investment portfolio varies based on the duration of pension liabilities and local government rules and regulations. Although a significant percentage of plan assets are invested in U.S. equities, concentration risk is mitigated through the use of strategies that are diversified within management guidelines.

Actuarial assumptions are based upon management's best estimates and judgment. A reasonably possible change of plus (minus) 25 basis points in the discount rate assumption, with other assumptions held constant, would have had an estimated $80 million favorable (unfavorable) impact on the Company's net periodic benefit cost in 2020. A reasonably possible change of plus (minus) 25 basis points in the expected rate of return assumption, with other assumptions held constant, would have had an estimated $40 million favorable (unfavorable) impact on Merck's net periodic benefit cost in 2020. Required funding obligations for 2021 relating to the Company's pension and other postretirement benefit plans are not expected to be material. The preceding hypothetical changes in the discount rate and expected rate of return assumptions would not impact the Company's funding requirements.

Net loss amounts, which primarily reflect differences between expected and actual returns on plan assets as well as the effects of changes in actuarial assumptions, are recorded as a component of *AOCI*. Expected returns for pension plans are based on a calculated market-related value of assets. Net loss amounts in *AOCI* in excess of certain thresholds are amortized into net periodic benefit cost over the average remaining service life of employees.

Restructuring Costs

Restructuring costs have been recorded in connection with restructuring programs designed to streamline the Company's cost structure. As a result, the Company has made estimates and judgments regarding its future plans, including future termination benefits and other exit costs to be incurred when the restructuring actions take place. When accruing termination costs, the Company will recognize the amount within a range of costs that is the best estimate within the range. When no amount within the range is a better estimate than any other amount, the Company recognizes the minimum amount within the range. In connection with these actions, management also assesses the recoverability of long-lived assets employed in the business. In certain instances, asset lives have been shortened based on changes in the expected useful lives of the affected assets. Severance and other related costs are reflected within *Restructuring costs*. Asset-related charges are reflected within *Cost of sales*, *Selling, general and administrative* expenses and *Research and development* expenses depending upon the nature of the asset.

Impairments of Long-Lived Assets

The Company assesses changes in economic, regulatory and legal conditions and makes assumptions regarding estimated future cash flows in evaluating the value of the Company's property, plant and equipment, goodwill and other intangible assets.

The Company periodically evaluates whether current facts or circumstances indicate that the carrying values of its long-lived assets to be held and used may not be recoverable. If such circumstances are determined to exist, an estimate of the undiscounted future cash flows of these assets, or appropriate asset groupings, is compared to the carrying value to determine whether an impairment exists. If the asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows approach.

Goodwill represents the excess of the consideration transferred over the fair value of net assets of businesses acquired. Goodwill is assigned to reporting units and evaluated for impairment on at least an annual basis, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. Some of the factors considered in the assessment include general macroeconomic conditions, conditions specific to the industry and market, cost factors which could have a significant effect on earnings or cash flows, the overall financial performance of the reporting unit, and whether there have been sustained declines in the Company's share price. If the Company concludes it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a quantitative fair value test is performed. If the carrying value of a reporting unit is greater than its fair value, a goodwill impairment charge will be recorded for the difference (up to the carrying value of goodwill).

Other acquired intangible assets (excluding IPR&D) are initially recorded at fair value, assigned an estimated useful life, and amortized primarily on a straight-line basis over their estimated useful lives. When events or circumstances warrant a review, the Company will assess recoverability from future operations using pretax undiscounted cash flows derived from the lowest appropriate asset groupings. Impairments are recognized in operating results to the extent that the carrying value of the intangible asset exceeds its fair value, which is determined based on the net present value of estimated future cash flows.

IPR&D that the Company acquires in conjunction with the acquisition of a business represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. The amounts are capitalized and accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. The Company evaluates IPR&D for impairment at least annually, or more frequently if impairment indicators exist, by performing a quantitative test that compares the fair value of the IPR&D intangible asset with its carrying value. For impairment testing purposes, the Company may combine separately recorded IPR&D intangible assets into one unit of account based on the relevant facts and circumstances. Generally, the Company will combine IPR&D intangible assets for testing purposes if they operate as a single asset and are essentially inseparable. If the fair value is less than the carrying amount, an impairment loss is recognized in operating results.

The judgments made in evaluating impairment of long-lived intangibles can materially affect the Company's results of operations.

Impairments of Investments

The Company reviews its investments in marketable debt securities for impairments based on the determination of whether the decline in market value of the investment below the carrying value is other-than-temporary. The Company considers available evidence in evaluating potential impairments of its investments in marketable debt securities, including the duration and extent to which fair value is less than cost. Changes in fair value that are considered temporary are reported net of tax in *OCI*. An other-than-temporary impairment has occurred if the Company does not expect to recover the entire amortized cost basis of the marketable debt security. If the Company does not intend to sell the impaired debt security, and it is not more likely than not it will be required to sell the debt security before the recovery of its amortized cost basis, the amount of the other-than-temporary impairment recognized in earnings, recorded in *Other (income) expense, net*, is limited to the portion attributed to credit loss. The remaining portion of the other-than-temporary impairment related to other factors is recognized in *OCI*.

Investments in publicly traded equity securities are reported at fair value determined using quoted market prices in active markets for identical assets or quoted prices for similar assets or other inputs that are observable or can be corroborated by observable market data. Changes in fair value are included in *Other (income) expense, net*. Investments in equity securities without readily determinable fair values are recorded at cost, plus or minus subsequent observable price changes in orderly transactions for identical or similar investments, minus impairments. Such adjustments are recognized in *Other (income) expense, net*. Realized gains and losses for equity securities are included in *Other (income) expense, net*.

Taxes on Income

The Company's effective tax rate is based on pretax income, statutory tax rates and tax planning opportunities available in the various jurisdictions in which the Company operates. An estimated effective tax rate for a year is applied to the Company's quarterly operating results. In the event that there is a significant unusual or one-time item recognized, or expected to be recognized, in the Company's quarterly operating results, the tax attributable to that item would be separately calculated and recorded at the same time as the unusual or one-time item. The Company considers the resolution of prior year tax matters to be such items. Significant judgment is required in determining the Company's tax provision and in evaluating its tax positions. The recognition and measurement of a tax position is based on management's best judgment given the facts, circumstances and information available at the reporting date. The Company evaluates tax positions to determine whether the benefits of tax positions are more likely than not of being sustained upon audit based on the technical merits of the tax position. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely of being realized upon ultimate settlement in the

financial statements. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit in the financial statements. If the more likely than not threshold is not met in the period for which a tax position is taken, the Company may subsequently recognize the benefit of that tax position if the tax matter is effectively settled, the statute of limitations expires, or if the more likely than not threshold is met in a subsequent period (see Note 15 to the consolidated financial statements).

Tax regulations require items to be included in the tax return at different times than the items are reflected in the financial statements. Timing differences create deferred tax assets and liabilities. Deferred tax assets generally represent items that can be used as a tax deduction or credit in the tax return in future years for which the Company has already recorded the tax benefit in the financial statements. The Company establishes valuation allowances for its deferred tax assets when the amount of expected future taxable income is not likely to support the use of the deduction or credit. Deferred tax liabilities generally represent tax expense recognized in the financial statements for which payment has been deferred or expense for which the Company has already taken a deduction on the tax return, but has not yet recognized as expense in the financial statements.

Recently Issued Accounting Standards

For a discussion of recently issued accounting standards, see Note 2 to the consolidated financial statements.

Cautionary Factors That May Affect Future Results

This report and other written reports and oral statements made from time to time by the Company may contain so-called “forward-looking statements,” all of which are based on management’s current expectations and are subject to risks and uncertainties which may cause results to differ materially from those set forth in the statements. One can identify these forward-looking statements by their use of words such as “anticipates,” “expects,” “plans,” “will,” “estimates,” “forecasts,” “projects” and other words of similar meaning, or negative variations of any of the foregoing. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address the Company’s growth strategy, financial results, product approvals, product potential, development programs and include statements related to the expected impact of the COVID-19 pandemic. One must carefully consider any such statement and should understand that many factors could cause actual results to differ materially from the Company’s forward-looking statements. These factors include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. No forward-looking statement can be guaranteed and actual future results may vary materially.

The Company does not assume the obligation to update any forward-looking statement. One should carefully evaluate such statements in light of factors, including risk factors, described in the Company’s filings with the Securities and Exchange Commission, especially on this Form 10-K and Forms 10-Q and 8-K. In Item 1A. “Risk Factors” of this annual report on Form 10-K the Company discusses in more detail various important risk factors that could cause actual results to differ from expected or historic results. The Company notes these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. One should understand that it is not possible to predict or identify all such factors. Consequently, the reader should not consider any such list to be a complete statement of all potential risks or uncertainties.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

The information required by this Item is incorporated by reference to the discussion under “Financial Instruments Market Risk Disclosures” in Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

Item 8. Financial Statements and Supplementary Data.

(a) Financial Statements

The consolidated balance sheet of Merck & Co., Inc. and subsidiaries as of December 31, 2020 and 2019, and the related consolidated statements of income, of comprehensive income, of equity and of cash flows for each of the three years in the period ended December 31, 2020, the notes to consolidated financial statements, and the report dated February 25, 2021 of PricewaterhouseCoopers LLP, independent registered public accounting firm, are as follows:

Consolidated Statement of Income
Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions except per share amounts)

	2020	2019	2018
Sales	**$ 47,994**	$ 46,840	$ 42,294
Costs, Expenses and Other			
Cost of sales	**15,485**	14,112	13,509
Selling, general and administrative	**10,468**	10,615	10,102
Research and development	**13,558**	9,872	9,752
Restructuring costs	**578**	638	632
Other (income) expense, net	**(886)**	139	(402)
	39,203	35,376	33,593
Income Before Taxes	**8,791**	11,464	8,701
Taxes on Income	**1,709**	1,687	2,508
Net Income	**7,082**	9,777	6,193
Less: Net Income (Loss) Attributable to Noncontrolling Interests	**15**	(66)	(27)
Net Income Attributable to Merck & Co., Inc.	**$ 7,067**	$ 9,843	$ 6,220
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	**$ 2.79**	$ 3.84	$ 2.34
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	**$ 2.78**	$ 3.81	$ 2.32

Consolidated Statement of Comprehensive Income
Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions)

	2020	2019	2018
Net Income Attributable to Merck & Co., Inc.	**$ 7,067**	$ 9,843	$ 6,220
Other Comprehensive Loss Net of Taxes:			
Net unrealized (loss) gain on derivatives, net of reclassifications	**(297)**	(135)	297
Net unrealized (loss) gain on investments, net of reclassifications	**(18)**	96	(10)
Benefit plan net (loss) gain and prior service (cost) credit, net of amortization	**(279)**	(705)	(425)
Cumulative translation adjustment	**153**	96	(223)
	(441)	(648)	(361)
Comprehensive Income Attributable to Merck & Co., Inc.	**$ 6,626**	$ 9,195	$ 5,859

The accompanying notes are an integral part of these consolidated financial statements.

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Consolidated Balance Sheet
Merck & Co., Inc. and Subsidiaries
December 31
($ in millions except per share amounts)

	2020	2019
Assets		
Current Assets		
Cash and cash equivalents	**$ 8,062**	$ 9,676
Short-term investments	**—**	774
Accounts receivable (net of allowance for doubtful accounts of $85 in 2020 and $86 in 2019)	**7,851**	6,778
Inventories (excludes inventories of $2,197 in 2020 and $1,480 in 2019 classified in Other assets - see Note 7)	**6,310**	5,978
Other current assets	**5,541**	4,277
Total current assets	**27,764**	27,483
Investments	**785**	1,469
Property, Plant and Equipment (at cost)		
Land	**350**	343
Buildings	**12,645**	11,989
Machinery, equipment and office furnishings	**16,649**	15,394
Construction in progress	**7,324**	5,013
	36,968	32,739
Less: accumulated depreciation	**18,982**	17,686
	17,986	15,053
Goodwill	**20,238**	19,425
Other Intangibles, Net	**14,604**	14,196
Other Assets	**10,211**	6,771
	$ 91,588	$ 84,397
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	**$ 6,431**	$ 3,610
Trade accounts payable	**4,594**	3,738
Accrued and other current liabilities	**13,053**	12,549
Income taxes payable	**1,575**	736
Dividends payable	**1,674**	1,587
Total current liabilities	**27,327**	22,220
Long-Term Debt	**25,360**	22,736
Deferred Income Taxes	**1,015**	1,470
Other Noncurrent Liabilities	**12,482**	11,970
Merck & Co., Inc. Stockholders' Equity		
Common stock, $0.50 par value Authorized - 6,500,000,000 shares Issued - 3,577,103,522 shares in 2020 and 2019	**1,788**	1,788
Other paid-in capital	**39,588**	39,660
Retained earnings	**47,362**	46,602
Accumulated other comprehensive loss	**(6,634)**	(6,193)
	82,104	81,857
Less treasury stock, at cost: 1,046,877,695 shares in 2020 and 1,038,087,496 shares in 2019	**56,787**	55,950
Total Merck & Co., Inc. stockholders' equity	**25,317**	25,907
Noncontrolling Interests	**87**	94
Total equity	**25,404**	26,001
	$ 91,588	$ 84,397

The accompanying notes are an integral part of this consolidated financial statement.

Consolidated Statement of Equity
Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions except per share amounts)

	Common Stock	Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock	Non-controlling Interests	Total
Balance January 1, 2018	$1,788	$ 39,902	$ 41,350	$ (4,910)	$ (43,794)	$ 233	$ 34,569
Net income attributable to Merck & Co., Inc.	—	—	6,220	—	—	—	6,220
Adoption of new accounting standards	—	—	322	(274)	—	—	48
Other comprehensive loss, net of taxes	—	—	—	(361)	—	—	(361)
Cash dividends declared on common stock ($1.99 per share)	—	—	(5,313)	—	—	—	(5,313)
Treasury stock shares purchased	—	(1,000)	—	—	(8,091)	—	(9,091)
Net loss attributable to noncontrolling interests	—	—	—	—	—	(27)	(27)
Distributions attributable to noncontrolling interests	—	—	—	—	—	(25)	(25)
Share-based compensation plans and other	—	(94)	—	—	956	—	862
Balance December 31, 2018	1,788	38,808	42,579	(5,545)	(50,929)	181	26,882
Net income attributable to Merck & Co., Inc.	—	—	9,843	—	—	—	9,843
Other comprehensive loss, net of taxes	—	—	—	(648)	—	—	(648)
Cash dividends declared on common stock ($2.26 per share)	—	—	(5,820)	—	—	—	(5,820)
Treasury stock shares purchased	—	1,000	—	—	(5,780)	—	(4,780)
Net loss attributable to noncontrolling interests	—	—	—	—	—	(66)	(66)
Distributions attributable to noncontrolling interests	—	—	—	—	—	(21)	(21)
Share-based compensation plans and other	—	(148)	—	—	759	—	611
Balance December 31, 2019	1,788	39,660	46,602	(6,193)	(55,950)	94	26,001
Net income attributable to Merck & Co., Inc.	**—**	**—**	**7,067**	**—**	**—**	**—**	**7,067**
Other comprehensive loss, net of taxes	**—**	**—**	**—**	**(441)**	**—**	**—**	**(441)**
Cash dividends declared on common stock ($2.48 per share)	**—**	**—**	**(6,307)**	**—**	**—**	**—**	**(6,307)**
Treasury stock shares purchased	**—**	**—**	**—**	**—**	**(1,281)**	**—**	**(1,281)**
Net income attributable to noncontrolling interests	**—**	**—**	**—**	**—**	**—**	**15**	**15**
Distributions attributable to noncontrolling interests	**—**	**—**	**—**	**—**	**—**	**(22)**	**(22)**
Share-based compensation plans and other	**—**	**(72)**	**—**	**—**	**444**	**—**	**372**
Balance December 31, 2020	**$ 1,788**	**$ 39,588**	**$ 47,362**	**$ (6,634)**	**$ (56,787)**	**$ 87**	**$ 25,404**

The accompanying notes are an integral part of this consolidated financial statement.

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Consolidated Statement of Cash Flows
Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions)

	2020	2019	2018
Cash Flows from Operating Activities			
Net income	**$ 7,082**	$ 9,777	$ 6,193
Adjustments to reconcile net income to net cash provided by operating activities:			
Amortization	**1,899**	1,973	3,103
Depreciation	**1,726**	1,679	1,416
Intangible asset impairment charges	**1,718**	1,040	296
Charge for the acquisition of VelosBio Inc.	**2,660**	—	—
Charge for the acquisition of Peloton Therapeutics, Inc.	**—**	993	—
Charge for future payments related to collaboration license options	**—**	—	650
Deferred income taxes	**(668)**	(556)	(509)
Share-based compensation	**475**	417	348
Other	**(49)**	184	978
Net changes in assets and liabilities:			
Accounts receivable	**(1,002)**	294	(418)
Inventories	**(855)**	(508)	(911)
Trade accounts payable	**724**	399	230
Accrued and other current liabilities	**(1,138)**	376	(341)
Income taxes payable	**560**	(2,359)	827
Noncurrent liabilities	**(453)**	(237)	(266)
Other	**(2,426)**	(32)	(674)
Net Cash Provided by Operating Activities	**10,253**	13,440	10,922
Cash Flows from Investing Activities			
Capital expenditures	**(4,684)**	(3,473)	(2,615)
Purchase of Seagen Inc. common stock	**(1,000)**	—	—
Purchases of securities and other investments	**(95)**	(3,202)	(7,994)
Proceeds from sales of securities and other investments	**2,812**	8,622	15,252
Acquisition of VelosBio Inc., net of cash acquired	**(2,696)**	—	—
Acquisition of ArQule, Inc., net of cash acquired	**(2,545)**	—	—
Acquisition of Antelliq Corporation, net of cash acquired	**—**	(3,620)	—
Acquisition of Peloton Therapeutics, Inc., net of cash acquired	**—**	(1,040)	—
Other acquisitions, net of cash acquired	**(1,365)**	(294)	(431)
Other	**130**	378	102
Net Cash (Used in) Provided by Investing Activities	**(9,443)**	(2,629)	4,314
Cash Flows from Financing Activities			
Net change in short-term borrowings	**2,549**	(3,710)	5,124
Payments on debt	**(1,957)**	—	(4,287)
Proceeds from issuance of debt	**4,419**	4,958	—
Purchases of treasury stock	**(1,281)**	(4,780)	(9,091)
Dividends paid to stockholders	**(6,215)**	(5,695)	(5,172)
Proceeds from exercise of stock options	**89**	361	591
Other	**(436)**	5	(325)
Net Cash Used in Financing Activities	**(2,832)**	(8,861)	(13,160)
Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash	**253**	17	(205)
Net (Decrease) Increase in Cash, Cash Equivalents and Restricted Cash	**(1,769)**	1,967	1,871
Cash, Cash Equivalents and Restricted Cash at Beginning of Year (includes $258 of restricted cash at January 1, 2020 included in Other Assets - see Note 6)	**9,934**	7,967	6,096
Cash, Cash Equivalents and Restricted Cash at End of Year (includes $103 of restricted cash at December 31, 2020 included in Other Assets - see Note 6)	**$ 8,165**	$ 9,934	$ 7,967

The accompanying notes are an integral part of this consolidated financial statement.

Notes to Consolidated Financial Statements
Merck & Co., Inc. and Subsidiaries
($ in millions except per share amounts)

1. Nature of Operations

Merck & Co., Inc. (Merck or the Company) is a global health care company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies and animal health products. The Company's operations are principally managed on a products basis and include two operating segments, which are the Pharmaceutical and Animal Health segments, both of which are reportable segments.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities.

The Animal Health segment discovers, develops, manufactures and markets a wide range of veterinary pharmaceutical and vaccine products, as well as health management solutions and services, for the prevention, treatment and control of disease in all major livestock and companion animal species. The Company also offers an extensive suite of digitally connected identification, traceability and monitoring products. The Company sells its products to veterinarians, distributors and animal producers.

The Company previously had a Healthcare Services segment that provided services and solutions focused on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company divested the remaining businesses in this segment in the first quarter of 2020.

The Company previously had an Alliances segment that primarily included activity from the Company's relationship with AstraZeneca LP related to sales of Nexium and Prilosec, which concluded in 2018.

Planned Spin-Off of Women's Health, Biosimilars and Established Brands into a New Company

In February 2020, Merck announced its intention to spin-off products from its women's health, biosimilars and established brands businesses into a new, independent, publicly traded company named Organon & Co. (Organon) through a distribution of Organon's publicly traded stock to Company shareholders. The distribution is expected to qualify as tax-free to the Company and its shareholders for U.S. federal income tax purposes. The established brands included in the transaction consist of dermatology, non-opioid pain management, respiratory, and select cardiovascular products including *Zetia* and *Vytorin*, as well as the rest of Merck's diversified brands franchise. Merck's existing research pipeline programs will continue to be owned and developed within Merck as planned. Organon will have development capabilities initially focused on late-stage development and life-cycle management and is expected over time to develop research capabilities in selected therapeutic areas. The spin-off is expected to be completed late in the second quarter of 2021, subject to market and certain other conditions. Subsequent to the spin-off, the historical results of the women's health, biosimilars and established brands businesses will be reflected as discontinued operations in the Company's consolidated financial statements.

2. Summary of Accounting Policies

Principles of Consolidation — The consolidated financial statements include the accounts of the Company and all of its subsidiaries in which a controlling interest is maintained. Intercompany balances and transactions are eliminated. Controlling interest is determined by majority ownership interest and the absence of substantive third-party participating rights or, in the case of variable interest entities, by majority exposure to expected losses, residual returns or both. For those consolidated subsidiaries where Merck ownership is less than 100%, the outside shareholders' interests are shown as *Noncontrolling interests* in equity. Investments in affiliates

over which the Company has significant influence but not a controlling interest, such as interests in entities owned equally by the Company and a third party that are under shared control, are carried on the equity basis.

Acquisitions — In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the acquisition at their respective fair values with limited exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are generally recognized at fair value. If fair value cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Accordingly, the Company may be required to value assets at fair value measures that do not reflect the Company's intended use of those assets. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in the Company's consolidated financial statements after the date of the acquisition. If the Company determines the assets acquired do not meet the definition of a business under the acquisition method of accounting, the transaction will be accounted for as an acquisition of assets rather than a business combination and, therefore, no goodwill will be recorded. In an asset acquisition, acquired in-process research and development (IPR&D) with no alternative future use is charged to expense and contingent consideration is not recognized at the acquisition date.

Foreign Currency Translation — The net assets of international subsidiaries where the local currencies have been determined to be the functional currencies are translated into U.S. dollars using current exchange rates. The U.S. dollar effects that arise from translating the net assets of these subsidiaries at changing rates are recorded in the foreign currency translation account, which is included in *Accumulated other comprehensive income (loss)* (*AOCI*) and reflected as a separate component of equity. For those subsidiaries that operate in highly inflationary economies and for those subsidiaries where the U.S. dollar has been determined to be the functional currency, non-monetary foreign currency assets and liabilities are translated using historical rates, while monetary assets and liabilities are translated at current rates, with the U.S. dollar effects of rate changes included in *Other (income) expense, net*.

Cash Equivalents — Cash equivalents are comprised of certain highly liquid investments with original maturities of less than three months.

Inventories — Inventories are valued at the lower of cost or net realizable value. The cost of a substantial majority of U.S. pharmaceutical and vaccine inventories is determined using the last-in, first-out (LIFO) method for both financial reporting and tax purposes. The cost of all other inventories is determined using the first-in, first-out (FIFO) method. Inventories consist of currently marketed products, as well as certain inventories produced in preparation for product launches that are considered to have a high probability of regulatory approval. In evaluating the recoverability of inventories produced in preparation for product launches, the Company considers the likelihood that revenue will be obtained from the future sale of the related inventory together with the status of the product within the regulatory approval process.

Investments — Investments in marketable debt securities classified as available-for-sale are reported at fair value. Fair values of the Company's investments in marketable debt securities are determined using quoted market prices in active markets for identical assets or liabilities or quoted prices for similar assets or liabilities or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Changes in fair value that are considered temporary are reported net of tax in *Other Comprehensive Income* (*OCI*). The Company considers available evidence in evaluating potential impairments of its investments in marketable debt securities, including the duration and extent to which fair value is less than cost. An other-than-temporary impairment has occurred if the Company does not expect to recover the entire amortized cost basis of the marketable debt security. If the Company does not intend to sell the impaired debt security, and it is not more likely than not it will be required to sell the debt security before the recovery of its amortized cost basis, the amount of the other-than-temporary impairment recognized in earnings, recorded in *Other (income) expense, net*, is limited to the portion attributed to credit loss. The remaining portion of the other-than-temporary impairment related

to other factors is recognized in *OCI*. Realized gains and losses for debt securities are included in *Other (income) expense, net*.

Investments in publicly traded equity securities are reported at fair value determined using quoted market prices in active markets for identical assets or quoted prices for similar assets or other inputs that are observable or can be corroborated by observable market data. Changes in fair value are included in *Other (income) expense, net*. Investments in equity securities without readily determinable fair values are recorded at cost, plus or minus subsequent observable price changes in orderly transactions for identical or similar investments, minus impairments. Such adjustments are recognized in *Other (income) expense, net*. Realized gains and losses for equity securities are included in *Other (income) expense, net*.

Revenue Recognition — Recognition of revenue requires evidence of a contract, probable collection of sales proceeds and completion of substantially all performance obligations. Merck acts as the principal in substantially all of its customer arrangements and therefore records revenue on a gross basis. The majority of the Company's contracts related to the Pharmaceutical and Animal Health segments have a single performance obligation - the promise to transfer goods. Shipping is considered immaterial in the context of the overall customer arrangement and damages or loss of goods in transit are rare. Therefore, shipping is not deemed a separately recognized performance obligation.

The vast majority of revenues from sales of products are recognized at a point in time when control of the goods is transferred to the customer, which the Company has determined is when title and risks and rewards of ownership transfer to the customer and the Company is entitled to payment. The Company recognizes revenue from the sales of vaccines to the Federal government for placement into vaccine stockpiles in accordance with Securities and Exchange Commission (SEC) Interpretation*, Commission Guidance Regarding Accounting for Sales of Vaccines and BioTerror Countermeasures to the Federal Government for Placement into the Pediatric Vaccine Stockpile or the Strategic National Stockpile*. This interpretation allows companies to recognize revenue for sales of vaccines into U.S. government stockpiles even though these sales might not meet the criteria for revenue recognition under other accounting guidance. For certain services in the Animal Health segment, revenue is recognized over time, generally ratably over the contract term as services are provided. These service revenues are not material.

The nature of the Company's business gives rise to several types of variable consideration including discounts and returns, which are estimated at the time of sale generally using the expected value method, although the most likely amount method is used for prompt pay discounts.

In the United States, sales discounts are issued to customers at the point-of-sale, through an intermediary wholesaler (known as chargebacks), or in the form of rebates. Additionally, sales are generally made with a limited right of return under certain conditions. Revenues are recorded net of provisions for sales discounts and returns, which are established at the time of sale. In addition, revenues are recorded net of time value of money discounts if collection of accounts receivable is expected to be in excess of one year.

The U.S. provision for aggregate customer discounts covering chargebacks and rebates was $13.1 billion in 2020, $11.8 billion in 2019 and $10.7 billion in 2018. Chargebacks are discounts that occur when a contracted customer purchases through an intermediary wholesaler. The contracted customer generally purchases product from the wholesaler at its contracted price plus a mark-up. The wholesaler, in turn, charges the Company back for the difference between the price initially paid by the wholesaler and the contract price paid to the wholesaler by the customer. The provision for chargebacks is based on expected sell-through levels by the Company's wholesale customers to contracted customers, as well as estimated wholesaler inventory levels. Rebates are amounts owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. The Company uses historical customer segment utilization mix, sales forecasts, changes to product mix and price, inventory levels in the distribution channel, government pricing calculations and prior payment history in order to estimate the expected provision. Amounts accrued for aggregate customer discounts are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal

and state agencies, and other customers to the amounts accrued. The accrued balances relative to the provisions for chargebacks and rebates included in *Accounts receivable* and *Accrued and other current liabilities* were $249

million and $2.9 billion, respectively, at December 31, 2020 and were $233 million and $2.2 billion, respectively, at December 31, 2019.

Outside of the United States, variable consideration in the form of discounts and rebates are a combination of commercially-driven discounts in highly competitive product classes, discounts required to gain or maintain reimbursement, or legislatively mandated rebates. In certain European countries, legislatively mandated rebates are calculated based on an estimate of the government's total unbudgeted spending and the Company's specific payback obligation. Rebates may also be required based on specific product sales thresholds. The Company applies an estimated factor against its actual invoiced sales to represent the expected level of future discount or rebate obligations associated with the sale.

The Company maintains a returns policy that allows its U.S. pharmaceutical customers to return product within a specified period prior to and subsequent to the expiration date (generally, three to six months before and 12 months after product expiration). The estimate of the provision for returns is based upon historical experience with actual returns. Additionally, the Company considers factors such as levels of inventory in the distribution channel, product dating and expiration period, whether products have been discontinued, entrance in the market of generic competition, changes in formularies or launch of over-the-counter products, among others. Outside of the United States, returns are only allowed in certain countries on a limited basis.

Merck's payment terms for U.S. pharmaceutical customers are typically 36 days from receipt of invoice and for U.S. animal health customers are typically 30 days from receipt of invoice; however, certain products, including *Keytruda*, have longer payment terms, some of which are up to 90 days. Outside of the United States, payment terms are typically 30 days to 90 days, although certain markets have longer payment terms.

See Note 18 for disaggregated revenue disclosures.

Depreciation — Depreciation is provided over the estimated useful lives of the assets, principally using the straight-line method. For tax purposes, accelerated tax methods are used. The estimated useful lives primarily range from 25 to 45 years for *Buildings*, and from 3 to 15 years for *Machinery, equipment and office furnishings*. Depreciation expense was $1.7 billion in 2020, $1.7 billion in 2019 and $1.4 billion in 2018.

Advertising and Promotion Costs — Advertising and promotion costs are expensed as incurred. The Company recorded advertising and promotion expenses of $2.0 billion in 2020, $2.1 billion in 2019 and $2.1 billion in 2018.

Software Capitalization — The Company capitalizes certain costs incurred in connection with obtaining or developing internal-use software including external direct costs of material and services, and payroll costs for employees directly involved with the software development. These costs are included in *Property, plant and equipment*. In addition, the Company capitalizes certain costs incurred to implement a cloud computing arrangement that is considered a service agreement, which are included in *Other Assets*. Capitalized software costs are being amortized over periods ranging from 3 to 10 years, with the longer lives generally associated with enterprise-wide projects implemented over multiple years. Costs incurred during the preliminary project stage and post-implementation stage, as well as maintenance and training costs, are expensed as incurred.

Goodwill — Goodwill represents the excess of the consideration transferred over the fair value of net assets of businesses acquired. Goodwill is assigned to reporting units and evaluated for impairment on at least an annual basis, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If the Company concludes it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a quantitative fair value test is performed. If the carrying value of a reporting unit is greater than its fair value, a goodwill impairment charge will be recorded for the difference (up to the carrying value of goodwill).

Acquired Intangibles — Acquired intangibles include products and product rights, licenses, trade names and patents, which are initially recorded at fair value, assigned an estimated useful life, and amortized primarily on a straight-line basis over their estimated useful lives ranging from 2 to 24 years (see Note 8). The Company periodically evaluates whether current facts or circumstances indicate that the carrying values of its acquired intangibles may not be recoverable. If such circumstances are determined to exist, an estimate of the undiscounted

future cash flows of these assets, or appropriate asset groupings, is compared to the carrying value to determine whether an impairment exists. If the asset is determined to be impaired, the loss is measured based on the difference between the carrying value of the intangible asset and its fair value, which is determined based on the net present value of estimated future cash flows.

Acquired In-Process Research and Development — IPR&D that the Company acquires in conjunction with the acquisition of a business represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. The amounts are capitalized and are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, Merck will make a determination as to the then-useful life of the intangible asset, generally determined by the period in which the substantial majority of the cash flows are expected to be generated, and begin amortization. The Company evaluates IPR&D for impairment at least annually, or more frequently if impairment indicators exist, by performing a quantitative test that compares the fair value of the IPR&D intangible asset with its carrying value. If the fair value is less than the carrying amount, an impairment loss is recognized in operating results.

Contingent Consideration — Certain of the Company's acquisitions involve the potential for future payment of consideration that is contingent upon the achievement of performance milestones, including product development milestones and royalty payments on future product sales. If the transaction is accounted for as an acquisition of a business, the fair value of contingent consideration liabilities is determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date, at each reporting period until the contingency is resolved, the contingent consideration liability is remeasured at current fair value with changes (either expense or income) recorded in earnings. Significant events that increase or decrease the probability of achieving development and regulatory milestones or that increase or decrease projected cash flows will result in corresponding increases or decreases in the fair values of the related contingent consideration obligations. If the transaction is accounted for as an acquisition of an asset rather than a business, contingent consideration is not recognized at the acquisition date. In these instances, product development milestones are recognized upon achievement and sales-based milestones are recognized when the milestone is deemed probable by the Company of being achieved.

Research and Development — Research and development is expensed as incurred. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Research and development expenses include restructuring costs and IPR&D impairment charges. In addition, research and development expenses include expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration. Research and development expenses also include upfront and milestone payments related to asset acquisitions and licensing transactions involving clinical development programs that have not yet received regulatory approval.

Collaborative Arrangements — Merck has entered into collaborative arrangements that provide the Company with varying rights to develop, produce and market products together with its collaborative partners. When Merck is the principal on sales transactions with third parties, the Company recognizes sales, cost of sales and selling, general and administrative expenses on a gross basis. Profit sharing amounts it pays to its collaborative partners are recorded within *Cost of sales*. When the collaborative partner is the principal on sales transactions with third parties, the Company records profit sharing amounts received from its collaborative partners as alliance revenue (within *Sales*). Alliance revenue is recorded net of cost of sales and includes an adjustment to share commercialization costs between the partners in accordance with the collaboration agreement. The adjustment is determined by comparing the commercialization costs Merck has incurred directly and reported within *Selling, general and administrative* expenses with the costs the collaborative partner has incurred. Research and development costs Merck incurs related to collaborations are recorded within *Research and development* expenses. Cost reimbursements to the collaborative partner or payments received from the collaborative partner to share these costs pursuant to the terms of the collaboration agreements are recorded as increases or decreases to *Research and development* expenses.

In addition, the terms of the collaboration agreements may require the Company to make payments based upon the achievement of certain developmental, regulatory approval or commercial milestones. Upfront and milestone payments payable by Merck to collaborative partners prior to regulatory approval are expensed as incurred and included in *Research and development* expenses. Payments due to collaborative partners upon or subsequent to regulatory approval are capitalized and amortized over the estimated useful life of the corresponding intangible asset to *Cost of sales* provided that future cash flows support the amounts capitalized. Sales-based milestones payable by Merck to collaborative partners are accrued and capitalized, subject to cumulative amortization catch-up, when probable of being achieved. The amortization catch-up is calculated either from the time of the first regulatory approval for indications that were unapproved at the time the collaboration was formed, or from time of the formation of the collaboration for approved products. The related intangible asset that is recognized is amortized to *Cost of sales* over its remaining useful life, subject to impairment testing.

Share-Based Compensation — The Company expenses all share-based payments to employees over the requisite service period based on the grant-date fair value of the awards.

Restructuring Costs — The Company records liabilities for costs associated with exit or disposal activities in the period in which the liability is incurred. In accordance with existing benefit arrangements, employee termination costs are accrued when the restructuring actions are probable and estimable. When accruing these costs, the Company will recognize the amount within a range of costs that is the best estimate within the range. When no amount within the range is a better estimate than any other amount, the Company recognizes the minimum amount within the range. Costs for one-time termination benefits in which the employee is required to render service until termination in order to receive the benefits are recognized ratably over the future service period.

Contingencies and Legal Defense Costs — The Company records accruals for contingencies and legal defense costs expected to be incurred in connection with a loss contingency when it is probable that a liability has been incurred and the amount can be reasonably estimated.

Taxes on Income — Deferred taxes are recognized for the future tax effects of temporary differences between financial and income tax reporting based on enacted tax laws and rates. The Company evaluates tax positions to determine whether the benefits of tax positions are more likely than not of being sustained upon audit based on the technical merits of the tax position. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely of being realized upon ultimate settlement in the financial statements. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit in the financial statements. The Company recognizes interest and penalties associated with uncertain tax positions as a component of *Taxes on income*. The Company accounts for the tax effects of the tax on global intangible low-taxed income (GILTI) of certain foreign subsidiaries in the income tax provision in the period the tax arises.

Use of Estimates — The consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States (GAAP) and, accordingly, include certain amounts that are based on management's best estimates and judgments. Estimates are used when accounting for amounts recorded in connection with acquisitions, including initial fair value determinations of assets and liabilities (primarily IPR&D, other intangible assets and contingent consideration), as well as subsequent fair value measurements. Additionally, estimates are used in determining such items as provisions for sales discounts and returns, depreciable and amortizable lives, recoverability of inventories, including those produced in preparation for product launches, amounts recorded for contingencies, environmental liabilities, accruals for contingent sales-based milestone payments and other reserves, pension and other postretirement benefit plan assumptions, share-based compensation assumptions, restructuring costs, impairments of long-lived assets (including intangible assets and goodwill) and investments, and taxes on income. Because of the uncertainty inherent in such estimates, actual results may differ from these estimates.

Reclassifications — Certain reclassifications have been made to prior year amounts to conform to the current year presentation.

Recently Adopted Accounting Standards — In June 2016, the Financial Accounting Standards Board (FASB) issued new guidance on the accounting for credit losses on financial instruments. The new guidance introduces an expected loss model for estimating credit losses, replacing the incurred loss model. The new guidance also changes the impairment model for available-for-sale debt securities, requiring the use of an allowance to record estimated credit losses (and subsequent recoveries). The Company adopted the new guidance effective January 1, 2020. There was no impact to the Company's consolidated financial statements upon adoption.

In November 2018, the FASB issued new guidance for collaborative arrangements intended to reduce diversity in practice by clarifying whether certain transactions between collaborative arrangement participants should be accounted for under revenue recognition guidance (ASC 606). The Company retrospectively adopted the new guidance effective January 1, 2020, which resulted in minor changes to the presentation of information related to the Company's collaborative arrangements (see Note 4 and Note 18).

In December 2019, the FASB issued amended guidance on the accounting and reporting of income taxes. The guidance is intended to simplify the accounting for income taxes by removing exceptions related to certain intraperiod tax allocations and deferred tax liabilities; clarifying guidance primarily related to evaluating the step-up tax basis for goodwill in a business combination; and reflecting enacted changes in tax laws or rates in the annual effective tax rate. The Company adopted the new guidance effective January 1, 2021. There was no impact to the Company's consolidated financial statements upon adoption.

In January 2020, the FASB issued new guidance intended to clarify certain interactions between accounting standards related to equity securities, equity method investments and certain derivatives. The guidance addresses accounting for the transition into and out of the equity method of accounting and measuring certain purchased options and forward contracts to acquire investments. The Company adopted the new guidance effective January 1, 2021. There was no impact to the Company's consolidated financial statements upon adoption.

Recently Issued Accounting Standard Not Yet Adopted — In March 2020, the FASB issued optional guidance to ease the potential burden in accounting for (or recognizing the effects of) reference rate reform on financial reporting and subsequently issued clarifying amendments. The guidance provides optional expedients and exceptions for applying GAAP to contracts, hedging relationships, and other transactions that reference the London Interbank Offered Rate (LIBOR) or another reference rate expected to be discontinued because of reference rate reform. The optional guidance is effective upon issuance and can be applied on a prospective basis at any time between January 1, 2020 through December 31, 2022. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

3. Acquisitions, Divestitures, Research Collaborations and License Agreements

The Company continues to pursue acquisitions and the establishment of external alliances such as research collaborations and licensing agreements to complement its internal research capabilities. These arrangements often include upfront payments, as well as expense reimbursements or payments to the third party, and milestone, royalty or profit share arrangements, contingent upon the occurrence of certain future events linked to the success of the asset in development. The Company also reviews its marketed products and pipeline to examine candidates which may provide more value through out-licensing and, as part of its portfolio assessment process, may also divest certain assets. Pro forma financial information for acquired businesses is not presented if the historical financial results of the acquired entity are not significant when compared with the Company's financial results.

2020 Transactions

In December 2020, Merck acquired OncoImmune, a privately held, clinical-stage biopharmaceutical company, for an upfront payment of $423 million. In addition, OncoImmune shareholders will be eligible to receive up to $255 million of future contingent regulatory approval milestone payments and tiered royalties ranging from 10% to 20%. OncoImmune's lead therapeutic candidate MK-7110 (also known as CD24Fc) is being evaluated for the treatment of patients hospitalized with coronavirus disease 2019 (COVID-19). The transaction was accounted for as an acquisition of an asset. Under the agreement, prior to the completion of the acquisition, OncoImmune spun-out certain rights and assets unrelated to the MK-7110 program to a new entity owned by the existing shareholders of OncoImmune. In connection with the closing of the acquisition, Merck invested $50 million for a 20% ownership interest in the new entity, which was valued at $33 million resulting in a $17 million premium. Merck also

recognized other net liabilities of $22 million. The Company recorded *Research and development* expenses of $462 million in 2020 related to this transaction.

Also in December 2020, Merck acquired VelosBio Inc. (VelosBio), a privately held, clinical-stage biopharmaceutical company, for $2.8 billion. VelosBio's lead investigational candidate is MK-2140 (formerly known as VLS-101), an antibody-drug conjugate targeting receptor tyrosine kinase-like orphan receptor 1 (ROR1) that is currently being evaluated for the treatment of patients with hematologic malignancies and solid tumors. The transaction was accounted for as an acquisition of an asset. Merck recorded net assets of $180 million (primarily cash) and *Research and development* expenses of $2.7 billion in 2020 related to the transaction.

In September 2020, Merck and Seagen Inc. (Seagen, formerly known as Seattle Genetics, Inc.) announced an oncology collaboration to globally develop and commercialize Seagen's ladiratuzumab vedotin (MK-6440), an investigational antibody-drug conjugate targeting LIV-1, which is currently in Phase 2 clinical trials for breast cancer and other solid tumors. The collaboration will pursue a broad joint development program evaluating ladiratuzumab vedotin as monotherapy and in combination with *Keytruda* (pembrolizumab) in triple-negative breast cancer, hormone receptor-positive breast cancer and other LIV-1-expressing solid tumors. The companies will equally share profits worldwide. Under the terms of the agreement, Merck made an upfront payment of $600 million and a $1.0 billion equity investment in 5 million shares of Seagen common stock at a price of $200 per share. Merck recorded $616 million in *Research and development* expenses in 2020 related to this transaction reflecting the upfront payment as well as a $16 million premium relating to the equity shares based on the price of Seagen common stock on the closing date. Seagen is also eligible to receive future contingent milestone payments of up to $2.6 billion, including $850 million in development milestones and $1.75 billion in sales-based milestones.

Concurrent with the above transaction, Seagen granted Merck an exclusive license to commercialize Tukysa (tucatinib), a small molecule tyrosine kinase inhibitor, for the treatment of HER2-positive cancers, in Asia, the Middle East and Latin America and other regions outside of the United States, Canada and Europe. Merck will be responsible for marketing applications seeking approval in its territories, supported by the positive results from the HER2CLIMB clinical trial. Merck will also co-fund a portion of the Tukysa global development plan, which encompasses several ongoing and planned trials across HER2-positive cancers, including breast, colorectal, gastric and other cancers set forth in a global product development plan. Merck will solely fund and conduct country-specific clinical trials necessary to support anticipated regulatory applications in its territories. Under the terms of the agreement, Merck made upfront payments aggregating $210 million, which were recorded as *Research and development* expenses in 2020. Seagen is also eligible to receive future contingent regulatory approval milestones of up to $65 million and will receive tiered royalties ranging from 20% to 33% based on annual sales levels of Tukysa in Merck's territories.

Additionally in September 2020, Merck acquired a biologics manufacturing facility located in Dunboyne, Ireland from Takeda Pharmaceutical Company Limited for €256 million ($302 million). The transaction was accounted for as an acquisition of an asset. Merck recorded property, plant and equipment of $289 million and other net assets of $13 million. There are no future contingent payments associated with the acquisition.

In July 2020, Merck acquired the U.S. rights to Sentinel Flavor Tabs and Sentinel Spectrum Chews from Virbac Corporation for $410 million. Sentinel products provide protection against common parasites in dogs. The transaction was accounted for as an acquisition of an asset. Merck recognized intangible assets of $401 million related to currently marketed products and inventory of $9 million at the acquisition date. The estimated fair values of the identifiable intangible assets related to currently marketed products were determined using an income approach. Actual cash flows are likely to be different than those assumed. The intangible assets related to currently marketed products will be amortized over their estimated useful lives of 15 years. There are no future contingent payments associated with the acquisition.

Also in July 2020, Merck and Ridgeback Biotherapeutics LP (Ridgeback Bio), a closely held biotechnology company, closed a collaboration agreement to develop molnupiravir (MK-4482, also known as EIDD-2801), an orally available antiviral candidate in clinical development for the treatment of patients with COVID-19. Merck gained exclusive worldwide rights to develop and commercialize molnupiravir and related molecules. Under the terms of the agreement, Ridgeback Bio received an upfront payment and also is eligible to receive future contingent payments dependent upon the achievement of certain developmental and regulatory approval milestones, as well as a share of the net profits of molnupiravir and related molecules, if approved. Merck

and Ridgeback are committed to ensure that any medicines developed for SARS-CoV-2 (the causative agent of COVID-19) will be accessible and affordable globally.

In June 2020, Merck acquired privately held Themis Bioscience GmbH (Themis), a company focused on vaccines (including a COVID-19 vaccine candidate, V591) and immune-modulation therapies for infectious diseases and cancer for $366 million. The acquisition originally provided for Merck to make additional contingent payments of up to $740 million. The transaction was accounted for as an acquisition of a business. The Company determined the fair value of the contingent consideration was $97 million at the acquisition date utilizing a probability-weighted estimated cash flow stream using an appropriate discount rate dependent on the nature and timing of the milestone payments. Merck recognized intangible assets for IPR&D of $136 million, cash of $59 million, deferred tax assets of $70 million and other net liabilities of $32 million. The excess of the consideration transferred over the fair value of net assets acquired of $230 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair values of the identifiable intangible assets related to IPR&D were determined using an income approach. Actual cash flows are likely to be different than those assumed. In January 2021, the Company announced it was discontinuing development of V591 as discussed below. As a result, in 2020, the Company recorded an IPR&D impairment charge of $90 million within *Research and development* expenses. The Company also recorded a reduction in *Research and development* expenses resulting from a decrease in the related liability for contingent consideration of $45 million since future contingent milestone payments have been reduced to $450 million in the aggregate, including up to $60 million for development milestones, up to $196 million for regulatory approval milestones, and up to $194 million for commercial milestones.

In May 2020, Merck and the International AIDS Vaccine Initiative, Inc. (IAVI), a nonprofit scientific research organization dedicated to addressing urgent, unmet global health challenges, announced a collaboration to develop V590, an investigational vaccine against SARS-CoV-2 being studied for the prevention of COVID-19. The agreement provided for an upfront payment by Merck of $6.5 million and also provided for future contingent payments based on sales. Merck also signed an agreement with the Biomedical Advanced Research and Development Authority (BARDA), part of the office of the Assistant Secretary for Preparedness and Response within an agency of the United States Department of Health and Human Services, to provide initial funding support to Merck for this effort. In January 2021, the Company announced it was discontinuing development of V590 as discussed below.

In January 2021, the Company announced the discontinuation of the development programs for its COVID-19 vaccine candidates, V590 and V591, following Merck's review of findings from Phase 1 clinical studies for the vaccines. In these studies, both V590 and V591 were generally well tolerated, but the immune responses were inferior to those seen following natural infection and those reported for other SARS-CoV-2/COVID-19 vaccines. Due to the discontinuation, the Company recorded a charge of $305 million in 2020, of which $260 million was reflected in *Cost of sales* and related to fixed-asset and materials write-offs, as well as the recognition of liabilities for purchase commitments. The remaining $45 million of costs were reflected in *Research and development* expenses and represent amounts related to the Themis acquisition noted above (an IPR&D impairment charge, partially offset by a reduction in the related liability for contingent consideration).

In January 2020, Merck acquired ArQule, Inc. (ArQule), a publicly traded biopharmaceutical company focused on kinase inhibitor discovery and development for the treatment of patients with cancer and other diseases. Total consideration paid of $2.7 billion included $138 million of share-based compensation payments to settle equity awards attributable to precombination service and cash paid for transaction costs on behalf of ArQule. The Company incurred $95 million of transaction costs directly related to the acquisition of ArQule, consisting almost entirely of share-based compensation payments to settle non-vested equity awards attributable to postcombination service. These costs were included in *Selling, general and administrative* expenses in 2020. ArQule's lead investigational candidate, MK-1026 (formerly known as ARQ 531), is a novel, oral Bruton's tyrosine kinase (BTK) inhibitor currently being evaluated for the treatment of B-cell malignancies. The transaction was accounted for as an acquisition of a business.

The estimated fair value of assets acquired and liabilities assumed from ArQule is as follows:

($ in millions)		January 16, 2020
Cash and cash equivalents	$	145
IPR&D MK-1026 (formerly ARQ 531) [(1)]		2,280
Licensing arrangement for ARQ 087		80
Deferred income tax liabilities		(361)
Other assets and liabilities, net		34
Total identifiable net assets		2,178
Goodwill [(2)]		512
Consideration transferred	$	2,690

[(1)] *The estimated fair value of the identifiable intangible asset related to IPR&D was determined using an income approach. The future net cash flows were discounted to present value utilizing a discount rate of 12.5%. Actual cash flows are likely to be different than those assumed.*

[(2)] *The goodwill was allocated to the Pharmaceutical segment and is not deductible for tax purposes.*

2019 Transactions

In July 2019, Merck acquired Peloton Therapeutics, Inc. (Peloton), a clinical-stage biopharmaceutical company focused on the development of novel small molecule therapeutic candidates targeting hypoxia-inducible factor-2α (HIF-2α) for the treatment of patients with cancer and other non-oncology diseases. Peloton's lead candidate, MK-6482 (formerly known as PT2977), is a novel investigational oral HIF-2α inhibitor in late-stage development for renal cell carcinoma. Merck made an upfront payment of $1.2 billion; additionally, former Peloton shareholders will be eligible to receive $50 million upon U.S. regulatory approval, $50 million upon first commercial sale in the United States, and up to $1.05 billion of sales-based milestones. The transaction was accounted for as an acquisition of an asset. Merck recorded cash of $157 million, deferred tax liabilities of $52 million, and other net liabilities of $4 million at the acquisition date, as well as *Research and development* expenses of $993 million in 2019 related to the transaction.

On April 1, 2019, Merck acquired Antelliq Corporation (Antelliq), a leader in digital animal identification, traceability and monitoring solutions. These solutions help veterinarians, farmers and pet owners gather critical data to improve management, health and well-being of livestock and pets. Merck paid $2.3 billion to acquire all outstanding shares of Antelliq and spent $1.3 billion to repay Antelliq's debt. The transaction was accounted for as an acquisition of a business.

The estimated fair value of assets acquired and liabilities assumed from Antelliq is as follows:

($ in millions)		April 1, 2019
Cash and cash equivalents	$	31
Accounts receivable		73
Inventories		93
Property, plant and equipment		60
Identifiable intangible assets (useful lives ranging from 18-24 years) [(1)]		2,689
Deferred income tax liabilities		(589)
Other assets and liabilities, net		(82)
Total identifiable net assets		2,275
Goodwill [(2)]		1,376
Consideration transferred	$	3,651

[(1)] *The estimated fair values of identifiable intangible assets relate primarily to trade names and were determined using an income approach. The future net cash flows were discounted to present value utilizing a discount rate of 11.5%. Actual cash flows are likely to be different than those assumed.*

(2) *The goodwill recognized is largely attributable to anticipated synergies expected to arise after the acquisition and was allocated to the Animal Health segment. The goodwill is not deductible for tax purposes.*

The Company's results for 2019 include eight months of activity for Antelliq, while the Company's results in 2020 include 13 months of activity. The Company incurred $47 million of transaction costs directly related to the acquisition of Antelliq, consisting largely of advisory fees, which are reflected in *Selling, general and administrative* expenses in 2019.

Also in April 2019, Merck acquired Immune Design, a late-stage immunotherapy company employing next-generation *in vivo* approaches to enable the body's immune system to fight disease, for $301 million in cash. The transaction was accounted for as an acquisition of a business. Merck recognized intangible assets of $156 million, cash of $83 million and other net assets of $42 million. The excess of the consideration transferred over the fair value of net assets acquired of $20 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair values of the identifiable intangible assets related to IPR&D were determined using an income approach. Actual cash flows are likely to be different than those assumed.

2018 Transactions

In 2018, the Company recorded an aggregate charge of $423 million within *Cost of sales* in conjunction with the termination of a collaboration agreement entered into in 2014 with Samsung Bioepis Co., Ltd. (Samsung) for insulin glargine. The charge reflects a termination payment of $155 million, which represents the reimbursement of all fees previously paid by Samsung to Merck under the agreement, plus interest, as well as the release of Merck's ongoing obligations under the agreement. The charge also included fixed asset abandonment charges of $137 million, inventory write-offs of $122 million, as well as other related costs of $9 million. The termination of this agreement had no impact on the Company's other collaboration with Samsung.

In June 2018, Merck acquired Viralytics Limited (Viralytics), an Australian publicly traded company focused on oncolytic immunotherapy treatments for a range of cancers, for AUD 502 million ($378 million). The transaction provided Merck with full rights to V937 (formerly known as CVA21), an investigational oncolytic immunotherapy. The transaction was accounted for as an acquisition of an asset. Merck recorded net assets of $34 million (primarily cash) at the acquisition date and *Research and development* expenses of $344 million in 2018 related to the transaction. There are no future contingent payments associated with the acquisition.

In March 2018, Merck and Eisai Co., Ltd. (Eisai) entered into a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima, an orally available tyrosine kinase inhibitor discovered by Eisai (see Note 4).

Remicade/Simponi

In 1998, a subsidiary of Schering-Plough entered into a licensing agreement with Centocor Ortho Biotech Inc. (Centocor), a Johnson & Johnson (J&J) company, to market *Remicade,* which is prescribed for the treatment of inflammatory diseases. In 2005, Schering-Plough's subsidiary exercised an option under its contract with Centocor for license rights to develop and commercialize *Simponi*, a fully human monoclonal antibody. The Company has marketing rights to both products throughout Europe, Russia and Turkey. *Remicade* lost market exclusivity in major European markets in 2015 and the Company no longer has market exclusivity in any of its marketing territories. The Company continues to have market exclusivity for *Simponi* in all of its marketing territories. All profits derived from Merck's distribution of the two products in these countries are equally divided between Merck and J&J. The Company's marketing rights with respect to these products will revert to Janssen Pharmaceuticals, Inc. in the second half of 2024.

4. Collaborative Arrangements

Merck has entered into collaborative arrangements that provide the Company with varying rights to develop, produce and market products together with its collaborative partners. Both parties in these arrangements are active participants and exposed to significant risks and rewards dependent on the commercial success of the activities of the collaboration. Merck's more significant collaborative arrangements are discussed below.

AstraZeneca

In July 2017, Merck and AstraZeneca PLC (AstraZeneca) entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza (olaparib) for multiple cancer types. Lynparza is an oral poly (ADP-ribose) polymerase (PARP) inhibitor currently approved for certain types of

advanced ovarian, breast, pancreatic and prostate cancers. The companies are jointly developing and commercializing Lynparza, both as monotherapy and in combination trials with other potential medicines. Independently, Merck and AstraZeneca will develop and commercialize Lynparza in combinations with their respective PD-1 and PD-L1 medicines, *Keytruda* and Imfinzi. The companies are also jointly developing and commercializing AstraZeneca's Koselugo (selumetinib), an oral, selective inhibitor of MEK, part of the mitogen-activated protein kinase (MAPK) pathway, for multiple indications. In April 2020, Koselugo was approved by the U.S. Food and Drug Administration (FDA) for the treatment of pediatric patients two years of age and older with neurofibromatosis type 1 who have symptomatic, inoperable plexiform neurofibromas. Under the terms of the agreement, AstraZeneca and Merck will share the development and commercialization costs for Lynparza and Koselugo monotherapy and non-PD-L1/PD-1 combination therapy opportunities.

Profits from Lynparza and Koselugo product sales generated through monotherapies or combination therapies are shared equally. Merck will fund all development and commercialization costs of *Keytruda* in combination with Lynparza or Koselugo. AstraZeneca will fund all development and commercialization costs of Imfinzi in combination with Lynparza or Koselugo. AstraZeneca is the principal on Lynparza and Koselugo sales transactions. Merck records its share of Lynparza and Koselugo product sales, net of cost of sales and commercialization costs, as alliance revenue and its share of development costs associated with the collaboration as part of *Research and development* expenses. Reimbursements received from AstraZeneca for research and development expenses are recognized as reductions to *Research and development* costs.

As part of the agreement, Merck made an upfront payment to AstraZeneca of $1.6 billion in 2017 and made payments of $750 million over a multi-year period for certain license options (of which $250 million was paid in December 2017, $400 million was paid in December 2018 and $100 million was paid in December 2019). The upfront payment and license option payments were reflected in *Research and development* expenses in 2017. In addition, the agreement provides for additional contingent payments from Merck to AstraZeneca related to the successful achievement of sales-based and regulatory milestones.

In 2020, Merck determined it was probable that sales of Lynparza in the future would trigger $400 million of sales-based milestone payments from Merck to AstraZeneca. Accordingly, Merck recorded $400 million of liabilities and corresponding increases to the intangible asset related to Lynparza. Prior to 2020, Merck accrued sales-based milestone payments aggregating $1.0 billion related to Lynparza, of which $550 million, $200 million and $250 million was paid to AstraZeneca in 2020, 2019 and 2018, respectively. Potential future sales-based milestone payments of $2.7 billion have not yet been accrued as they are not deemed by the Company to be probable at this time.

In 2020, 2019 and 2018, Lynparza received regulatory approvals triggering capitalized milestone payments of $160 million, $60 million and $140 million, respectively, in the aggregate from Merck to AstraZeneca. Potential future regulatory milestone payments of $1.4 billion remain under the agreement.

The intangible asset balance related to Lynparza (which includes capitalized sales-based and regulatory milestone payments) was $1.3 billion at December 31, 2020 and is included in *Other Intangibles, Net*. The amount is being amortized over its estimated useful life through 2028 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

Years Ended December 31	**2020**	2019	2018
Alliance revenue - Lynparza	**$ 725**	$ 444	$ 187
Alliance revenue - Koselugo	**8**	—	—
Total alliance revenue	**$ 733**	$ 444	$ 187
Cost of sales [1]	**247**	148	93
Selling, general and administrative	**160**	138	48
Research and development	**133**	168	152

December 31	**2020**	2019
Receivables from AstraZeneca included in *Other current assets*	**$ 215**	$ 128
Payables to AstraZeneca included in *Accrued and other current liabilities* [2]	**423**	577

[1] *Represents amortization of capitalized milestone payments.*

[2] *Includes accrued milestone payments.*

Eisai

In March 2018, Merck and Eisai Co., Ltd. (Eisai) announced a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima (lenvatinib), an orally available tyrosine kinase inhibitor discovered by Eisai. Lenvima is currently approved for the treatment of certain types of thyroid cancer, hepatocellular carcinoma, in combination with everolimus for certain patients with renal cell carcinoma, and in combination with *Keytruda* for the treatment of certain patients with endometrial carcinoma. Under the agreement, Merck and Eisai will develop and commercialize Lenvima jointly, both as monotherapy and in combination with *Keytruda*. Eisai records Lenvima product sales globally (Eisai is the principal on Lenvima sales transactions), and Merck and Eisai share applicable profits equally. Merck records its share of Lenvima product sales, net of cost of sales and commercialization costs, as alliance revenue. Expenses incurred during co-development are shared by the two companies in accordance with the collaboration agreement and reflected in *Research and development* expenses. Certain expenses incurred solely by Merck or Eisai are not shareable under the collaboration agreement, including costs incurred in excess of agreed upon caps and costs related to certain combination studies of *Keytruda* and Lenvima.

Under the agreement, Merck made an upfront payment to Eisai of $750 million in 2018 and agreed to make payments of up to $650 million for certain option rights through 2021 (of which $325 million was paid in March 2019, $200 million was paid in March 2020 and $125 million is expected to be paid in March 2021). The Company recorded an aggregate charge of $1.4 billion in *Research and development* expenses in 2018 related to the upfront payment and future option payments. In addition, the agreement provides for additional contingent payments from Merck to Eisai related to the successful achievement of sales-based and regulatory milestones.

In 2020, Merck determined it was probable that sales of Lenvima in the future would trigger sales-based milestone payments aggregating $400 million from Merck to Eisai. Accordingly, Merck recorded liabilities of $400 million and corresponding increases to the intangible asset related to Lenvima. Prior to 2020, Merck accrued sales-based milestone payments aggregating $950 million related to Lenvima, of which $500 million and $50 million was paid to Eisai in 2020 and 2019, respectively. Potential future sales-based milestone payments of $2.6 billion have not yet been accrued as they are not deemed by the Company to be probable at this time.

In 2020 and 2018, Lenvima received regulatory approvals triggering capitalized milestone payments of $10 million and $250 million, respectively, from Merck to Eisai. Potential future regulatory milestone payments of $125 million remain under the agreement.

The intangible asset balance related to Lenvima (which includes capitalized sales-based and regulatory milestone payments) was $1.1 billion at December 31, 2020 and is included in *Other Intangibles, Net*. The amount is being amortized over its estimated useful life through 2026 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

Years Ended December 31	**2020**	2019	2018
Alliance revenue - Lenvima	**$ 580**	$ 404	$ 149
Cost of sales [1]	**271**	206	39
Selling, general and administrative	**73**	80	13
Research and development [2]	**185**	189	1,489

December 31	**2020**	2019
Receivables from Eisai included in *Other current assets*	**$ 157**	$ 150
Payables to Eisai included in *Accrued and other current liabilities* [3]	**335**	700
Payables to Eisai included in *Other Noncurrent Liabilities* [4]	**600**	525

[1] *Represents amortization of capitalized milestone payments.*

[2] *Amount for 2018 includes $1.4 billion related to the upfront payment and option payments.*

[3] *Includes accrued milestone and future option payments.*

[4] *Includes accrued milestone payments.*

Bayer AG

In 2014, the Company entered into a worldwide clinical development collaboration with Bayer AG (Bayer) to market and develop soluble guanylate cyclase (sGC) modulators including Bayer's Adempas (riociguat), which is approved to treat pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension. The two companies have implemented a joint development and commercialization strategy. The collaboration also includes clinical development of Bayer's Verquvo (vericiguat), which was approved by the FDA in January 2021 to reduce the risk of cardiovascular death and heart failure hospitalization following a hospitalization for heart failure or need for outpatient intravenous diuretics in adults. Verquvo is under review by regulatory authorities in other territories including the EU and Japan. Under the agreement, Bayer commercializes Adempas in the Americas, while Merck commercializes in the rest of the world. For Verquvo, Merck will commercialize in the United States and Bayer will commercialize in the rest of the world. Both companies share in development costs and profits on sales. Merck records sales of Adempas (and will record sales of Verquvo) in its marketing territories, as well as alliance revenue. Alliance revenue represents Merck's share of profits from sales in Bayer's marketing territories, which are product sales net of cost of sales and commercialization costs. In addition, the agreement provides for contingent payments from Merck to Bayer related to the successful achievement of sales-based milestones.

Prior to 2020, Merck accrued $725 million of sales-based milestone payments for this collaboration, of which $375 million and $350 million was paid to Bayer in 2020 and 2018, respectively. Following the 2021 FDA approval of Verquvo noted above, Merck determined it was probable that sales of Adempas and Verquvo in the future would trigger the remaining $400 million sales-based milestone payment. Accordingly, Merck will record a liability of $400 million and a corresponding increase in intangible assets related to this collaboration in the first quarter of 2021.

The intangible asset balance related to this collaboration (which includes the acquired intangible asset balance, as well as capitalized sales-based milestone payments) was $849 million at December 31, 2020 and is included in *Other Intangibles, Net*. The amount is being amortized over its estimated useful life through 2027 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

Years Ended December 31	**2020**	2019	2018
Alliance revenue - Adempas	**$ 281**	$ 204	$ 139
Net sales of Adempas recorded by Merck	**220**	215	190
Total sales	**$ 501**	$ 419	$ 329
Cost of sales [1]	**115**	113	216
Selling, general and administrative	**61**	41	35
Research and development	**63**	126	127

December 31	**2020**	2019
Receivables from Bayer included in *Other current assets*	**$ 65**	$ 49
Payables to Bayer included in *Other Noncurrent Liabilities* [2]	**—**	375

[1] *Includes amortization of intangible assets.*

[2] *Represents accrued milestone payment.*

5. Restructuring

In early 2019, Merck approved a new global restructuring program (Restructuring Program) as part of a worldwide initiative focused on further optimizing the Company's manufacturing and supply network, as well as reducing its global real estate footprint. This program is a continuation of the Company's plant rationalization, builds on prior restructuring programs and does not include any actions associated with the planned spin-off of Organon. As the Company continues to evaluate its global footprint and overall operating model, it subsequently identified additional actions under the Restructuring Program, and could identify further actions over time. The actions currently contemplated under the Restructuring Program are expected to be substantially completed by the end of 2023, with the cumulative pretax costs to be incurred by the Company to implement the program now estimated to be approximately $3.0 billion. The Company estimates that approximately 70% of the cumulative pretax costs will result in cash outlays, primarily related to employee separation expense and facility shut-down costs. Approximately 30% of the cumulative pretax costs will be non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested. The Company expects to record charges of approximately $700 million in 2021 related to the Restructuring Program. Actions under previous global restructuring programs have been substantially completed.

The Company recorded total pretax costs of $883 million in 2020, $927 million in 2019 and $658 million in 2018 related to restructuring program activities. Since inception of the Restructuring Program through December 31, 2020, Merck has recorded total pretax accumulated costs of approximately $1.8 billion. For segment reporting, restructuring charges are unallocated expenses.

The following table summarizes the charges related to restructuring program activities by type of cost:

	Separation Costs	Accelerated Depreciation	Other	Total
Year Ended December 31, 2020				
Cost of sales	**$ —**	**$ 143**	**$ 32**	**$ 175**
Selling, general and administrative	**—**	**44**	**3**	**47**
Research and development	**—**	**81**	**2**	**83**
Restructuring costs	**385**	**—**	**193**	**578**
	$ 385	**$ 268**	**$ 230**	**$ 883**
Year Ended December 31, 2019				
Cost of sales	$ —	$ 198	$ 53	$ 251
Selling, general and administrative	—	33	1	34
Research and development	—	2	2	4
Restructuring costs	572	—	66	638
	$ 572	$ 233	$ 122	$ 927
Year Ended December 31, 2018				
Cost of sales	$ —	$ 10	$ 11	$ 21
Selling, general and administrative	—	2	1	3
Research and development	—	(13)	15	2
Restructuring costs	473	—	159	632
	$ 473	$ (1)	$ 186	$ 658

Separation costs are associated with actual headcount reductions, as well as those headcount reductions which were probable and could be reasonably estimated.

Accelerated depreciation costs primarily relate to manufacturing, research and administrative facilities and equipment to be sold or closed as part of the programs. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the asset, based upon the anticipated date the site will be closed or divested or the equipment disposed of, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. All the sites have and will continue to operate up through the respective closure dates and, since future undiscounted cash flows are sufficient to recover the respective book values, Merck is recording accelerated depreciation over the revised useful life of the site assets. Anticipated site closure dates, particularly related to manufacturing locations, have been and may continue to be adjusted to reflect changes resulting from regulatory or other factors.

Other activity in 2020, 2019 and 2018 includes asset abandonment, facility shut-down and other related costs, as well as pretax gains and losses resulting from the sales of facilities and related assets. Additionally, other activity includes certain employee-related costs associated with pension and other postretirement benefit plans (see Note 13) and share-based compensation.

The following table summarizes the charges and spending relating to restructuring program activities:

	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2019	$ 443	$ —	$ 91	$ 534
Expenses	572	233	122	927
(Payments) receipts, net	(325)	—	(136)	(461)
Non-cash activity	—	(233)	(8)	(241)
Restructuring reserves December 31, 2019	690	—	69	759
Expenses	**385**	**268**	**230**	**883**
(Payments) receipts, net	**(508)**	**—**	**(301)**	**(809)**
Non-cash activity	**—**	**(268)**	**38**	**(230)**
Restructuring reserves December 31, 2020 [1]	**$ 567**	**$ —**	**$ 36**	**$ 603**

[1] *The remaining cash outlays are expected to be substantially completed by the end of 2023.*

6. Financial Instruments

Derivative Instruments and Hedging Activities

The Company manages the impact of foreign exchange rate movements and interest rate movements on its earnings, cash flows and fair values of assets and liabilities through operational means and through the use of various financial instruments, including derivative instruments.

A significant portion of the Company's revenues and earnings in foreign affiliates is exposed to changes in foreign exchange rates. The objectives and accounting related to the Company's foreign currency risk management program, as well as its interest rate risk management activities are discussed below.

Foreign Currency Risk Management

The Company has established revenue hedging, balance sheet risk management and net investment hedging programs to protect against volatility of future foreign currency cash flows and changes in fair value caused by changes in foreign exchange rates.

The objective of the revenue hedging program is to reduce the variability caused by changes in foreign exchange rates that would affect the U.S. dollar value of future cash flows derived from foreign currency denominated sales, primarily the euro, Japanese yen and Chinese renminbi. To achieve this objective, the Company will hedge a portion of its forecasted foreign currency denominated third-party and intercompany distributor entity sales (forecasted sales) that are expected to occur over its planning cycle, typically no more than two years into the future. The Company will layer in hedges over time, increasing the portion of forecasted sales hedged as it gets closer to the expected date of the forecasted sales. The portion of forecasted sales hedged is based on assessments of cost-benefit profiles that consider natural offsetting exposures, revenue and exchange rate volatilities and correlations, and the cost of hedging instruments. The Company manages its anticipated transaction exposure principally with purchased local currency put options, forward contracts, and purchased collar options.

The fair values of these derivative contracts are recorded as either assets (gain positions) or liabilities (loss positions) in the Consolidated Balance Sheet. Changes in the fair value of derivative contracts are recorded each period in either current earnings or *OCI*, depending on whether the derivative is designated as part of a hedge transaction and, if so, the type of hedge transaction. For derivatives that are designated as cash flow hedges, the unrealized gains or losses on these contracts are recorded in *AOCI* and reclassified into *Sales* when the hedged anticipated revenue is recognized. For those derivatives which are not designated as cash flow hedges, but serve as economic hedges of forecasted sales, unrealized gains or losses are recorded in *Sales* each period. The cash flows from both designated and non-designated contracts are reported as operating activities in the Consolidated Statement of Cash Flows. The Company does not enter into derivatives for trading or speculative purposes.

The Company manages operating activities and net asset positions at each local subsidiary in order to mitigate the effects of exchange on monetary assets and liabilities. The Company also uses a balance sheet risk management program to mitigate the exposure of net monetary assets that are denominated in a currency other than a subsidiary's functional currency from the effects of volatility in foreign exchange. In these instances, Merck principally utilizes forward exchange contracts to offset the effects of exchange on exposures denominated in developed country currencies, primarily the euro and Japanese yen. For exposures in developing country currencies, the Company will enter into forward contracts to partially offset the effects of exchange on exposures when it is deemed economical to do so based on a cost-benefit analysis that considers the magnitude of the exposure, the volatility of the exchange rate and the cost of the hedging instrument. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

Monetary assets and liabilities denominated in a currency other than the functional currency of a given subsidiary are remeasured at spot rates in effect on the balance sheet date with the effects of changes in spot rates reported in *Other (income) expense, net*. The forward contracts are not designated as hedges and are marked to market through *Other (income) expense, net*. Accordingly, fair value changes in the forward contracts help mitigate the changes in the value of the remeasured assets and liabilities attributable to changes in foreign currency exchange rates, except to the extent of the spot-forward differences. These differences are not significant due to the short-term nature of the contracts, which typically have average maturities at inception of less than one year.

The Company also uses forward exchange contracts to hedge a portion of its net investment in foreign operations against movements in exchange rates. The forward contracts are designated as hedges of the net investment in a foreign operation. The unrealized gains or losses on these contracts are recorded in foreign currency translation adjustment within *OCI*, and remain in *AOCI* until either the sale or complete or substantially complete liquidation of the subsidiary. The Company excludes certain portions of the change in fair value of its derivative instruments from the assessment of hedge effectiveness (excluded components). Changes in fair value of the excluded components are recognized in *OCI*. The Company recognizes in earnings the initial value of the excluded components on a straight-line basis over the life of the derivative instrument, rather than using the mark-to-market approach. The cash flows from these contracts are reported as investing activities in the Consolidated Statement of Cash Flows.

Foreign exchange risk is also managed through the use of foreign currency debt. The Company's senior unsecured euro-denominated notes have been designated as, and are effective as, economic hedges of the net investment in a foreign operation. Accordingly, foreign currency transaction gains or losses due to spot rate fluctuations on the euro-denominated debt instruments are included in foreign currency translation adjustment within *OCI*.

The effects of the Company's net investment hedges on *OCI* and the Consolidated Statement of Income are shown below:

	Amount of Pretax (Gain) Loss Recognized in Other Comprehensive Income [1]			Amount of Pretax (Gain) Loss Recognized in *Other (income) expense, net* for Amounts Excluded from Effectiveness Testing		
Years Ended December 31	**2020**	2019	2018	**2020**	2019	2018
Net Investment Hedging Relationships						
Foreign exchange contracts	**$ 26**	$ (10)	$ (18)	**$ (19)**	$ (31)	$ (11)
Euro-denominated notes	**385**	(75)	(183)	**—**	—	—

[1] *No amounts were reclassified from AOCI into income related to the sale of a subsidiary.*

Interest Rate Risk Management

The Company may use interest rate swap contracts on certain investing and borrowing transactions to manage its net exposure to interest rate changes and to reduce its overall cost of borrowing. The Company does not use leveraged swaps and, in general, does not leverage any of its investment activities that would put principal capital at risk.

In February 2020, five interest rate swaps with notional amounts of $250 million each matured. These swaps effectively converted the Company's $1.25 billion, 1.85% fixed-rate notes due 2020 to variable rate debt. At December 31, 2020, the Company was a party to 14 pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes as detailed in the table below:

	2020		
Debt Instrument	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
3.875% notes due 2021 [1]	$ 1,150	5	$ 1,150
2.40% notes due 2022	1,000	4	1,000
2.35% notes due 2022	1,250	5	1,250

[1] *These interest rate swaps matured in January 2021.*

The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in the benchmark LIBOR swap rate. The fair value changes in the notes attributable to changes in the LIBOR swap rate are recorded in interest expense along with the offsetting fair value changes in the swap contracts. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

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The table below presents the location of amounts recorded on the Consolidated Balance Sheet related to cumulative basis adjustments for fair value hedges as of December 31:

	Carrying Amount of Hedged Liabilities		Cumulative Amount of Fair Value Hedging Adjustment Increase (Decrease) Included in the Carrying Amount	
	2020	2019	**2020**	2019
Balance Sheet Line Item in which Hedged Item is Included				
Loans payable and current portion of long-term debt	**$ 1,150**	$ 1,249	**$ —**	$ (1)
Long-Term Debt	**2,301**	3,409	**53**	14

Presented in the table below is the fair value of derivatives on a gross basis segregated between those derivatives that are designated as hedging instruments and those that are not designated as hedging instruments as of December 31:

		2020			2019		
		Fair Value of Derivative			Fair Value of Derivative		
	Balance Sheet Caption	**Asset**	**Liability**	**U.S. Dollar Notional**	Asset	Liability	U.S. Dollar Notional
Derivatives Designated as Hedging Instruments							
Interest rate swap contracts	Other current assets	**$ 1**	**$ —**	**$ 1,150**	$ —	$ —	$ —
Interest rate swap contracts	Other Assets	**54**	**—**	**2,250**	15	—	3,400
Interest rate swap contracts	Accrued and other current liabilities	**—**	**—**	**—**	—	1	1,250
Foreign exchange contracts	Other current assets	**12**	**—**	**3,183**	152	—	6,117
Foreign exchange contracts	Other Assets	**45**	**—**	**2,030**	55	—	2,160
Foreign exchange contracts	Accrued and other current liabilities	**—**	**217**	**5,049**	—	22	1,748
Foreign exchange contracts	Other Noncurrent Liabilities	**—**	**1**	**52**	—	1	53
		$ 112	**$ 218**	**$ 13,714**	$ 222	$ 24	$ 14,728
Derivatives Not Designated as Hedging Instruments							
Foreign exchange contracts	Other current assets	**$ 70**	**$ —**	**$ 7,260**	$ 66	$ —	$ 7,245
Foreign exchange contracts	Accrued and other current liabilities	**—**	**307**	**11,810**	—	73	8,693
		$ 70	**$ 307**	**$ 19,070**	$ 66	$ 73	$ 15,938
		$ 182	**$ 525**	**$ 32,784**	$ 288	$ 97	$ 30,666

As noted above, the Company records its derivatives on a gross basis in the Consolidated Balance Sheet. The Company has master netting agreements with several of its financial institution counterparties (see *Concentrations of Credit Risk* below). The following table provides information on the Company's derivative positions subject to these master netting arrangements as if they were presented on a net basis, allowing for the right of offset by counterparty and cash collateral exchanged per the master agreements and related credit support annexes at December 31:

	2020		2019	
	Asset	**Liability**	Asset	Liability
Gross amounts recognized in the consolidated balance sheet	**$ 182**	**$ 525**	$ 288	$ 97
Gross amounts subject to offset in master netting arrangements not offset in the consolidated balance sheet	**(156)**	**(156)**	(84)	(84)
Cash collateral posted/received	**—**	**(36)**	(34)	—
Net amounts	**$ 26**	**$ 333**	$ 170	$ 13

The table below provides information regarding the location and amount of pretax (gains) losses of derivatives designated in fair value or cash flow hedging relationships:

	Sales			Other (income) expense, net [1]			Other comprehensive income (loss)		
Years Ended December 31	**2020**	2019	2018	**2020**	2019	2018	**2020**	2019	2018
Financial Statement Line Items in which Effects of Fair Value or Cash Flow Hedges are Recorded	**$ 47,994**	$ 46,840	$ 42,294	**$ (886)**	139	(402)	**$ (441)**	$ (648)	$ (361)
(Gain) loss on fair value hedging relationships									
Interest rate swap contracts									
Hedged items	**—**	—	—	**40**	95	(27)	**—**	—	—
Derivatives designated as hedging instruments	**—**	—	—	**(76)**	(65)	50	**—**	—	—
Impact of cash flow hedging relationships									
Foreign exchange contracts									
Amount of (loss) gain recognized in *OCI* on derivatives	**—**	—	—	**—**	—	—	**(383)**	87	228
(Decrease) increase in *Sales* as a result of *AOCI* reclassifications	**(6)**	255	(160)	**—**	—	—	**6**	(255)	160
Interest rate contracts									
Amount of gain recognized in *Other (income) expense, net* on derivatives	**—**	—	—	**(4)**	(4)	(4)	**—**	—	—
Amount of loss recognized in *OCI* on derivatives	**—**	—	—	**—**	—	—	**(4)**	(6)	(4)

[1] *Interest expense is a component of* Other (income) expense, net.

The table below provides information regarding the income statement effects of derivatives not designated as hedging instruments:

		Amount of Derivative Pretax (Gain) Loss Recognized in Income		
Years Ended December 31		**2020**	2019	2018
Derivatives Not Designated as Hedging Instruments	*Income Statement Caption*			
Foreign exchange contracts [1]	Other (income) expense, net	**$ (12)**	$ 174	$ (260)
Foreign exchange contracts [2]	Sales	**13**	1	(8)
Interest rate contracts [3]	Other (income) expense, net	**9**	—	—
Forward contract related to Seagen common stock	Research and development expenses	**15**	—	—

[1] *These derivative contracts mitigate changes in the value of remeasured foreign currency denominated monetary assets and liabilities attributable to changes in foreign currency exchange rates.*

[2] *These derivative contracts serve as economic hedges of forecasted transactions.*

[3] *These derivatives serve as economic hedges against rising treasury rates.*

At December 31, 2020, the Company estimates $331 million of pretax net unrealized losses on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from *AOCI* to *Sales*. The amount ultimately reclassified to *Sales* may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.

Investments in Debt and Equity Securities

Information on investments in debt and equity securities at December 31 is as follows:

	2020				2019			
		Gross Unrealized				Gross Unrealized		
	Amortized Cost	Gains	Losses	Fair Value	Amortized Cost	Gains	Losses	Fair Value
U.S. government and agency securities	$ 84	$ —	$ —	$ 84	$ 266	$ 3	$ —	$ 269
Foreign government bonds	5	—	—	5	—	—	—	—
Commercial paper	—	—	—	—	668	—	—	668
Corporate notes and bonds	—	—	—	—	608	13	—	621
Asset-backed securities	—	—	—	—	226	1	—	227
Total debt securities	89	—	—	89	1,768	17	—	1,785
Publicly traded equity securities [1]				1,787				838
Total debt and publicly traded equity securities				$ 1,876				$ 2,623

[1] *Unrealized net gains recognized in* Other (income) expense, net *on equity securities still held at December 31, 2020 were $163 million during 2020. Unrealized net gains recognized in* Other (income) expense, net *on equity securities still held at December 31, 2019 were $160 million during 2019.*

At December 31, 2020 and 2019, the Company also had $586 million and $420 million, respectively, of equity investments without readily determinable fair values included in *Other Assets*. During 2020 and 2019, the Company recognized unrealized gains of $62 million and $20 million, respectively, in *Other (income) expense, net*, on certain of these equity investments based on favorable observable price changes from transactions involving similar investments of the same investee. In addition, during 2020 and 2019, the Company recognized unrealized losses of $3 million and $13 million, respectively, in *Other (income) expense, net*, related to certain of these investments based on unfavorable observable price changes. Cumulative unrealized gains and cumulative unrealized losses based on observable prices changes for investments in equity investments without readily determinable fair values were $169 million and $24 million, respectively.

Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company uses a fair value hierarchy which maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest:

Level 1 — Quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 — Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity. Level 3 assets or liabilities are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as assets or liabilities for which the determination of fair value requires significant judgment or estimation.

If the inputs used to measure the financial assets and liabilities fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

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Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

Financial assets and liabilities measured at fair value on a recurring basis at December 31 are summarized below:

	Fair Value Measurements Using				Fair Value Measurements Using			
	Level 1	**Level 2**	**Level 3**	**Total**	Level 1	Level 2	Level 3	Total
			2020				2019	
Assets								
Investments								
Foreign government bonds	**$ —**	**$ 5**	**$ —**	**$ 5**	$ —	$ —	$ —	$ —
Commercial paper	**—**	**—**	**—**	**—**	—	668	—	668
Corporate notes and bonds	**—**	**—**	**—**	**—**	—	621	—	621
Asset-backed securities	**—**	**—**	**—**	**—**	—	227	—	227
U.S. government and agency securities	**—**	**—**	**—**	**—**	—	209	—	209
Publicly traded equity securities	**780**	**—**	**—**	**780**	518	—	—	518
	780	**5**	**—**	**785**	518	1,725	—	2,243
Other assets [1]								
U.S. government and agency securities	**84**	**—**	**—**	**84**	60	—	—	60
Publicly traded equity securities	**1,007**	**—**	**—**	**1,007**	320	—	—	320
	1,091	**—**	**—**	**1,091**	380	—	—	380
Derivative assets [2]								
Forward exchange contracts	**—**	**90**	**—**	**90**	—	169	—	169
Interest rate swaps	**—**	**55**	**—**	**55**	—	15	—	15
Purchased currency options	**—**	**37**	**—**	**37**	—	104	—	104
	—	**182**	**—**	**182**	—	288	—	288
Total assets	**$ 1,871**	**$ 187**	**$ —**	**$ 2,058**	$ 898	$ 2,013	$ —	$ 2,911
Liabilities								
Other liabilities								
Contingent consideration	**$ —**	**$ —**	**$ 841**	**$ 841**	$ —	$ —	$ 767	$ 767
Derivative liabilities [2]								
Forward exchange contracts	**—**	**505**	**—**	**505**	—	95	—	95
Written currency options	**—**	**20**	**—**	**20**	—	1	—	1
Interest rate swaps	**—**	**—**	**—**	**—**	—	1	—	1
	—	**525**	**—**	**525**	—	97	—	97
Total liabilities	**$ —**	**$ 525**	**$ 841**	**$ 1,366**	$ —	$ 97	$ 767	$ 864

[1] *Investments included in other assets are restricted as to use, including for the payment of benefits under employee benefit plans.*

[2] *The fair value determination of derivatives includes the impact of the credit risk of counterparties to the derivatives and the Company's own credit risk, the effects of which were not significant.*

As of December 31, 2020 and 2019, *Cash and cash equivalents* include $6.8 billion and $8.9 billion, respectively, of cash equivalents (which would be considered Level 2 in the fair value hierarchy).

Contingent Consideration

Summarized information about the changes in liabilities for contingent consideration associated with business acquisitions is as follows:

	2020	2019
Fair value January 1	**$ 767**	$ 788
Additions	**97**	—
Changes in estimated fair value [(1)]	**83**	64
Payments	**(106)**	(85)
Fair value December 31 [(2)(3)]	**$ 841**	$ 767

[(1)] *Recorded in* Cost of sales, Research and development *expenses, and* Other (income) expense, net. *Includes cumulative translation adjustments.*

[(2)] *Balance at December 31, 2020 includes $148 million recorded as a current liability for amounts expected to be paid within the next 12 months.*

[(3)] *At December 31, 2020 and 2019, $711 million and $625 million, respectively, of the liabilities relate to the termination of the Sanofi Pasteur MSD joint venture in 2016. As part of the termination, Merck recorded a liability for contingent future royalty payments of 11.5% on net sales of all Merck products that were previously sold by the joint venture through December 31, 2024. The fair value of this liability is determined utilizing the estimated amount and timing of projected cash flows and a risk-adjusted discount rate of 8% to present value the cash flows.*

The additions to contingent consideration in 2020 relate to the acquisition of Themis. The changes in the estimated fair value of liabilities for contingent consideration in 2020 and 2019 were largely attributable to increases in the liabilities recorded in connection with the termination of the Sanofi Pasteur MSD (SPMSD) joint venture in 2016. In 2020, the increase was partially offset by a decline related to the discontinuation of a COVID-19 vaccine program obtained through the acquisition of Themis. The payments of contingent consideration in both years relate to the SPMSD liabilities described above.

Other Fair Value Measurements

Some of the Company's financial instruments, such as cash and cash equivalents, receivables and payables, are reflected in the balance sheet at carrying value, which approximates fair value due to their short-term nature.

The estimated fair value of loans payable and long-term debt (including current portion) at December 31, 2020, was $36.0 billion compared with a carrying value of $31.8 billion and at December 31, 2019, was $28.8 billion compared with a carrying value of $26.3 billion. Fair value was estimated using recent observable market prices and would be considered Level 2 in the fair value hierarchy.

Concentrations of Credit Risk

On an ongoing basis, the Company monitors concentrations of credit risk associated with corporate and government issuers of securities and financial institutions with which it conducts business. Credit exposure limits are established to limit a concentration with any single issuer or institution. Cash and investments are placed in instruments that meet high credit quality standards, as specified in the Company's investment policy guidelines.

The majority of the Company's accounts receivable arise from product sales in the United States, Europe and China and are primarily due from drug wholesalers and retailers, hospitals, government agencies, managed health care providers and pharmacy benefit managers. The Company monitors the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in their credit profile. The Company also continues to monitor global economic conditions, including the volatility associated with international sovereign economies, and associated impacts on the financial markets and its business.

The Company's customers with the largest accounts receivable balances are: McKesson Corporation, AmerisourceBergen Corporation and Cardinal Health, Inc., which represented, in aggregate, approximately 45% of total accounts receivable at December 31, 2020. The Company monitors the creditworthiness of its customers to which it grants credit terms in the normal course of business. Bad debts have been minimal. The Company does not normally require collateral or other security to support credit sales.

The Company has accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable. The Company factored $2.3 billion and $2.7 billion of accounts receivable in the fourth quarter of 2020 and 2019, respectively, under these factoring arrangements, which reduced outstanding accounts receivable. The cash received from the financial institutions is reported within operating activities in the

Consolidated Statement of Cash Flows. In certain of these factoring arrangements, for ease of administration, the Company will collect customer payments related to the factored receivables, which it then remits to the financial institutions. At December 31, 2020 and 2019, the Company had collected $102 million and $256 million, respectively, on behalf of the financial institutions, which is reflected as restricted cash in *Other current assets* and the related obligation to remit the cash within *Accrued and other current liabilities*. The Company remitted the cash to the financial institutions in January 2021 and 2020, respectively. The net cash flows relating to these collections are reported as financing activities in the Consolidated Statement of Cash Flows. The cost of factoring such accounts receivable was *de minimis*.

Derivative financial instruments are executed under International Swaps and Derivatives Association master agreements. The master agreements with several of the Company's financial institution counterparties also include credit support annexes. These annexes contain provisions that require collateral to be exchanged depending on the value of the derivative assets and liabilities, the Company's credit rating, and the credit rating of the counterparty. Cash collateral advanced by the Company to counterparties was $36 million at December 31, 2020. Cash collateral received by the Company from various counterparties was $34 million at December 31, 2019. The obligation to return such collateral is recorded in *Accrued and other current liabilities*.

7. Inventories

Inventories at December 31 consisted of:

	2020	2019
Finished goods	**$ 1,963**	$ 1,772
Raw materials and work in process	**6,420**	5,650
Supplies	**206**	207
Total (approximates current cost)	**8,589**	7,629
Decrease to LIFO cost	**(82)**	(171)
	$ 8,507	$ 7,458
Recognized as:		
Inventories	**$ 6,310**	$ 5,978
Other assets	**2,197**	1,480

Inventories valued under the LIFO method comprised approximately $2.9 billion and $2.6 billion at December 31, 2020 and 2019, respectively. Amounts recognized as *Other assets* are comprised almost entirely of raw materials and work in process inventories. At December 31, 2020 and 2019, these amounts included $1.9 billion and $1.3 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included $279 million and $168 million at December 31, 2020 and 2019, respectively, of inventories produced in preparation for product launches.

8. Goodwill and Other Intangibles

The following table summarizes goodwill activity by segment:

	Pharmaceutical	Animal Health	All Other	Total
Balance January 1, 2019	$ 16,162	$ 1,870	$ 221	$ 18,253
Acquisitions	19	1,322	—	1,341
Impairments	—	—	(162)	(162)
Other [1]	—	—	(7)	(7)
Balance December 31, 2019 [2]	16,181	3,192	52	19,425
Acquisitions	**742**	**105**	**—**	**847**
Divestitures	**—**	**—**	**(54)**	**(54)**
Other [1]	**47**	**(29)**	**2**	**20**
Balance December 31, 2020 [2]	**$ 16,970**	**$ 3,268**	**$ —**	**$ 20,238**

[1] *Other includes cumulative translation adjustments on goodwill balances and certain other adjustments.*

[2] *Accumulated goodwill impairment losses were $531 million at both December 31, 2020 and 2019.*

The additions to goodwill in the Pharmaceutical segment in 2020 were primarily related to the acquisitions of ArQule and Themis (see Note 3). The additions to goodwill within the Animal Health segment in 2019 primarily relate to the acquisition of Antelliq (see Note 3). The impairments of goodwill within other non-reportable segments in 2019 relate to certain businesses within the Healthcare Services segment. The Healthcare Services segment was fully divested in the first quarter of 2020.

Other intangibles at December 31 consisted of:

	2020			2019		
	Gross Carrying Amount	**Accumulated Amortization**	**Net**	Gross Carrying Amount	Accumulated Amortization	Net
Products and product rights	**$ 45,087**	**$ 39,925**	**$ 5,162**	$ 45,947	$ 38,852	$ 7,095
Licenses	**4,177**	**1,387**	**2,790**	3,185	824	2,361
IPR&D	**3,228**	**—**	**3,228**	1,032	—	1,032
Trade names	**2,882**	**352**	**2,530**	2,899	217	2,682
Other	**2,223**	**1,329**	**894**	2,261	1,235	1,026
	$ 57,597	**$ 42,993**	**$ 14,604**	$ 55,324	$ 41,128	$ 14,196

Acquired intangibles include products and product rights, licenses, trade names and patents, which are initially recorded at fair value, assigned an estimated useful life, and amortized primarily on a straight-line basis over their estimated useful lives. Some of the Company's more significant acquired intangibles, on a net basis, related to human health marketed products (included in products and product rights above) at December 31, 2020 include *Zerbaxa*, $551 million; *Implanon/Nexplanon,* $354 million; *Gardasil/Gardasil* 9, $276 million; *Dificid*, $228 million; *Bridion*, $185 million; *Sivextro*, $154 million; and *Simponi*, $132 million. Additionally, the Company had $5.4 billion of net acquired intangibles related to animal health marketed products at December 31, 2020, of which $2.5 billion relate primarily to trade names obtained through the 2019 acquisition of Antelliq (see Note 3). Some of the Company's more significant net intangible assets included in licenses above at December 31, 2020 include Lynparza, $1.3 billion and Lenvima, $1.1 billion as a result of collaborations with AstraZeneca and Eisai (see Note 4). At December 31, 2020, IPR&D primarily relates to MK-1026 obtained through the acquisition of ArQule in 2020 (see Note 3) and MK-7264 (gefapixant) obtained through the acquisition of Afferent Pharmaceuticals in 2016. The Company has an intangible asset related to a collaboration with Bayer (see Note 4) that had a carrying value of $849 million at December 31, 2020 reflected in "Other" in the table above.

In 2020, the Company recorded an impairment charge of $1.6 billion within *Cost of sales* related to *Zerbaxa* for injection, a combination antibacterial and beta-lactamase inhibitor for the treatment of certain bacterial infections. In December 2020, the Company temporarily suspended sales of *Zerbaxa*, and subsequently issued a product recall, following the identification of product sterility issues. The recall constituted a triggering event requiring the evaluation of the *Zerbaxa* intangible asset for impairment. The Company revised its cash flow forecasts for *Zerbaxa* utilizing certain assumptions around the return to market timeline and anticipated uptake in sales thereafter. These revised cash flow forecasts indicated that the *Zerbaxa* intangible asset value was not fully recoverable on an undiscounted cash flows basis. The Company utilized market participant assumptions to determine its best estimate of the fair value of the intangible asset related to *Zerbaxa* that, when compared with its related carrying value, resulted in the impairment charge noted above. The Company also wrote-off inventory of $120 million to *Cost of sales* in 2020 related to the *Zerbaxa* recall. The remaining intangible asset balance related to *Zerbaxa* was $551 million at December 31, 2020.

In 2019, the Company recorded impairment charges related to marketed products and other intangibles of $705 million. Of this amount, $612 million related to *Sivextro*, a product for the treatment of acute bacterial skin and skin structure infections caused by designated susceptible Gram-positive organisms. As part of a reorganization and reprioritization of its internal sales force, the Company made the decision to cease promotion of *Sivextro* in the U.S. market by the end of 2019. This decision resulted in reduced cash flow projections for *Sivextro*, which indicated that the *Sivextro* intangible asset value was not fully recoverable on an undiscounted cash flows basis. The Company utilized market participant assumptions to determine its best estimate of the fair value of the intangible asset related to *Sivextro* that, when compared with its related carrying value, resulted in the impairment charge noted above.

IPR&D that the Company acquires through business combinations represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. Amounts capitalized as IPR&D are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, the Company will make a separate determination as to the then useful life of the asset and begin amortization.

In 2020, the Company recorded a $90 million IPR&D impairment charge within *Research and development* expenses related to a decision to discontinue the development program for COVID-19 vaccine candidate V591 following Merck's review of findings from a Phase 1 clinical study for the vaccine. In the study, V591 was generally well tolerated, but the immune responses were inferior to those seen following natural infection and those reported for other SARS-CoV-2/COVID-19 vaccines. The discontinuation of this development program also resulted in a reversal of the related liability for contingent consideration of $45 million (see Note 6).

In 2019, the Company recorded $172 million of IPR&D impairment charges. Of this amount, $155 million relates to the write-off of the intangible asset balance for programs obtained in connection with the acquisition of IOmet Pharma Ltd following a review of clinical trial results conducted by Merck, along with external clinical trial results for similar compounds. The discontinuation of this clinical development program also resulted in a reversal of the related liability for contingent consideration of $11 million.

In 2018, the Company recorded $152 million of IPR&D impairment charges. Of this amount, $139 million relates to the write-off of the remaining intangible asset balance for a program obtained in connection with the SmartCells acquisition following a decision to terminate the program due to product development issues. The discontinuation of this clinical development program also resulted in a reversal of the related liability for contingent consideration of $60 million.

The IPR&D projects that remain in development are subject to the inherent risks and uncertainties in drug development and it is possible that the Company will not be able to successfully develop and complete the IPR&D programs and profitably commercialize the underlying product candidates.

The Company may recognize additional non-cash impairment charges in the future related to other marketed products or pipeline programs and such charges could be material.

Aggregate amortization expense primarily recorded within *Cost of sales* was $1.9 billion in 2020, $2.0 billion in 2019 and $3.1 billion in 2018. The estimated aggregate amortization expense for each of the next five years is as follows: 2021, $1.5 billion; 2022, $1.5 billion; 2023, $1.4 billion; 2024, $1.3 billion; 2025, $1.2 billion.

9. Loans Payable, Long-Term Debt and Leases

Loans Payable

Loans payable at December 31, 2020 included $2.3 billion of notes due in 2021, $4.0 billion of commercial paper and $73 million of long-dated notes that are subject to repayment at the option of the holders. Loans payable at December 31, 2019 included $1.9 billion of notes due in 2020, $1.4 billion of commercial paper and $226 million of long-dated notes that are subject to repayment at the option of the holders. The weighted-average interest rate of commercial paper borrowings was 0.79% and 2.23% for the years ended December 31, 2020 and 2019, respectively.

Long-Term Debt

Long-term debt at December 31 consisted of:

	2020	2019
2.75% notes due 2025	**$ 2,493**	$ 2,492
3.70% notes due 2045	**1,976**	1,975
2.80% notes due 2023	**1,748**	1,747
3.40% notes due 2029	**1,734**	1,732
4.00% notes due 2049	**1,469**	1,468
2.35% notes due 2022	**1,269**	1,248
4.15% notes due 2043	**1,238**	1,238
1.45% notes due 2030	**1,233**	—
1.875% euro-denominated notes due 2026	**1,218**	1,107
2.45% notes due 2050	**1,211**	—
2.40% notes due 2022	**1,032**	1,010
0.75% notes due 2026	**991**	—
3.90% notes due 2039	**983**	982
2.35% notes due 2040	**982**	—
2.90% notes due 2024	**746**	745
6.50% notes due 2033	**719**	722
0.50% euro-denominated notes due 2024	**611**	555
1.375% euro-denominated notes due 2036	**606**	551
2.50% euro-denominated notes due 2034	**605**	550
3.60% notes due 2042	**491**	490
6.55% notes due 2037	**411**	412
5.75% notes due 2036	**338**	338
5.95% debentures due 2028	**306**	306
5.85% notes due 2039	**271**	271
6.40% debentures due 2028	**250**	250
6.30% debentures due 2026	**135**	135
3.875% notes due 2021	**—**	1,151
1.125% euro-denominated notes due 2021	**—**	1,113
Other	**294**	148
	$ 25,360	$ 22,736

Other (as presented in the table above) includes $294 million and $147 million at December 31, 2020 and 2019, respectively, of borrowings at variable rates that resulted in effective interest rates of 0.45% and 2.54% for 2020 and 2019, respectively.

With the exception of the 6.30% debentures due 2026, the notes listed in the table above are redeemable in whole or in part, at Merck's option at any time, at varying redemption prices.

In June 2020, the Company issued $4.5 billion principal amount of senior unsecured notes consisting of $1.0 billion of 0.75% notes due 2026, $1.25 billion of 1.45% notes due 2030, $1.0 billion of 2.35% notes due 2040 and $1.25 billion of 2.45% notes due 2050. Merck used the net proceeds from the offering for general corporate purposes, including without limitation the repayment of outstanding commercial paper borrowings and other indebtedness with upcoming maturities.

Effective as of November 3, 2009, the Company executed a full and unconditional guarantee of the then existing debt of its subsidiary Merck Sharp & Dohme Corp. (MSD) and MSD executed a full and unconditional

guarantee of the then existing debt of the Company (excluding commercial paper), including for payments of principal and interest. These guarantees do not extend to debt issued subsequent to that date.

Certain of the Company's borrowings require that Merck comply with covenants and, at December 31, 2020, the Company was in compliance with these covenants.

The aggregate maturities of long-term debt for each of the next five years are as follows: 2021, $2.3 billion; 2022, $2.3 billion; 2023, $1.7 billion; 2024, $1.4 billion; 2025, $2.5 billion.

The Company has a $6.0 billion credit facility that matures in June 2024. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

Leases

The Company has operating leases primarily for manufacturing facilities, research and development facilities, corporate offices, employee housing, vehicles and certain equipment. The Company determines if an arrangement is a lease at inception. When evaluating contracts for embedded leases, the Company exercises judgment to determine if there is an explicit or implicit identified asset in the contract and if Merck controls the use of that asset. Embedded leases, primarily associated with contract manufacturing organizations, are immaterial. The lease term includes options to extend or terminate the lease when it is reasonably certain that Merck will exercise that option. Real estate leases for facilities have an average remaining lease term of eight years, which include options to extend the leases for up to four years where applicable. Vehicle leases are generally in effect for four years. The Company does not record short-term leases (leases with an initial term of 12 months or less) on the balance sheet; however, Merck currently has no short-term leases.

Lease expense for operating lease payments is recognized on a straight-line basis over the term of the lease. Operating lease assets and liabilities are recognized based on the present value of lease payments over the lease term. Since the Company's leases do not have a readily determinable implicit discount rate, the Company uses its incremental borrowing rate to calculate the present value of lease payments by asset class. On a quarterly basis, an updated incremental borrowing rate is determined based on the average remaining lease term of each asset class and the Company's pretax cost of debt for that same term. The updated rates for each asset class are applied prospectively to new leases. The Company does not separate lease components (e.g. payments for rent, real estate taxes and insurance costs) from non-lease components (e.g. common-area maintenance costs) in the event that the agreement contains both. Merck includes both the lease and non-lease components for purposes of calculating the right-of-use asset and related lease liability (if the non-lease components are fixed). For vehicle leases and employee housing, the Company applies a portfolio approach to effectively account for the operating lease assets and liabilities.

Certain of the Company's lease agreements contain variable lease payments that are adjusted periodically for inflation or for actual operating expense true-ups compared with estimated amounts; however, these amounts are immaterial. Sublease income and activity related to sale and leaseback transactions are immaterial. Merck's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

Operating lease cost was $346 million in 2020 and $339 million in 2019. Rental expense under operating leases, net of sublease income, was $322 million in 2018. Cash paid for amounts included in the measurement of operating lease liabilities was $340 million in 2020 and $281 million in 2019. Operating lease assets obtained in exchange for lease obligations was $495 million in 2020 and $129 million in 2019.

Supplemental balance sheet information related to operating leases is as follows:

December 31		**2020**		2019
Assets				
Other Assets [1]	**$**	**1,725**	$	1,073
Liabilities				
Accrued and other current liabilities		**300**		236
Other Noncurrent Liabilities		**1,362**		768
	$	**1,662**	$	1,004
Weighted-average remaining lease term (years)		**8.0**		7.4
Weighted-average discount rate		**2.8 %**		3.2 %

[1] *Includes prepaid leases that have no related lease liability.*

Maturities of operating leases liabilities are as follows:

2021	$ 336
2022	277
2023	252
2024	187
2025	162
Thereafter	665
Total lease payments	1,879
Less: Imputed interest	217
	$ 1,662

At December 31, 2020, the Company had entered into additional real estate operating leases that had not yet commenced; the obligations associated with these leases total $475 million.

10. Contingencies and Environmental Liabilities

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property, and commercial litigation, as well as certain additional matters including governmental and environmental matters. In the opinion of the Company, it is unlikely that the resolution of these matters will be material to the Company's financial condition, results of operations or cash flows.

Given the nature of the litigation discussed below and the complexities involved in these matters, the Company is unable to reasonably estimate a possible loss or range of possible loss for such matters until the Company knows, among other factors, (i) what claims, if any, will survive dispositive motion practice, (ii) the extent of the claims, including the size of any potential class, particularly when damages are not specified or are indeterminate, (iii) how the discovery process will affect the litigation, (iv) the settlement posture of the other parties to the litigation and (v) any other factors that may have a material effect on the litigation.

The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. For product liability claims, a portion of the overall accrual is actuarially determined and considers such factors as past experience, number of claims reported and estimates of claims incurred but not yet reported. Individually significant contingent losses are accrued when probable and reasonably estimable. Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable.

The Company's decision to obtain insurance coverage is dependent on market conditions, including cost and availability, existing at the time such decisions are made. The Company has evaluated its risks and has determined that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and, as such, has no insurance for most product liabilities.

Product Liability Litigation

Fosamax

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Fosamax* (*Fosamax* Litigation). As of December 31, 2020, approximately 3,520 cases are pending against Merck in either federal or state court. Plaintiffs in the vast majority of these cases generally allege that they sustained femur fractures and/or other bone injuries (Femur Fractures) in association with the use of *Fosamax*.

All federal cases involving allegations of Femur Fractures have been or will be transferred to a multidistrict litigation in the District of New Jersey (Femur Fracture MDL). In the only bellwether case tried to date in the Femur Fracture MDL, *Glynn v. Merck*, the jury returned a verdict in Merck's favor. In addition, in June 2013, the Femur Fracture MDL court granted Merck's motion for judgment as a matter of law in the *Glynn* case and held that the plaintiff's failure to warn claim was preempted by federal law.

In August 2013, the Femur Fracture MDL court entered an order requiring plaintiffs in the Femur Fracture MDL to show cause why those cases asserting claims for a femur fracture injury that took place prior to September 14, 2010, should not be dismissed based on the court's preemption decision in the *Glynn* case. Pursuant to the show cause order, in March 2014, the Femur Fracture MDL court dismissed with prejudice approximately 650 cases on preemption grounds. Plaintiffs in approximately 515 of those cases appealed that decision to the U.S. Court of Appeals for the Third Circuit (Third Circuit). In March 2017, the Third Circuit issued a decision reversing the Femur Fracture MDL court's preemption ruling and remanding the appealed cases back to the Femur Fracture MDL court. In May 2019, the U.S. Supreme Court decided that the Third Circuit had incorrectly concluded that the issue of preemption should be resolved by a jury, and accordingly vacated the judgment of the Third Circuit and remanded the proceedings back to the Third Circuit to address the issue in a manner consistent with the Supreme Court's opinion. In November 2019, the Third Circuit remanded the cases back to the District Court in order to allow that court to determine in the first instance whether the plaintiffs' state law claims are preempted by federal law under the standards described by the Supreme Court in its opinion. Briefing on the issue is closed, and the parties await the decision of the District Court.

Accordingly, as of December 31, 2020, approximately 970 cases were actively pending in the Femur Fracture MDL.

As of December 31, 2020, approximately 2,270 cases alleging Femur Fractures have been filed in New Jersey state court and are pending before Judge James Hyland in Middlesex County. The parties selected an initial group of cases to be reviewed through fact discovery, and Merck has continued to select additional cases to be reviewed.

As of December 31, 2020, approximately 275 cases alleging Femur Fractures have been filed and are pending in California state court. All of the Femur Fracture cases filed in California state court have been coordinated before a single judge in Orange County, California.

Additionally, there are four Femur Fracture cases pending in other state courts.

Discovery is presently stayed in the Femur Fracture MDL and in the state court in California. Merck intends to defend against these lawsuits.

Januvia/Janumet

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Januvia* and/or *Janumet*. As of December 31, 2020, Merck is aware of approximately 1,480 product users alleging that *Januvia* and/or *Janumet* caused the development of pancreatic cancer and other injuries.

Most claims have been filed in multidistrict litigation before the U.S. District Court for the Southern District of California (MDL). Outside of the MDL, the majority of claims have been filed in coordinated proceedings before the Superior Court of California, County of Los Angeles (California State Court).

In November 2015, the MDL and California State Court, in separate opinions, granted summary judgment to defendants on grounds of federal preemption.

Plaintiffs appealed in both forums. In November 2017, the U.S. Court of Appeals for the Ninth Circuit vacated the judgment and remanded for further discovery. In November 2018, the California state appellate court reversed and remanded on similar grounds. In March 2019, the parties in the MDL and the California coordinated proceedings agreed to coordinate and adopt a schedule for completing discovery on general causation and preemption issues and for renewing summary judgment and expert motions. Briefing of those motions is complete and hearings before both the MDL and California State Court judges took place on October 20 and December 8, 2020, respectively.

As of December 31, 2020, six product users have claims pending against Merck in state courts other than California, including Illinois. In June 2017, the Illinois trial court denied Merck's motion for summary judgment based on federal preemption. Merck appealed, and the Illinois appellate court affirmed in December 2018. Merck filed a petition for leave to appeal to the Illinois Supreme Court in February 2019. In April 2019, the Illinois Supreme Court stayed consideration of the pending petition to appeal until the U.S. Supreme Court issued its opinion in *Merck Sharp & Dohme Corp. v. Albrecht* (relating to the *Fosamax* matter discussed above). Merck filed

the opinion in *Albrecht* with the Illinois Supreme Court in June 2019. The petition for leave to appeal was decided in September 2019, in which the Illinois Supreme Court directed the intermediate appellate court to reconsider its earlier ruling. The Illinois Appellate Court issued a favorable decision concluding, consistent with *Albrecht*, that preemption presents a legal question to be resolved by the court. In May 2020, the Illinois Appellate Court issued a mandate to the state trial court, which, as of December 31, 2020, had not scheduled a case management conference.

In addition to the claims noted above, the Company has agreed to toll the statute of limitations for approximately 50 additional claims. The Company intends to continue defending against these lawsuits.

Vioxx

Merck reached a settlement with the Attorney General of Utah to fully resolve the state's previously disclosed civil lawsuit alleging that Merck misrepresented the safety of *Vioxx*. As part of the resolution, Merck paid the state $25 million. The settlement does not constitute an admission by Merck of any liability or wrongdoing. This agreement marks the final resolution of litigation involving *Vioxx* in the United States. There is ongoing *Vioxx* litigation in certain countries outside the United States.

Governmental Proceedings

As previously disclosed, in the fall of 2018, the Company received a records subpoena from the U.S. Attorney's Office for the District of Vermont (VT USAO) pursuant to Section 248 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) relating to an investigation of potential health care offenses. The subpoena sought information relating to any actual or potential business relationship or arrangement Merck has had with Practice Fusion, Inc. (PFI), a cloud-based, electronic health records (EHR) company that was acquired by Allscripts in January 2018. The Company cooperated with the government and responded to that subpoena. Subsequently, in May 2019, Merck received a second records subpoena from the VT USAO that broadened the government's information request by seeking information relating to Merck's relationship with any EHR company. Shortly thereafter, the VT USAO served a Civil Investigation Demand (CID) upon Merck similarly seeking information on the Company's relationships with EHR vendors. The CID explains that the government is conducting a False Claims Act investigation concerning whether Merck and/or PFI submitted claims to federal health care programs that violate the Federal Anti-Kickback Statute. Merck is cooperating with the government's investigation.

As previously disclosed, in April 2019, Merck received a set of investigative interrogatories from the California Attorney General's Office pursuant to its investigation of conduct and agreements that allegedly affected or delayed competition to Lantus in the insulin market. The interrogatories seek information concerning Merck's development of an insulin glargine product, and its subsequent termination, as well as Merck's patent litigation against Sanofi S.A. concerning Lantus and the resolution of that litigation. Merck is cooperating with the California Attorney General's investigation.

As previously disclosed, in June 2020, Merck received a CID from the U.S. Department of Justice. The CID requests answers to interrogatories, as well as various documents, regarding temperature excursions at a third-party storage facility containing certain Merck products. Merck is cooperating with the government's investigation and intends to produce information and/or documents as necessary in response to the CID.

As previously disclosed, the Company's subsidiaries in China have received and may continue to receive inquiries regarding their operations from various Chinese governmental agencies. Some of these inquiries may be related to matters involving other multinational pharmaceutical companies, as well as Chinese entities doing business with such companies. The Company's policy is to cooperate with these authorities and to provide responses as appropriate.

As previously disclosed, from time to time, the Company receives inquiries and is the subject of preliminary investigation activities from competition and other governmental authorities in markets outside the United States. These authorities may include regulators, administrative authorities, and law enforcement and other similar officials, and these preliminary investigation activities may include site visits, formal or informal requests or demands for documents or materials, inquiries or interviews and similar matters. Certain of these preliminary inquiries or activities may lead to the commencement of formal proceedings. Should those proceedings be determined adversely to the Company, monetary fines and/or remedial undertakings may be required.

Commercial and Other Litigation

Zetia Antitrust Litigation

As previously disclosed, Merck, MSD, Schering Corporation and MSP Singapore Company LLC (collectively, the Merck Defendants) are defendants in putative class action and opt-out lawsuits filed in 2018 on behalf of direct and indirect purchasers of *Zetia* alleging violations of federal and state antitrust laws, as well as other state statutory and common law causes of action. The cases have been consolidated for pretrial purposes in a federal multidistrict litigation before Judge Rebecca Beach Smith in the Eastern District of Virginia. In December 2018, the court denied the Merck Defendants' motions to dismiss or stay the direct purchaser putative class actions pending bilateral arbitration. In August 2019, the district court adopted in full the report and recommendation of the magistrate judge with respect to the Merck Defendants' motions to dismiss on non-arbitration issues, thereby granting in part and denying in part Merck Defendants' motions to dismiss. In addition, in June 2019, the representatives of the putative direct purchaser class filed an amended complaint and, in August 2019, retailer opt-out plaintiffs filed an amended complaint. In December 2019, the district court granted the Merck Defendants' motion to dismiss to the extent the motion sought dismissal of claims for overcharges paid by entities that purchased generic ezetimibe from Par Pharmaceutical, Inc. (Par Pharmaceutical) and dismissed any claims for such overcharges. In November 2019, the direct purchaser plaintiffs and the indirect purchaser plaintiffs filed motions for class certification. On August 21, 2020, the district court granted in part the direct purchasers' motion for class certification and certified a class of 35 direct purchasers, and on November 2, 2020, the U.S. Court of Appeals for the Fourth Circuit granted the Merck Defendants' motion for permission to appeal the district court's order. Also, on August 14, 2020, the magistrate judge recommended that the court grant the motion for class certification filed by the putative indirect purchaser class. The Merck Defendants objected to this report and recommendation and are awaiting a decision from the district court.

On August 10, 2020, the Merck Defendants filed a motion for summary judgment and other motions, and plaintiffs filed a motion for partial summary judgment, and other motions. Those motions are now fully briefed, and the court will likely hold a hearing on the competing motions. Trial in this matter has been adjourned.

On September 4, 2020, United Healthcare Services, Inc. filed a lawsuit in the United States District Court for the District of Minnesota against Merck and others (the UHC Action). The UHC Action makes similar allegations as those made in the *Zetia* class action. On September 23, 2020, the United States Judicial Panel on Multidistrict Litigation transferred the case to the Eastern District of Virginia to proceed with the multidistrict *Zetia* litigation already in progress.

On December 11, 2020, Humana Inc. filed a lawsuit in the Superior Court of the State of California, County of San Francisco, against Merck and others, alleging defendants violated state antitrust laws in multiple states. Also, on December 11, 2020, Centene Corporation and others filed a lawsuit in the Superior Court of the State of California, County of San Francisco, against the same defendants as Humana. Both lawsuits allege similar anticompetitive acts to those alleged in the *Zetia* class action.

Rotavirus Vaccines Antitrust Litigation

As previously disclosed, MSD is a defendant in putative class action lawsuits filed in 2018 on behalf of direct purchasers of *RotaTeq*, alleging violations of federal antitrust laws. The cases were consolidated in the Eastern District of Pennsylvania. In January 2019, the court denied MSD's motions to compel arbitration and to dismiss the consolidated complaint. In February 2019, MSD appealed the court's order on arbitration to the Third Circuit. In October 2019, the Third Circuit vacated the district court's order and remanded for limited discovery on the issue of arbitrability. On July 6, 2020, MSD filed a renewed motion to compel arbitration, and plaintiffs filed a cross motion for summary judgment as to arbitrability. On November 20, 2020, the district court denied MSD's motion and granted plaintiffs' motion. On December 4, 2020, MSD filed a notice of appeal to the Third Circuit.

Bravecto Litigation

As previously disclosed, in January 2020, the Company was served with a complaint in the United States District Court for the District of New Jersey, seeking to certify a nationwide class action of purchasers or users of *Bravecto* (fluralaner) products in the United States or its territories between May 1, 2014 and December 27, 2019. The complaint contends *Bravecto* causes neurological events and alleges violations of the New Jersey Consumer

Fraud Act, Breach of Warranty, Product Liability, and related theories. A similar case was filed in Quebec, Canada in May 2019.

Qui Tam Litigation

As previously disclosed, in June 2012, the U.S. District Court for the Eastern District of Pennsylvania unsealed a complaint that had been filed against the Company under the federal False Claims Act by two former employees alleging, among other things, that the Company defrauded the U.S. government by falsifying data in connection with a clinical study conducted on the mumps component of the Company's *M-M-R* II vaccine. The complaint alleges the fraud took place between 1999 and 2001. The U.S. government had the right to participate in and take over the prosecution of this lawsuit but notified the court that it declined to exercise that right. The two former employees are pursuing the lawsuit without the involvement of the U.S. government. In addition, as previously disclosed, two putative class action lawsuits on behalf of direct purchasers of the *M-M-R* II vaccine, which charge that the Company misrepresented the efficacy of the *M-M-R* II vaccine in violation of federal antitrust laws and various state consumer protection laws, are pending in the Eastern District of Pennsylvania. In September 2014, the court denied Merck's motion to dismiss the False Claims Act suit and granted in part and denied in part its motion to dismiss the then-pending antitrust suit. As a result, both the False Claims Act suit and the antitrust suits have proceeded into discovery, which is now complete, and the parties have filed and briefed cross-motions for summary judgment, which are currently pending before the Court. The Company continues to defend against these lawsuits.

Merck KGaA Litigation

As previously disclosed, in January 2016, to protect its long-established brand rights in the United States, the Company filed a lawsuit against Merck KGaA, Darmstadt, Germany (KGaA), historically operating as the EMD Group in the United States, alleging it improperly uses the name "Merck" in the United States. KGaA has filed suit against the Company in France, the UK, Germany, Switzerland, Mexico, India, Australia, Singapore, Hong Kong, and China alleging, among other things, unfair competition, trademark infringement and/or corporate name infringement. In the UK, Australia, Singapore, Hong Kong, and India, KGaA also alleges breach of the parties' coexistence agreement. The litigation is ongoing in the United States with no trial date set, and also ongoing in numerous jurisdictions outside of the United States; the Company is defending those suits in each jurisdiction.

Patent Litigation

From time to time, generic manufacturers of pharmaceutical products file abbreviated New Drug Applications (NDAs) with the FDA seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned by the Company. To protect its patent rights, the Company may file patent infringement lawsuits against such generic companies. Similar lawsuits defending the Company's patent rights may exist in other countries. The Company intends to vigorously defend its patents, which it believes are valid, against infringement by companies attempting to market products prior to the expiration of such patents. As with any litigation, there can be no assurance of the outcomes, which, if adverse, could result in significantly shortened periods of exclusivity for these products and, with respect to products acquired through acquisitions, potentially significant intangible asset impairment charges.

Bridion — Between January and November 2020, the Company received multiple Paragraph IV Certification Letters under the Hatch-Waxman Act notifying the Company that generic drug companies have filed applications to the FDA seeking pre-patent expiry approval to sell generic versions of *Bridion* (sugammadex) Injection. In March, April and December 2020, the Company filed patent infringement lawsuits in the U.S. District Courts for the District of New Jersey and the Northern District of West Virginia against those generic companies. All actions in the District of New Jersey have been consolidated. These lawsuits, which assert one or more patents covering sugammadex and methods of using sugammadex, automatically stay FDA approval of the generic applications until June 2023 or until adverse court decisions, if any, whichever may occur earlier.

Mylan Pharmaceuticals Inc., Mylan API US LLC, and Mylan Inc. (Mylan) have filed motions to dismiss in the District of New Jersey for lack of venue and failure to state a claim against certain defendants, and in the Northern District of West Virginia for failure to state a claim against certain defendants. The New Jersey motion has not yet been decided, and the West Virginia action is stayed pending resolution of the New Jersey motion.

Januvia, Janumet, Janumet XR — The FDA has granted pediatric exclusivity with respect to *Januvia*, *Janumet*, and *Janumet XR*, which provides a further six months of exclusivity in the United States beyond the expiration of all patents listed in the FDA's Orange Book. Including this exclusivity, key patent protection extends to January 2023. The Company anticipates that sales of *Januvia* and *Janumet* in the United States will decline significantly after this loss of market exclusivity. However, *Januvia*, *Janumet*, and *Janumet XR* contain sitagliptin phosphate monohydrate and the Company has another patent covering certain phosphate salt and polymorphic forms of sitagliptin, which, if determined to be valid, would preclude generic manufacturers from making sitagliptin phosphate salt and polymorphic forms before that patent, inclusive of pediatric exclusivity, expires in 2027 (2027 salt/polymorph patent). In 2019, Par Pharmaceutical filed suit against the Company in the U.S. District Court for the District of New Jersey, seeking a declaratory judgment of invalidity of the 2027 salt/polymorph patent. In response, the Company filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Par Pharmaceutical and additional companies that also indicated an intent to market generic versions of *Januvia*, *Janumet*, and *Janumet XR* following expiration of key patent protection, but prior to the expiration of the 2027 salt/polymorph patent, and a later granted patent owned by the Company covering the *Janumet* formulation which, inclusive of pediatric exclusivity, expires in 2029. The Company also filed a patent infringement lawsuit against Mylan in the Northern District of West Virginia. The Judicial Panel of Multidistrict Litigation entered an order transferring the Company's lawsuit against Mylan to the U.S. District Court for the District of Delaware for coordinated and consolidated pretrial proceedings with the other cases pending in that district. The U.S. District Court for the District of Delaware has scheduled the lawsuits for a single three-day trial on invalidity issues in October 2021. The Court has scheduled separate one-day trials on infringement issues in November 2021 through January 2022, to the extent such trials are necessary. In the Company's case against Mylan, the U.S. District Court for the Northern District of West Virginia has conditionally scheduled a three-day trial in December 2021 on all issues.

The Company has settled with nine generic companies providing that these generic companies can bring their products to the market in May 2027 or earlier under certain circumstances.

Additionally, in 2019, Mylan filed a petition for *Inter Partes* Review (IPR) at the United States Patent and Trademark Office (USPTO) seeking invalidity of some, but not all, of the claims of the 2027 salt/polymorph patent, which other manufacturers joined. The USPTO instituted IPR proceedings in May 2020, finding a reasonable likelihood that the challenged claims are not valid. A trial was held in February 2021 and a final decision is expected in May 2021. If the challenges are successful, the unchallenged claims of the 2027 salt/polymorph patent will remain valid, subject to the court proceedings described above.

In Germany, two generic companies have sought the revocation of the Supplementary Protection Certificate (SPC) for *Janumet*. If the generic companies are successful, *Janumet* could lose market exclusivity in Germany as early as July 2022. Challenges to the *Janumet* SPC have also occurred in Portugal and Finland, and could occur in other European countries.

Nexplanon — In June 2017, Microspherix LLC (Microspherix) sued the Company in the U.S District Court for the District of New Jersey asserting that the manufacturing, use, sale and importation of *Nexplanon* infringed several of Microspherix's patents that claim radio-opaque, implantable drug delivery devices. Microspherix is claiming damages from September 2014 until those patents expire in May 2021. The Company brought IPR proceedings in the USPTO and successfully stayed the district court action. The USPTO invalidated some, but not all, of the claims asserted against the Company. The Company appealed the decisions finding claims valid, and the Court of Appeals for the Federal Circuit affirmed the USPTO's decisions. The matter is no longer stayed in the district court, and the Company is currently litigating the invalidity and non-infringement of the remaining asserted claims.

Other Litigation

There are various other pending legal proceedings involving the Company, principally product liability and intellectual property lawsuits. While it is not feasible to predict the outcome of such proceedings, in the opinion of the Company, either the likelihood of loss is remote or any reasonably possible loss associated with the resolution of such proceedings is not expected to be material to the Company's financial condition, results of operations or cash flows either individually or in the aggregate.

Legal Defense Reserves

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of December 31, 2020 and 2019 of approximately $250 million and $240 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

Environmental Matters

The Company and its subsidiaries are parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund, and other federal and state equivalents. These proceedings seek to require the operators of hazardous waste disposal facilities, transporters of waste to the sites and generators of hazardous waste disposed of at the sites to clean up the sites or to reimburse the government for cleanup costs. The Company has been made a party to these proceedings as an alleged generator of waste disposed of at the sites. In each case, the government alleges that the defendants are jointly and severally liable for the cleanup costs. Although joint and several liability is alleged, these proceedings are frequently resolved so that the allocation of cleanup costs among the parties more nearly reflects the relative contributions of the parties to the site situation. The Company's potential liability varies greatly from site to site. For some sites the potential liability is *de minimis* and for others the final costs of cleanup have not yet been determined. While it is not feasible to predict the outcome of many of these proceedings brought by federal or state agencies or private litigants, in the opinion of the Company, such proceedings should not ultimately result in any liability which would have a material adverse effect on the financial condition, results of operations or liquidity of the Company. The Company has taken an active role in identifying and accruing for these costs and such amounts do not include any reduction for anticipated recoveries of cleanup costs from former site owners or operators or other recalcitrant potentially responsible parties.

In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $67 million at both December 31, 2020 and 2019. These liabilities are undiscounted, do not consider potential recoveries from other parties and will be paid out over the periods of remediation for the applicable sites, which are expected to occur primarily over the next 15 years. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed approximately $65 million in the aggregate. Management also does not believe that these expenditures should result in a material adverse effect on the Company's financial condition, results of operations or liquidity for any year.

11. Equity

The Merck certificate of incorporation authorizes 6,500,000,000 shares of common stock and 20,000,000 shares of preferred stock.

Capital Stock

A summary of common stock and treasury stock transactions (shares in millions) is as follows:

	2020		2019		2018	
	Common Stock	**Treasury Stock**	Common Stock	Treasury Stock	Common Stock	Treasury Stock
Balance January 1	**3,577**	**1,038**	3,577	985	3,577	880
Purchases of treasury stock	**—**	**16**	—	66	—	122
Issuances [(1)]	**—**	**(7)**	—	(13)	—	(17)
Balance December 31	**3,577**	**1,047**	3,577	1,038	3,577	985

[(1)] *Issuances primarily reflect activity under share-based compensation plans.*

In 2018, the Company entered into accelerated share repurchase (ASR) agreements with two third-party financial institutions (the Dealers). Under the ASR agreements, Merck agreed to purchase $5 billion of Merck's common stock, in total, with an initial delivery of 56.7 million shares of Merck's common stock, based on the then-current market price, made by the Dealers to Merck, and payments of $5 billion made by Merck to the Dealers, which were funded with existing cash and investments, as well as short-term borrowings. Upon settlement of the ASR agreements in 2019, Merck received an additional 7.7 million shares as determined by the average daily volume weighted-average price of Merck's common stock during the term of the ASR program, less a negotiated discount, bringing the total shares received by Merck under this program to 64.4 million.

12. Share-Based Compensation Plans

The Company has share-based compensation plans under which the Company grants restricted stock units (RSUs) and performance share units (PSUs) to certain management level employees. In addition, employees and non-employee directors may be granted options to purchase shares of Company common stock at the fair market value at the time of grant. These plans were approved by the Company's shareholders.

At December 31, 2020, 100 million shares collectively were authorized for future grants under the Company's share-based compensation plans. These awards are settled with treasury shares.

Employee stock options are granted to purchase shares of Company stock at the fair market value at the time of grant. These awards generally vest one-third each year over a three-year period, with a contractual term of 7-10 years. RSUs are stock awards that are granted to employees and entitle the holder to shares of common stock as the awards vest. The fair value of the stock option and RSU awards is determined and fixed on the grant date based on the Company's stock price. PSUs are stock awards where the ultimate number of shares issued will be contingent on the Company's performance against a pre-set objective or set of objectives. The fair value of each PSU is determined on the date of grant based on the Company's stock price. For RSUs and PSUs, dividends declared during the vesting period are payable to the employees only upon vesting. Over the PSU performance period, the number of shares of stock that are expected to be issued will be adjusted based on the probability of achievement of a performance target and final compensation expense will be recognized based on the ultimate number of shares issued. RSU and PSU distributions will be in shares of Company stock after the end of the vesting or performance period, subject to the terms applicable to such awards. PSU awards generally vest after three years. RSU awards generally vest one-third each year over a three-year period.

Total pretax share-based compensation cost recorded in 2020, 2019 and 2018 was $475 million, $417 million and $348 million, respectively, with related income tax benefits of $65 million, $57 million and $55 million, respectively.

The Company uses the Black-Scholes option pricing model for determining the fair value of option grants. In applying this model, the Company uses both historical data and current market data to estimate the fair value of its options. The Black-Scholes model requires several assumptions including expected dividend yield, risk-

free interest rate, volatility, and term of the options. The expected dividend yield is based on historical patterns of dividend payments. The risk-free interest rate is based on the rate at grant date of zero-coupon U.S. Treasury Notes with a term equal to the expected term of the option. Expected volatility is estimated using a blend of historical and implied volatility. The historical component is based on historical monthly price changes. The implied volatility is obtained from market data on the Company's traded options. The expected life represents the amount of time that options granted are expected to be outstanding, based on historical and forecasted exercise behavior.

The weighted average exercise price of options granted in 2020, 2019 and 2018 was $77.67, $80.05 and $58.15 per option, respectively. The weighted average fair value of options granted in 2020, 2019 and 2018 was $9.93, $10.63 and $8.26 per option, respectively, and were determined using the following assumptions:

Years Ended December 31	**2020**	2019	2018
Expected dividend yield	**3.1 %**	3.2 %	3.4 %
Risk-free interest rate	**0.4 %**	2.4 %	2.9 %
Expected volatility	**22.1 %**	18.7 %	19.1 %
Expected life (years)	**5.8**	5.9	6.1

Summarized information relative to stock option plan activity (options in thousands) is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2020	17,868	$ 59.88		
Granted	**3,564**	**77.67**		
Exercised	**(1,685)**	**52.73**		
Forfeited	**(301)**	**67.73**		
Outstanding December 31, 2020	**19,446**	**$ 63.64**	**6.27**	**$ 353**
Exercisable December 31, 2020	**13,141**	**$ 58.30**	**5.13**	**$ 309**

Additional information pertaining to stock option plans is provided in the table below:

Years Ended December 31	**2020**	2019	2018
Total intrinsic value of stock options exercised	**$ 51**	$ 295	$ 348
Fair value of stock options vested	**25**	27	29
Cash received from the exercise of stock options	**89**	361	591

A summary of nonvested RSU and PSU activity (shares in thousands) is as follows:

	RSUs		PSUs	
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested January 1, 2020	13,527	$ 67.58	1,972	$ 69.18
Granted	**6,627**	**77.79**	**996**	**77.82**
Vested	**(7,511)**	**65.70**	**(824)**	**64.01**
Forfeited	**(728)**	**72.06**	**(44)**	**80.06**
Nonvested December 31, 2020	**11,915**	**$ 74.17**	**2,100**	**$ 75.08**

At December 31, 2020, there was $678 million of total pretax unrecognized compensation expense related to nonvested stock options, RSU and PSU awards which will be recognized over a weighted average period of 1.9 years. For segment reporting, share-based compensation costs are unallocated expenses.

13. Pension and Other Postretirement Benefit Plans

The Company has defined benefit pension plans covering eligible employees in the United States and in certain of its international subsidiaries. In addition, the Company provides medical benefits, principally to its eligible U.S. retirees and their dependents, through its other postretirement benefit plans. The Company uses December 31 as the year-end measurement date for all of its pension plans and other postretirement benefit plans.

Net Periodic Benefit Cost

The net periodic benefit cost (credit) for pension and other postretirement benefit plans consisted of the following components:

	Pension Benefits								
	U.S.			International			Other Postretirement Benefits		
Years Ended December 31	**2020**	2019	2018	**2020**	2019	2018	**2020**	2019	2018
Service cost	**$ 360**	$ 293	$ 326	**$ 301**	$ 238	$ 238	**$ 52**	$ 48	$ 57
Interest cost	**431**	458	432	**137**	177	178	**57**	69	69
Expected return on plan assets	**(774)**	(817)	(851)	**(415)**	(426)	(431)	**(75)**	(72)	(83)
Amortization of unrecognized prior service cost	**(49)**	(49)	(50)	**(18)**	(12)	(13)	**(73)**	(78)	(84)
Net loss (gain) amortization	**303**	151	232	**127**	64	84	**(18)**	(10)	1
Termination benefits	**10**	31	19	**3**	8	2	**2**	5	3
Curtailments	**10**	14	10	**—**	6	1	**(4)**	(11)	(8)
Settlements	**13**	—	5	**15**	1	13	**—**	—	—
Net periodic benefit cost (credit)	**$ 304**	$ 81	$ 123	**$ 150**	$ 56	$ 72	**$ (59)**	$ (49)	$ (45)

The changes in net periodic benefit cost year over year for pension plans are largely attributable to changes in the discount rate affecting net loss amortization.

In connection with restructuring actions (see Note 5), termination charges were recorded in 2020, 2019 and 2018 on pension and other postretirement benefit plans related to expanded eligibility for certain employees exiting Merck. Also, in connection with these restructuring activities, curtailments were recorded on pension and other postretirement benefit plans and settlements were recorded on certain U.S. and international pension plans as reflected in the table above.

The components of net periodic benefit cost (credit) other than the service cost component are included in *Other (income) expense, net* (see Note 14), with the exception of certain amounts for termination benefits, curtailments and settlements, which are recorded in *Restructuring costs* if the event giving rise to the termination benefits, curtailment or settlement is related to restructuring actions as noted above.

Obligations and Funded Status

Summarized information about the changes in plan assets and benefit obligations, the funded status and the amounts recorded at December 31 is as follows:

	Pension Benefits				Other Postretirement Benefits	
	U.S.		International			
	2020	2019	**2020**	2019	**2020**	2019
Fair value of plan assets January 1	**$ 11,361**	$ 9,648	**$ 10,163**	$ 8,580	**$ 1,102**	$ 968
Actual return on plan assets	**1,908**	2,165	**1,026**	1,505	**175**	203
Company contributions	**199**	130	**387**	262	**19**	14
Effects of exchange rate changes	**—**	—	**746**	31	**—**	—
Benefits paid	**(751)**	(582)	**(215)**	(230)	**(93)**	(104)
Settlements	**(45)**	—	**(117)**	(12)	**—**	—
Other	**—**	—	**59**	27	**18**	21
Fair value of plan assets December 31	**$ 12,672**	$ 11,361	**$ 12,049**	$ 10,163	**$ 1,221**	$ 1,102
Benefit obligation January 1	**$ 13,003**	$ 10,620	**$ 10,612**	$ 9,083	**$ 1,673**	$ 1,615
Service cost	**360**	293	**301**	238	**52**	48
Interest cost	**431**	458	**137**	177	**57**	69
Actuarial losses (gains) [(1)]	**1,594**	2,165	**1,036**	1,313	**(98)**	21
Benefits paid	**(751)**	(582)	**(215)**	(230)	**(93)**	(104)
Effects of exchange rate changes	**—**	—	**794**	4	**(3)**	1
Plan amendments	**—**	—	**(64)**	1	**—**	—
Curtailments	**11**	18	**(8)**	3	**(1)**	—
Termination benefits	**10**	31	**3**	8	**2**	5
Settlements	**(45)**	—	**(117)**	(12)	**—**	—
Other	**—**	—	**55**	27	**18**	18
Benefit obligation December 31	**$ 14,613**	$ 13,003	**$ 12,534**	$ 10,612	**$ 1,607**	$ 1,673
Funded status December 31	**$ (1,941)**	$ (1,642)	**$ (485)**	$ (449)	**$ (386)**	$ (571)
Recognized as:						
Other Assets	**$ —**	$ —	**$ 941**	$ 837	**$ —**	$ —
Accrued and other current liabilities	**(82)**	(92)	**(13)**	(18)	**(9)**	(10)
Other Noncurrent Liabilities	**(1,859)**	(1,550)	**(1,413)**	(1,268)	**(377)**	(561)

[(1)] *Actuarial losses (gains) primarily reflect changes in discount rates.*

At December 31, 2020 and 2019, the accumulated benefit obligation was $26.4 billion and $22.8 billion, respectively, for all pension plans, of which $14.4 billion and $12.8 billion, respectively, related to U.S. pension plans.

Information related to the funded status of selected pension plans at December 31 is as follows:

	U.S.		International	
	2020	2019	**2020**	2019
Pension plans with a projected benefit obligation in excess of plan assets				
Projected benefit obligation	**$ 14,613**	$ 13,003	**$ 8,951**	$ 7,421
Fair value of plan assets	**12,672**	11,361	**7,526**	6,135
Pension plans with an accumulated benefit obligation in excess of plan assets				
Accumulated benefit obligation	**$ 13,489**	$ 12,009	**$ 4,288**	$ 2,476
Fair value of plan assets	**11,685**	10,484	**3,033**	1,501

Plan Assets

Entities are required to use a fair value hierarchy which maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest:

Level 1 — Quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 — Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity. The Level 3 assets are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as instruments for which the determination of fair value requires significant judgment or estimation. At December 31, 2020 and 2019, $942 million and $860 million, respectively, or approximately 4% of the Company's pension investments were categorized as Level 3 assets.

If the inputs used to measure the financial assets fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

The fair values of the Company's pension plan assets at December 31 by asset category are as follows:

	Fair Value Measurements Using					Fair Value Measurements Using				
	Level 1	**Level 2**	**Level 3**	**NAV [1]**	**Total**	Level 1	Level 2	Level 3	NAV [1]	Total
	2020					2019				
U.S. Pension Plans										
Cash and cash equivalents	**$ 5**	**$ —**	**$ —**	**$ 303**	**$ 308**	$ 3	$ —	$ —	$ 236	$ 239
Investment funds										
Developed markets equities	**206**	**—**	**—**	**3,884**	**4,090**	205	—	—	3,542	3,747
Emerging markets equities	**169**	**—**	**—**	**927**	**1,096**	165	—	—	723	888
Mortgage and asset-backed securities	**—**	**89**	**—**	**—**	**89**	—	—	—	—	—
Government and agency obligations	**—**	**—**	**—**	**—**	**—**	—	—	—	173	173
Equity securities										
Developed markets	**2,819**	**—**	**—**	**—**	**2,819**	2,451	—	—	—	2,451
Fixed income securities										—
Government and agency obligations	**—**	**2,236**	**—**	**—**	**2,236**	—	2,094	—	—	2,094
Corporate obligations	**—**	**1,994**	**—**	**—**	**1,994**	—	1,582	—	—	1,582
Mortgage and asset-backed securities	**—**	**33**	**—**	**—**	**33**	—	178	—	—	178
Other investments	**—**	**—**	**7**	**—**	**7**	—	—	9	—	9
Plan assets at fair value	**$ 3,199**	**$ 4,352**	**$ 7**	**$ 5,114**	**$ 12,672**	$ 2,824	$ 3,854	$ 9	$ 4,674	$ 11,361
International Pension Plans										
Cash and cash equivalents	**$ 110**	**$ 1**	**$ —**	**$ 20**	**$ 131**	$ 70	$ 1	$ —	$ 15	$ 86
Investment funds										
Developed markets equities	**475**	**4,286**	**—**	**118**	**4,879**	546	3,761	—	96	4,403
Government and agency obligations	**1,516**	**2,614**	**—**	**172**	**4,302**	462	2,534	—	207	3,203
Emerging markets equities	**154**	**—**	**—**	**92**	**246**	66	96	—	90	252
Corporate obligations	**5**	**12**	**—**	**172**	**189**	5	11	—	109	125
Other fixed income obligations	**9**	**11**	**—**	**4**	**24**	9	6	—	—	15
Real estate	**—**	**1**	**—**	**15**	**16**	—	1	—	—	1
Equity securities										
Developed markets	**505**	**—**	**—**	**—**	**505**	565	—	—	—	565
Fixed income securities										
Government and agency obligations	**3**	**486**	**—**	**3**	**492**	3	376	—	—	379
Corporate obligations	**1**	**174**	**—**	**2**	**177**	1	135	—	—	136
Mortgage and asset-backed securities	**—**	**70**	**—**	**—**	**70**	—	61	—	—	61
Other investments										
Insurance contracts [2]	**—**	**76**	**935**	**1**	**1,012**	—	65	851	—	916
Other	**1**	**5**	**—**	**—**	**6**	—	5	—	16	21
Plan assets at fair value	**$ 2,779**	**$ 7,736**	**$ 935**	**$ 599**	**$ 12,049**	$ 1,727	$ 7,052	$ 851	$ 533	$ 10,163

[1] *Certain investments that were measured at net asset value (NAV) per share or its equivalent have not been classified in the fair value hierarchy. The NAV amounts presented in this table are intended to permit reconciliation of the fair value hierarchy to the fair value of plan assets at December 31, 2020 and 2019.*

[2] *The plans' Level 3 investments in insurance contracts are generally valued using a crediting rate that approximates market returns and invest in underlying securities whose market values are unobservable and determined using pricing models, discounted cash flow methodologies, or similar techniques.*

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The table below provides a summary of the changes in fair value, including transfers in and/or out, of all financial assets measured at fair value using significant unobservable inputs (Level 3) for the Company's pension plan assets:

	2020				2019			
	Insurance Contracts	**Real Estate**	**Other**	**Total**	Insurance Contracts	Real Estate	Other	Total
U.S. Pension Plans								
Balance January 1	**$ —**	**$ —**	**$ 9**	**$ 9**	$ —	$ —	$ 13	$ 13
Actual return on plan assets:								
Relating to assets still held at December 31	**—**	**—**	**(5)**	**(5)**	—	—	(8)	(8)
Relating to assets sold during the year	**—**	**—**	**5**	**5**	—	—	8	8
Purchases and sales, net	**—**	**—**	**(2)**	**(2)**	—	—	(4)	(4)
Balance December 31	**$ —**	**$ —**	**$ 7**	**$ 7**	$ —	$ —	$ 9	$ 9
International Pension Plans								
Balance January 1	**$ 851**	**$ —**	**$ —**	**$ 851**	$ 811	$ 1	$ 1	$ 813
Actual return on plan assets:								
Relating to assets still held at December 31	**103**	**—**	**—**	**103**	54	—	—	54
Purchases and sales, net	**(17)**	**—**	**—**	**(17)**	(14)	(1)	(1)	(16)
Transfers out of Level 3	**(2)**	**—**	**—**	**(2)**	—	—	—	—
Balance December 31	**$ 935**	**$ —**	**$ —**	**$ 935**	$ 851	$ —	$ —	$ 851

The fair values of the Company's other postretirement benefit plan assets at December 31 by asset category are as follows:

	Fair Value Measurements Using					Fair Value Measurements Using				
	Level 1	**Level 2**	**Level 3**	**NAV [1]**	**Total**	Level 1	Level 2	Level 3	NAV [1]	Total
	2020					2019				
Cash and cash equivalents	**$ 31**	**$ —**	**$ —**	**$ 28**	**$ 59**	$ 52	$ —	$ —	$ 22	$ 74
Investment funds										
Developed markets equities	**19**	**—**	**—**	**355**	**374**	19	—	—	324	343
Emerging markets equities	**16**	**—**	**—**	**85**	**101**	15	—	—	66	81
Government and agency obligations	**1**	**—**	**—**	**—**	**1**	1	—	—	16	17
Mortgage and asset-backed securities	**—**	**8**	**—**	**—**	**8**	—	—	—	—	—
Equity securities										—
Developed markets	**258**	**—**	**—**	**—**	**258**	225	—	—	—	225
Fixed income securities										
Government and agency obligations	**—**	**221**	**—**	**—**	**221**	—	196	—	—	196
Corporate obligations	**—**	**196**	**—**	**—**	**196**	—	149	—	—	149
Mortgage and asset-backed securities	**—**	**3**	**—**	**—**	**3**	—	17	—	—	17
Plan assets at fair value	**$ 325**	**$ 428**	**$ —**	**$ 468**	**$ 1,221**	$ 312	$ 362	$ —	$ 428	$ 1,102

[1] *Certain investments that were measured at net asset value (NAV) per share or its equivalent have not been classified in the fair value hierarchy. The NAV amounts presented in this table are intended to permit reconciliation of the fair value hierarchy to the fair value of plan assets at December 31, 2020 and 2019.*

The Company has established investment guidelines for its U.S. pension and other postretirement plans to create an asset allocation that is expected to deliver a rate of return sufficient to meet the long-term obligation of each plan, given an acceptable level of risk. The target investment portfolio of the Company's U.S. pension and other postretirement benefit plans is allocated 30% to 45% in U.S. equities, 15% to 30% in international equities, 35% to 45% in fixed-income investments, and up to 5% in cash and other investments. The portfolio's equity weighting is consistent with the long-term nature of the plans' benefit obligations. The expected annual standard deviation of returns of the target portfolio, which approximates 11%, reflects both the equity allocation and the diversification benefits among the asset classes in which the portfolio invests. For international pension plans, the

targeted investment portfolio varies based on the duration of pension liabilities and local government rules and regulations. Although a significant percentage of plan assets are invested in U.S. equities, concentration risk is mitigated through the use of strategies that are diversified within management guidelines.

Expected Contributions

Expected contributions during 2021 are approximately $300 million for U.S. pension plans, approximately $170 million for international pension plans and approximately $35 million for other postretirement benefit plans.

Expected Benefit Payments

Expected benefit payments are as follows:

	U.S. Pension Benefits	International Pension Benefits	Other Postretirement Benefits
2021	$ 816	$ 274	$ 85
2022	786	277	86
2023	781	284	87
2024	772	285	89
2025	782	287	91
2026 — 2030	4,271	1,688	474

Expected benefit payments are based on the same assumptions used to measure the benefit obligations and include estimated future employee service.

Amounts Recognized in Other Comprehensive Income

Net loss amounts reflect differences between expected and actual returns on plan assets as well as the effects of changes in actuarial assumptions. Net loss amounts in excess of certain thresholds are amortized into net periodic benefit cost over the average remaining service life of employees. The following amounts were reflected as components of *OCI*:

	Pension Plans								
	U.S.			International			Other Postretirement Benefit Plans		
Years Ended December 31	**2020**	2019	2018	**2020**	2019	2018	**2020**	2019	2018
Net (loss) gain arising during the period	**$ (448)**	$ (816)	$ (397)	**$ (407)**	$ (227)	$ (505)	**$ 198**	$ 112	$ 186
Prior service (cost) credit arising during the period	**(1)**	(4)	(4)	**62**	(1)	(10)	**(3)**	(11)	2
	$ (449)	$ (820)	$ (401)	**$ (345)**	$ (228)	$ (515)	**$ 195**	$ 101	$ 188
Net loss (gain) amortization included in benefit cost	**$ 303**	$ 151	$ 232	**$ 127**	$ 64	$ 84	**$ (18)**	$ (10)	$ 1
Prior service credit amortization included in benefit cost	**(49)**	(49)	(50)	**(18)**	(12)	(13)	**(73)**	(78)	(84)
	$ 254	$ 102	$ 182	**$ 109**	$ 52	$ 71	**$ (91)**	$ (88)	$ (83)

Actuarial Assumptions

The Company reassesses its benefit plan assumptions on a regular basis. The weighted average assumptions used in determining U.S. pension and other postretirement benefit plan and international pension plan information are as follows:

	U.S. Pension and Other Postretirement Benefit Plans			International Pension Plans		
December 31	**2020**	2019	2018	**2020**	2019	2018
Net periodic benefit cost						
Discount rate	**3.40 %**	4.40 %	3.70 %	**1.50 %**	2.20 %	2.10 %
Expected rate of return on plan assets	**7.30 %**	8.10 %	8.20 %	**4.40 %**	4.90 %	5.10 %
Salary growth rate	**4.20 %**	4.30 %	4.30 %	**2.80 %**	2.80 %	2.90 %
Interest crediting rate	**4.90 %**	3.40 %	3.30 %	**2.80 %**	2.90 %	2.80 %
Benefit obligation						
Discount rate	**2.70 %**	3.40 %	4.40 %	**1.10 %**	1.50 %	2.20 %
Salary growth rate	**4.60 %**	4.20 %	4.30 %	**2.80 %**	2.80 %	2.80 %
Interest crediting rate	**4.70 %**	4.90 %	3.40 %	**3.00 %**	2.80 %	2.90 %

For both the pension and other postretirement benefit plans, the discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due. The expected rate of return for both the pension and other postretirement benefit plans represents the average rate of return to be earned on plan assets over the period the benefits included in the benefit obligation are to be paid and is determined on a plan basis. The expected rate of return for each plan is developed considering long-term historical returns data, current market conditions, and actual returns on the plan assets. Using this reference information, the long-term return expectations for each asset category and a weighted-average expected return for each plan's target portfolio is developed according to the allocation among those investment categories. The expected portfolio performance reflects the contribution of active management as appropriate. For 2021, the expected rate of return for the Company's U.S. pension and other postretirement benefit plans will range from 6.50% to 6.70%, as compared to a range of 7.00% to 7.30% in 2020.

The health care cost trend rate assumptions for other postretirement benefit plans are as follows:

December 31	**2020**	2019
Health care cost trend rate assumed for next year	**6.6 %**	6.8 %
Rate to which the cost trend rate is assumed to decline	**4.5 %**	4.5 %
Year that the trend rate reaches the ultimate trend rate	**2032**	2032

Savings Plans

The Company also maintains defined contribution savings plans in the United States. The Company matches a percentage of each employee's contributions consistent with the provisions of the plan for which the employee is eligible. Total employer contributions to these plans in 2020, 2019 and 2018 were $166 million, $149 million and $136 million, respectively.

14. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

Years Ended December 31	**2020**	2019	2018
Interest income	**$ (59)**	$ (274)	$ (343)
Interest expense	**831**	893	772
Exchange losses	**145**	187	145
Income from investments in equity securities, net [1]	**(1,338)**	(170)	(324)
Net periodic defined benefit plan (credit) cost other than service cost	**(339)**	(545)	(512)
Other, net	**(126)**	48	(140)
	$ (886)	$ 139	$ (402)

[1] *Includes net realized and unrealized gains and losses from investments in equity securities either owned directly or through ownership interests in investment funds. Unrealized gains and losses from investments that are directly owned are determined at the end of the reporting period, while ownership interests in investment funds are accounted for on a one quarter lag.*

Other, net (as presented in the table above) in 2019 includes $162 million of goodwill impairment charges related to certain businesses in the Healthcare Services segment (see Note 8).

Other, net in 2018 includes a gain of $115 million related to the settlement of certain patent litigation, income of $99 million related to AstraZeneca's option exercise in 2014 in connection with the termination of the Company's relationship with AstraZeneca LP (AZLP), and a gain of $85 million resulting from the receipt of a milestone payment for an out-licensed migraine clinical development program. Other, net in 2018 also includes $144 million of goodwill impairment charges related to certain businesses in the Healthcare Services segment (see Note 8), as well as $41 million of charges related to the write-down of assets held for sale to fair value in anticipation of the dissolution of the Company's joint venture with Supera Farma Laboratorios S.A. in Brazil.

Interest paid was $822 million in 2020, $841 million in 2019 and $777 million in 2018.

15. Taxes on Income

A reconciliation between the effective tax rate and the U.S. statutory rate is as follows:

	2020		2019		2018	
	Amount	**Tax Rate**	Amount	Tax Rate	Amount	Tax Rate
U.S. statutory rate applied to income before taxes	**$ 1,846**	**21.0 %**	$ 2,408	21.0 %	$ 1,827	21.0 %
Differential arising from:						
Foreign earnings	**(1,242)**	**(14.1)**	(1,020)	(8.9)	(245)	(2.8)
GILTI and the foreign-derived intangible income deduction	**364**	**4.1**	336	2.9	(25)	(0.3)
R&D tax credit	**(110)**	**(1.3)**	(118)	(1.0)	(96)	(1.1)
Tax settlements	**(13)**	**(0.2)**	(403)	(3.5)	(22)	(0.3)
Acquisition of VelosBio	**559**	**6.3**	—	—	—	—
Restructuring	**105**	**1.2**	39	0.3	56	0.6
Acquisition of OncoImmune	**97**	**1.1**	—	—	—	—
State taxes	**67**	**0.8**	(2)	—	201	2.3
Acquisition-related costs, including amortization	**46**	**0.5**	95	0.8	267	3.1
Valuation allowances	**42**	**0.5**	113	1.0	269	3.1
Acquisition of Peloton	**—**	**—**	209	1.8	—	—
Tax Cuts and Jobs Act of 2017	**—**	**—**	117	1.0	289	3.3
Other	**(52)**	**(0.5)**	(87)	(0.7)	(13)	(0.1)
	$ 1,709	**19.4 %**	$ 1,687	14.7 %	$ 2,508	28.8 %

The Tax Cuts and Jobs Act (TCJA) was enacted in December 2017 and the Company reflected the impact of the TCJA in its 2017 financial statements. However, since application of certain provisions of the TCJA remained subject to further interpretation, in certain instances the Company made reasonable estimates of the effects of the TCJA, which were since finalized and resulted in additional income tax expense in 2018 and 2019. The Company's remaining transition tax liability under the TCJA, which has been reduced by payments and the utilization of foreign tax credits, was $3.0 billion at December 31, 2020, of which $390 million is included in *Income taxes payable* and the remainder of $2.6 billion is included in *Other Noncurrent Liabilities*. As a result of the transition tax under the TCJA, the Company is no longer indefinitely reinvested with respect to its undistributed earnings from foreign subsidiaries and has provided a deferred tax liability for foreign withholding taxes that would apply. The Company remains indefinitely reinvested with respect to its financial statement basis in excess of tax basis of its foreign subsidiaries. A determination of the deferred tax liability with respect to this basis difference is not practicable.

The foreign earnings tax rate differentials in the tax rate reconciliation above primarily reflect the impacts of operations in jurisdictions with different tax rates than the United States, particularly Ireland and Switzerland, as well as Singapore and Puerto Rico which operate under tax incentive grants (which begin to expire in 2022), thereby yielding a favorable impact on the effective tax rate compared with the U.S. statutory rate of 21%. Towards the end of 2020, a new reduced tax rate arrangement was agreed to in Switzerland for certain newly active legal entities.

Income before taxes consisted of:

Years Ended December 31	**2020**	2019	2018
Domestic	**$ (3,492)**	$ 439	$ 3,717
Foreign	**12,283**	11,025	4,984
	$ 8,791	$ 11,464	$ 8,701

Taxes on income consisted of:

Years Ended December 31	**2020**	2019	2018
Current provision			
Federal	**$ 962**	$ 514	$ 536
Foreign	**1,362**	1,806	2,281
State	**53**	(77)	200
	2,377	2,243	3,017
Deferred provision			
Federal	**(605)**	(330)	(402)
Foreign	**(40)**	(240)	(64)
State	**(23)**	14	(43)
	(668)	(556)	(509)
	$ 1,709	$ 1,687	$ 2,508

Deferred income taxes at December 31 consisted of:

	2020		2019	
	Assets	**Liabilities**	Assets	Liabilities
Product intangibles and licenses	**$ 141**	**$ 1,250**	$ 442	$ 1,778
Inventory related	**43**	**335**	32	354
Accelerated depreciation	**—**	**588**	—	594
Equity investments	**—**	**175**	—	—
Pensions and other postretirement benefits	**834**	**248**	785	191
Compensation related	**252**	**—**	322	—
Unrecognized tax benefits	**117**	**—**	109	—
Net operating losses and other tax credit carryforwards	**794**	**—**	897	—
Other	**808**	**81**	764	84
Subtotal	**2,989**	**2,677**	3,351	3,001
Valuation allowance	**(433)**		(1,100)	
Total deferred taxes	**$ 2,556**	**$ 2,677**	$ 2,251	$ 3,001
Net deferred income taxes		**$ 121**		$ 750
Recognized as:				
Other Assets	**$ 894**		$ 719	
Deferred Income Taxes		**$ 1,015**		$ 1,470

The Company has net operating loss (NOL) carryforwards in several jurisdictions. As of December 31, 2020, $464 million of deferred taxes on NOL carryforwards relate to foreign jurisdictions. Valuation allowances of $433 million have been established on these foreign NOL carryforwards and other foreign deferred tax assets. In addition, the Company has $330 million of deferred tax assets relating to various U.S. tax credit carryforwards and NOL carryforwards, all of which are expected to be fully utilized prior to expiry.

Income taxes paid in 2020, 2019 and 2018 were $2.7 billion, $4.5 billion and $1.5 billion, respectively. Tax benefits relating to stock option exercises were $55 million in 2020, $65 million in 2019 and $77 million in 2018.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	2020	2019	2018
Balance January 1	**$ 1,225**	$ 1,893	$ 1,723
Additions related to current year positions	**298**	199	221
Additions related to prior year positions	**110**	46	142
Reductions for tax positions of prior years [(1)]	**(4)**	(454)	(73)
Settlements [(1)]	**(70)**	(356)	(91)
Lapse of statute of limitations [(2)]	**(22)**	(103)	(29)
Balance December 31	**$ 1,537**	$ 1,225	$ 1,893

[(1)] *Amounts in 2019 reflects the settlement with the IRS discussed below.*

[(2)] *Amount in 2019 includes $78 million related to the divestiture of Merck's Consumer Care business in 2014.*

If the Company were to recognize the unrecognized tax benefits of $1.5 billion at December 31, 2020, the income tax provision would reflect a favorable net impact of $1.5 billion.

The Company is under examination by numerous tax authorities in various jurisdictions globally. The Company believes that it is reasonably possible that the total amount of unrecognized tax benefits as of December 31, 2020 could decrease by up to approximately $160 million in the next 12 months as a result of various audit closures, settlements or the expiration of the statute of limitations. The ultimate finalization of the Company's examinations with relevant taxing authorities can include formal administrative and legal proceedings, which could have a significant impact on the timing of the reversal of unrecognized tax benefits. The Company believes that its reserves for uncertain tax positions are adequate to cover existing risks or exposures.

Interest and penalties associated with uncertain tax positions amounted to an expense (benefit) of $27 million in 2020, $(101) million in 2019 and $51 million in 2018. These amounts reflect the beneficial impacts of various tax settlements, including the settlement discussed below. Liabilities for accrued interest and penalties were $268 million and $243 million as of December 31, 2020 and 2019, respectively.

In 2019, the Internal Revenue Service (IRS) concluded its examinations of Merck's 2012-2014 U.S. federal income tax returns. As a result, the Company was required to make a payment of $107 million. The Company's reserves for unrecognized tax benefits for the years under examination exceeded the adjustments relating to this examination period and therefore the Company recorded a $364 million net tax benefit in 2019. This net benefit reflects reductions in reserves for unrecognized tax benefits for tax positions relating to the years that were under examination, partially offset by additional reserves for tax positions not previously reserved for.

The IRS is currently conducting examinations of the Company's tax returns for the years 2015 and 2016. In addition, various state and foreign tax examinations are in progress and for these jurisdictions, the Company's income tax returns are open for examination for the period 2003 through 2020.

16. Earnings per Share

The calculations of earnings per share (shares in millions) are as follows:

Years Ended December 31	**2020**	2019	2018
Net income attributable to Merck & Co., Inc.	**$ 7,067**	$ 9,843	$ 6,220
Average common shares outstanding	**2,530**	2,565	2,664
Common shares issuable [(1)]	**11**	15	15
Average common shares outstanding assuming dilution	**2,541**	2,580	2,679
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	**$ 2.79**	$ 3.84	$ 2.34
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	**$ 2.78**	$ 3.81	$ 2.32

[(1)] *Issuable primarily under share-based compensation plans.*

In 2020, 2019 and 2018, 5 million, 2 million and 6 million, respectively, of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

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17. Other Comprehensive Income (Loss)

Changes in *AOCI* by component are as follows:

	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance January 1, 2018, net of taxes	$ (108)	$ (61)	$ (2,787)	$ (1,954)	$ (4,910)
Other comprehensive income (loss) before reclassification adjustments, pretax	228	(108)	(728)	(84)	(692)
Tax	(55)	1	169	(139)	(24)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	173	(107)	(559)	(223)	(716)
Reclassification adjustments, pretax	157 [(1)]	97 [(2)]	170 [(3)]	—	424
Tax	(33)	—	(36)	—	(69)
Reclassification adjustments, net of taxes	124	97	134	—	355
Other comprehensive income (loss), net of taxes	297	(10)	(425)	(223)	(361)
Adoption of ASU 2018-02	(23)	1	(344)	100	(266)
Adoption of ASU 2016-01	—	(8)	—	—	(8)
Balance at December 31, 2018, net of taxes	166	(78)	(3,556)	(2,077)	(5,545)
Other comprehensive income (loss) before reclassification adjustments, pretax	86	140	(948)	112	(610)
Tax	(15)	—	192	(16)	161
Other comprehensive income (loss) before reclassification adjustments, net of taxes	71	140	(756)	96	(449)
Reclassification adjustments, pretax	(261) [(1)]	(44) [(2)]	66 [(3)]	—	(239)
Tax	55	—	(15)	—	40
Reclassification adjustments, net of taxes	(206)	(44)	51	—	(199)
Other comprehensive income (loss), net of taxes	(135)	96	(705)	96	(648)
Balance at December 31, 2019, net of taxes	31	18	(4,261) [(4)]	(1,981)	(6,193)
Other comprehensive income (loss) before reclassification adjustments, pretax	**(383)**	**3**	**(599)**	**64**	**(915)**
Tax	**84**	**—**	**111**	**89**	**284**
Other comprehensive income (loss) before reclassification adjustments, net of taxes	**(299)**	**3**	**(488)**	**153**	**(631)**
Reclassification adjustments, pretax	**2** [(1)]	**(21)** [(2)]	**272** [(3)]	**—**	**253**
Tax	**—**	**—**	**(63)**	**—**	**(63)**
Reclassification adjustments, net of taxes	**2**	**(21)**	**209**	**—**	**190**
Other comprehensive income (loss), net of taxes	**(297)**	**(18)**	**(279)**	**153**	**(441)**
Balance at December 31, 2020, net of taxes	**$ (266)**	**$ —**	**$ (4,540)** [(4)]	**$ (1,828)**	**$ (6,634)**

[(1)] *Relates to foreign currency cash flow hedges that were reclassified from* AOCI *to* Sales.

[(2)] *Represents net realized (gains) losses on the sales of available-for-sale investments that were reclassified from* AOCI *to* Other (income) expense, net.

[(3)] *Includes net amortization of prior service cost and actuarial gains and losses included in net periodic benefit cost (see Note 13).*

[(4)] *Includes pension plan net loss of $5.4 billion and $5.1 billion at December 31, 2020 and 2019, respectively, and other postretirement benefit plan net gain of $391 million and $247 million at December 31, 2020 and 2019, respectively, as well as pension plan prior service credit of $255 million and $263 million at December 31, 2020 and 2019, respectively, and other postretirement benefit plan prior service credit of $244 million and $305 million at December 31, 2020 and 2019, respectively.*

18. Segment Reporting

The Company's operations are principally managed on a products basis and include two operating segments, which are the Pharmaceutical and Animal Health segments, both of which are reportable segments.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. A large component of pediatric and adolescent vaccine sales are made to the U.S. Centers for Disease Control and Prevention Vaccines for Children program, which is funded by the U.S. government. Additionally, the Company sells vaccines to the Federal government for placement into vaccine stockpiles.

The Animal Health segment discovers, develops, manufactures and markets a wide range of veterinary pharmaceutical and vaccine products, as well as health management solutions and services, for the prevention, treatment and control of disease in all major livestock and companion animal species. The Company also offers an extensive suite of digitally connected identification, traceability and monitoring products. The Company sells its products to veterinarians, distributors and animal producers.

The Company previously had a Healthcare Services segment that provided services and solutions focused on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company divested the remaining businesses in this segment in the first quarter of 2020.

The Company previously had an Alliances segment that primarily included activity from the Company's relationship with AstraZeneca LP related to sales of Nexium and Prilosec, which concluded in 2018.

Sales of the Company's products were as follows:

Years Ended December 31	**2020**			2019			2018		
	U.S.	**Int'l**	**Total**	U.S.	Int'l	Total	U.S.	Int'l	Total
Pharmaceutical:									
Oncology									
Keytruda	**$ 8,352**	**$ 6,028**	**$ 14,380**	$ 6,305	$ 4,779	$ 11,084	$ 4,150	$ 3,021	$ 7,171
Alliance revenue - Lynparza [(1)]	**417**	**308**	**725**	269	176	444	127	61	187
Alliance revenue - Lenvima [(1)]	**359**	**220**	**580**	239	165	404	95	54	149
Emend	**18**	**127**	**145**	183	205	388	312	210	522
Vaccines									
Gardasil/Gardasil 9	**1,755**	**2,184**	**3,938**	1,831	1,905	3,737	1,873	1,279	3,151
ProQuad/M-M-R II/Varivax	**1,378**	**500**	**1,878**	1,683	592	2,275	1,430	368	1,798
Pneumovax 23	**727**	**359**	**1,087**	679	247	926	627	281	907
RotaTeq	**486**	**311**	**797**	506	284	791	496	232	728
Vaqta	**103**	**67**	**170**	130	108	238	127	112	239
Hospital Acute Care									
Bridion	**583**	**615**	**1,198**	533	598	1,131	386	531	917
Noxafil	**42**	**287**	**329**	282	380	662	353	389	742
Prevymis	**119**	**162**	**281**	84	81	165	46	27	72
Primaxin	**2**	**248**	**251**	2	271	273	7	258	265
Cancidas	**7**	**207**	**213**	6	242	249	12	314	326
Invanz	**9**	**202**	**211**	30	233	263	253	243	496
Cubicin	**46**	**106**	**152**	92	165	257	191	176	367
Zerbaxa	**74**	**56**	**130**	63	58	121	42	45	87
Immunology									
Simponi	**—**	**838**	**838**	—	830	830	—	893	893
Remicade	**—**	**330**	**330**	—	411	411	—	582	582
Neuroscience									
Belsomra	**81**	**247**	**327**	92	214	306	96	164	260
Virology									
Isentress/Isentress HD	**326**	**531**	**857**	398	576	975	513	627	1,140
Zepatier	**60**	**107**	**167**	118	252	370	8	447	455
Cardiovascular									
Zetia	**(1)**	**483**	**482**	14	575	590	45	813	857
Vytorin	**12**	**171**	**182**	16	269	285	10	487	497
Atozet	**—**	**453**	**453**	—	391	391	—	347	347
Alliance revenue - Adempas [(2)]	**259**	**22**	**281**	194	10	204	134	5	139
Adempas	**—**	**220**	**220**	—	215	215	—	190	190
Diabetes									
Januvia	**1,470**	**1,836**	**3,306**	1,724	1,758	3,482	1,969	1,718	3,686
Janumet	**477**	**1,494**	**1,971**	589	1,452	2,041	811	1,417	2,228
Women's Health									
Implanon/Nexplanon	**488**	**192**	**680**	568	219	787	495	208	703
NuvaRing	**110**	**127**	**236**	742	136	879	722	180	902
Diversified Brands									
Singulair	**18**	**444**	**462**	29	669	698	20	688	708
Cozaar/Hyzaar	**21**	**365**	**386**	24	418	442	23	431	453
Arcoxia	**—**	**258**	**258**	—	288	288	—	335	335
Nasonex	**12**	**206**	**218**	9	284	293	23	353	376
Follistim AQ	**84**	**109**	**193**	103	138	241	115	153	268
Other pharmaceutical [(3)]	**1,555**	**3,152**	**4,709**	1,416	3,204	4,615	1,231	3,308	4,546
Total Pharmaceutical segment sales	**19,449**	**23,572**	**43,021**	18,953	22,798	41,751	16,742	20,947	37,689
Animal Health:									
Livestock	**612**	**2,327**	**2,939**	582	2,201	2,784	528	2,102	2,630
Companion Animals	**872**	**892**	**1,764**	724	885	1,609	710	872	1,582
Total Animal Health segment sales	**1,484**	**3,219**	**4,703**	1,306	3,086	4,393	1,238	2,974	4,212

U.S. plus international may not equal total due to rounding.

(1) *Alliance revenue represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs (see Note 4).*

(2) *Alliance revenue represents Merck's share of profits from sales in Bayer's marketing territories, which are product sales net of cost of sales and commercialization costs (see Note 4).*

(3) *Other pharmaceutical primarily reflects sales of other human health pharmaceutical products, including products within the franchises not listed separately.*

(4) *Represents sales for the non-reportable segments of Healthcare Services (fully divested in the first quarter of 2020) and Alliances (which concluded in 2018).*

(5) *Other is primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, as well as third-party manufacturing sales.*

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Consolidated sales by geographic area where derived are as follows:

Years Ended December 31	**2020**	2019	2018
United States	**$ 21,027**	$ 20,519	$ 18,346
Europe, Middle East and Africa	**13,600**	12,707	12,213
China	**3,624**	3,207	2,184
Japan	**3,376**	3,583	3,212
Asia Pacific (other than China and Japan)	**2,864**	2,943	2,909
Latin America	**2,274**	2,469	2,415
Other	**1,229**	1,412	1,015
	$ 47,994	$ 46,840	$ 42,294

A reconciliation of segment profits to *Income before taxes* is as follows:

Years Ended December 31	**2020**	2019	2018
Segment profits:			
Pharmaceutical segment	**$ 29,722**	$ 28,324	$ 24,871
Animal Health segment	**1,650**	1,609	1,659
Other segments	**1**	(7)	103
Total segment profits	**31,373**	29,926	26,633
Other profits	**140**	363	6
Unallocated:			
Interest income	**59**	274	343
Interest expense	**(831)**	(893)	(772)
Depreciation and amortization	**(1,602)**	(1,593)	(1,352)
Research and development	**(13,072)**	(9,499)	(9,432)
Amortization of purchase accounting adjustments	**(1,168)**	(1,406)	(2,664)
Restructuring costs	**(578)**	(638)	(632)
Charge related to the termination of a collaboration with Samsung	**—**	—	(423)
Other unallocated, net	**(5,530)**	(5,070)	(3,006)
Income Before Taxes	**$ 8,791**	$ 11,464	$ 8,701

Pharmaceutical segment profits are comprised of segment sales less standard costs, as well as selling, general and administrative expenses directly incurred by the segment. Animal Health segment profits are comprised of segment sales, less all cost of sales, as well as selling, general and administrative expenses and research and development costs directly incurred by the segment. For internal management reporting presented to the chief operating decision maker, Merck does not allocate the remaining cost of sales not included in segment profits as described above, research and development expenses incurred in Merck Research Laboratories, the Company's research and development division that focuses on human health-related activities, or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. In addition, costs related to restructuring activities, as well as the amortization of purchase accounting adjustments are not allocated to segments.

Other profits are primarily comprised of miscellaneous corporate profits, as well as operating profits related to third-party manufacturing sales.

Other unallocated, net includes expenses from corporate and manufacturing cost centers, goodwill and other intangible asset impairment charges, gains or losses on sales of businesses, expense or income related to changes in the estimated fair value of liabilities for contingent consideration, and other miscellaneous income or expense items.

Equity (income) loss from affiliates and depreciation and amortization included in segment profits is as follows:

	Pharmaceutical	Animal Health	All Other	Total
Year Ended December 31, 2020				
Included in segment profits:				
Equity (income) loss from affiliates	**$ 6**	**$ —**	**$ —**	**$ 6**
Depreciation and amortization	**690**	**164**	**1**	**855**
Year Ended December 31, 2019				
Included in segment profits:				
Equity (income) loss from affiliates	$ —	$ —	$ —	$ —
Depreciation and amortization	534	109	10	653
Year Ended December 31, 2018				
Included in segment profits:				
Equity (income) loss from affiliates	$ 4	$ —	$ —	$ 4
Depreciation and amortization	411	82	10	503

Property, plant and equipment, net, by geographic area where located is as follows:

December 31	**2020**	2019	2018
United States	**$ 10,526**	$ 8,974	$ 8,306
Europe, Middle East and Africa	**6,059**	4,767	3,706
Asia Pacific (other than China and Japan)	**761**	714	684
Latin America	**252**	266	264
China	**217**	174	167
Japan	**166**	152	159
Other	**5**	6	5
	$ 17,986	$ 15,053	$ 13,291

The Company does not disaggregate assets on a products and services basis for internal management reporting and, therefore, such information is not presented.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Merck & Co., Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheet of Merck & Co., Inc. and its subsidiaries (the "Company") as of December 31, 2020 and 2019, and the related consolidated statements of income, of comprehensive income, of equity and of cash flows for each of the three years in the period ended December 31, 2020, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Customer Discount Accruals in the U.S. - Medicaid, Managed Care and Medicare Part D Rebates

As described in Note 2 to the consolidated financial statements, the Company records certain variable consideration including discounts, which are estimated at the time of sale generally using the expected value method. Amounts accrued for aggregate customer discounts as of December 31, 2020 in the U.S. are $3.1 billion and are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal and state agencies, and other customers to the amounts accrued. Certain of these discounts take the form of rebates, which are amounts owed based upon definitive contractual agreements or legal requirements with private sector (Managed Care) and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. Management uses historical customer segment utilization mix, sales forecasts, changes to product mix and price, inventory levels in the distribution channel, government pricing calculations and prior payment history in order to estimate the expected provision.

The principal considerations for our determination that performing procedures relating to customer discount accruals in the U.S. - Medicaid, Managed Care, and Medicare Part D rebates is a critical audit matter are the significant judgment by management due to the significant measurement uncertainty involved in developing the provisions, as the provisions include assumptions related to changes to price and historical customer segment utilization mix, pertaining to forecasted customer claims that may not be fully paid until a subsequent period. This in turn led to a high degree of auditor judgment, subjectivity and effort in applying the procedures related to those assumptions and in evaluating the evidence obtained from these procedures.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to customer discount accruals in the U.S. - Medicaid, Managed Care, and Medicare Part D rebates, including management's controls over the assumptions used to estimate the corresponding rebate accruals. These procedures also included, among others, (i) developing an independent estimate of the rebate accruals by utilizing third party data on historical customer segment utilization mix in the U.S., changes to price, the terms of the specific rebate programs, and the historical trend of actual rebate claims paid, (ii) comparing the independent estimate to the rebate accruals recorded by management and (iii) testing actual rebate claims paid, including evaluating those claims for consistency with the contractual terms of the Company's rebate agreements.

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PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 25, 2021

We have served as the Company's auditor since 2002.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures. Based on their evaluation, as of the end of the period covered by this Form 10-K, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Act)) are effective. For the fourth quarter of 2020, there have been no changes in internal control over financial reporting that materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Act. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control — Integrated Framework* issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2020. PricewaterhouseCoopers LLP, an independent registered public accounting firm, has performed its own assessment of the effectiveness of the Company's internal control over financial reporting and its attestation report is included in this Form 10-K filing.

Management's Report

Management's Responsibility for Financial Statements

Responsibility for the integrity and objectivity of the Company's financial statements rests with management. The financial statements report on management's stewardship of Company assets. These statements are prepared in conformity with generally accepted accounting principles and, accordingly, include amounts that are based on management's best estimates and judgments. Nonfinancial information included in the Annual Report on Form 10-K has also been prepared by management and is consistent with the financial statements.

To assure that financial information is reliable and assets are safeguarded, management maintains an effective system of internal controls and procedures, important elements of which include: careful selection, training and development of operating and financial managers; an organization that provides appropriate division of responsibility; and communications aimed at assuring that Company policies and procedures are understood throughout the organization. A staff of internal auditors regularly monitors the adequacy and application of internal controls on a worldwide basis.

To ensure that personnel continue to understand the system of internal controls and procedures, and policies concerning good and prudent business practices, annually all employees of the Company are required to complete Code of Conduct training. This training reinforces the importance and understanding of internal controls by reviewing key corporate policies, procedures and systems. In addition, the Company has compliance programs, including an ethical business practices program to reinforce the Company's long-standing commitment to high ethical standards in the conduct of its business.

The financial statements and other financial information included in the Annual Report on Form 10-K fairly present, in all material respects, the Company's financial condition, results of operations and cash flows. Our formal certification to the Securities and Exchange Commission is included in this Form 10-K filing.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control — Integrated*

Framework issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2020.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2020, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

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Kenneth C. Frazier
Chairman, President
and Chief Executive Officer

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Robert M. Davis
Executive Vice President, Global Services,
and Chief Financial Officer

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The required information on directors and nominees is incorporated by reference from the discussion under Proposal 1. Election of Directors of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 25, 2021. Information on executive officers is set forth in Part I of this document on page 44.

The required information on compliance with Section 16(a) of the Securities Exchange Act of 1934, if applicable, is incorporated by reference from the discussion under the heading "Stock Ownership Information" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 25, 2021.

The Company has a Code of Conduct — *Our Values and Standards* applicable to all employees, including the principal executive officer, principal financial officer, principal accounting officer and Controller. The Code of Conduct is available on the Company's website at www.merck.com/company-overview/culture-and-values/code-of-conduct/values-and-standards. The Company intends to disclose future amendments to certain provisions of the Code of Conduct, and waivers of the Code of Conduct granted to executive officers and directors, if any, on the website within four business days following the date of any amendment or waiver. Every Merck employee is responsible for adhering to business practices that are in accordance with the law and with ethical principles that reflect the highest standards of corporate and individual behavior.

The required information on the identification of the audit committee and the audit committee financial expert is incorporated by reference from the discussion under the heading "Board Meetings and Committees" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 25, 2021.

Item 11. Executive Compensation.

The information required on executive compensation is incorporated by reference from the discussion under the headings "Compensation Discussion and Analysis," "Summary Compensation Table," "All Other Compensation" table, "Grants of Plan-Based Awards" table, "Outstanding Equity Awards" table, "Option Exercises and Stock Vested" table, "Pension Benefits" table, "Nonqualified Deferred Compensation" table, "Potential Payments Upon Termination or a Change in Control", including the discussion under the subheadings "Separation" and "Change in Control," as well as all footnote information to the various tables, of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 25, 2021.

The required information on director compensation is incorporated by reference from the discussion under the heading "Director Compensation" and related "2020 Schedule of Director Fees" table and "2020 Director Compensation" table of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 25, 2021.

The required information under the headings "Compensation and Benefits Committee Interlocks and Insider Participation" and "Compensation and Benefits Committee Report" is incorporated by reference from the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 25, 2021.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information with respect to security ownership of certain beneficial owners and management is incorporated by reference from the discussion under the heading "Stock Ownership Information" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 25, 2021.

Equity Compensation Plan Information

The following table summarizes information about the options, warrants and rights and other equity compensation under the Company's equity compensation plans as of the close of business on December 31, 2020. The table does not include information about tax qualified plans such as the Merck U.S. Savings Plan.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders[1]	19,446,307[2]	$ 63.64	100,353,680
Equity compensation plans not approved by security holders	—	—	—
Total	19,446,307	$ 63.64	100,353,680

[1] *Includes options to purchase shares of Company Common Stock and other rights under the following shareholder-approved plans: the Merck & Co., Inc. 2010 and 2019 Incentive Stock Plans, and the Merck & Co., Inc. 2010 Non-Employee Directors Stock Option Plan.*

[2] *Excludes approximately 11,914,491 shares of restricted stock units and 2,099,739 performance share units (assuming maximum payouts) under the Merck Sharp & Dohme 2010 and 2019 Incentive Stock Plans. Also excludes 193,746 shares of phantom stock deferred under the MSD Employee Deferral Program and 564,209 shares of phantom stock deferred under the Merck & Co., Inc. Plan for Deferred Payment of Directors' Compensation.*

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The required information on transactions with related persons is incorporated by reference from the discussion under the heading "Related Person Transactions" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 25, 2021.

The required information on director independence is incorporated by reference from the discussion under the heading "Independence of Directors" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 25, 2021.

Item 14. Principal Accountant Fees and Services.

The information required for this item is incorporated by reference from the discussion under Proposal 3. Ratification of Appointment of Independent Registered Public Accounting Firm for 2021 beginning with the caption "Pre-Approval Policy for Services of Independent Registered Public Accounting Firm" through "Fees for Services Provided by the Independent Registered Public Accounting Firm" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 25, 2021.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this Form 10-K

1. Financial Statements

Consolidated statement of income for the years ended December 31, 2020, 2019 and 2018

Consolidated statement of comprehensive income for the years ended December 31, 2020, 2019 and 2018

Consolidated balance sheet as of December 31, 2020 and 2019

Consolidated statement of equity for the years ended December 31, 2020, 2019 and 2018

Consolidated statement of cash flows for the years ended December 31, 2020, 2019 and 2018

Notes to consolidated financial statements

Report of PricewaterhouseCoopers LLP, independent registered public accounting firm

2. Financial Statement Schedules

Schedules are omitted because they are either not required or not applicable.

Financial statements of affiliates carried on the equity basis have been omitted because, considered individually or in the aggregate, such affiliates do not constitute a significant subsidiary.

3. Exhibits

Exhibit Number		Description
3.1	—	Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) — Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
3.2	—	By-Laws of Merck & Co., Inc. (effective July 22, 2015) — Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed July 28, 2015 (No. 1-6571)
4.1	—	Indenture, dated as of April 1, 1991, between Merck Sharp & Dohme Corp. (f/k/a Schering Corporation) and U.S. Bank Trust National Association (as successor to Morgan Guaranty Trust Company of New York), as Trustee (the 1991 Indenture) — Incorporated by reference to Exhibit 4 to MSD's Registration Statement on Form S-3 (No. 33-39349)
4.2	—	First Supplemental Indenture to the 1991 Indenture, dated as of October 1, 1997 — Incorporated by reference to Exhibit 4(b) to MSD's Registration Statement on Form S-3 filed September 25, 1997 (No. 333-36383)
4.3	—	Second Supplemental Indenture to the 1991 Indenture, dated November 3, 2009 — Incorporated by reference to Exhibit 4.3 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No.1-6571)
4.4	—	Third Supplemental Indenture to the 1991 Indenture, dated May 1, 2012 — Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the period ended March 31, 2012 (No. 1-6571)
4.5	—	Indenture, dated November 26, 2003, between Merck & Co., Inc. (f/k/a Schering-Plough Corporation) and The Bank of New York as Trustee (the 2003 Indenture) — Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed November 28, 2003 (No. 1-6571)
4.6	—	Second Supplemental Indenture to the 2003 Indenture (including Form of Note), dated November 26, 2003 — Incorporated by reference to Exhibit 4.3 to Schering-Plough's Current Report on Form 8-K filed November 28, 2003 (No. 1-6571)
4.7	—	Third Supplemental Indenture to the 2003 Indenture (including Form of Note), dated September 17, 2007 — Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed September 17, 2007 (No. 1-6571)

Exhibit Number		Description
4.8	—	Fifth Supplemental Indenture to the 2003 Indenture, dated November 3, 2009 — Incorporated by reference to Exhibit 4.4 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
4.9	—	Indenture, dated as of January 6, 2010, between Merck & Co., Inc. and U.S. Bank Trust National Association, as Trustee — Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed December 10, 2010 (No. 1-6571)
4.10	—	Description of the Registrant's Common Stock
4.11	—	Description of the Registrant's 1.125% Notes due 2021, 1.875% Notes due 2026, and 2.500% Notes due 2034
4.12	—	Description of the Registrant's 0.500% Notes due 2024 and 1.375% Notes due 2036
*10.1	—	Merck & Co., Inc. Executive Incentive Plan (as amended and restated effective June 1, 2015) — Incorporated by reference to Merck & Co., Inc.'s Schedule 14A filed April 13, 2015 (No. 1-6571)
*10.2	—	Merck & Co., Inc. Deferral Program Including the Base Salary Deferral Plan (Amended and Restated effective December 1, 2019) - Incorporated by reference to Exhibit 10.2 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2019 filed February 26, 2020 (No. 1-6571)
*10.3	—	Merck & Co., Inc. 2010 Incentive Stock Plan (as amended and restated June 1, 2015) — Incorporated by reference to Merck & Co., Inc.'s Schedule 14A filed April 13, 2015 (No. 1-6571)
*10.4	—	Form of stock option terms for 2011 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.2 to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the period ended March 31, 2011 filed May 9, 2011 (No. 1-6571)
*10.5	—	Form of stock option terms for 2012 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.20 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2011 filed February 28, 2012 (No. 1-6571)
*10.6	—	Form of stock option terms for 2013 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.19 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2012 filed February 28, 2013 (No. 1-6571)
*10.7	—	Form of stock option terms for 2014 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.18 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2014 filed February 27, 2015 (No. 1-6571)
*10.8	—	Form of stock option terms for 2015 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.20 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2015 filed February 26, 2016 (No. 1-6571)
*10.9	—	Form of stock option terms for 2018 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by referent to Exhibit 10.12 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2017 filed February 27, 2018 (No. 1-6571)

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Exhibit Number		Description
*10.10	—	Form of stock option terms for 2016 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.19 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2016 filed February 28, 2017 (No. 1-6571)
*10.11	—	Form of restricted stock unit terms for 2018 quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.17 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2017 filed on February 28, 2018 (No. 1-6571)
*10.12	—	2018 Performance Share Unit Award Terms under the Merck & Co., Inc. 2010 Stock Incentive Plan — Incorporated by reference to Exhibit 10 to Merck & Co., Inc.'s Current Report on Form 10-Q Quarterly Report for the period ended March 31, 2018 filed May 8, 2018 (No. 1-6571)
*10.13	—	Merck & Co., Inc. 2019 Incentive Stock Plan - Incorporated by reference to Appendix C to Merck & Co., Inc.'s Schedule 14A filed April 8, 2019 (No. 1-6571)
*10.14	—	Merck & Co., Inc. Change in Control Separation Benefits Plan (effective as amended and restated, as of January 1, 2013) — Incorporated by reference to Exhibit 10.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 29, 2012 (No. 1-6571)
*10.15	—	Merck & Co., Inc. U.S. Separation Benefits Plan (amended and restated as of January 1, 2019) - Incorporated by reference to Exhibit 10.19 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2018 filed February 27, 2019 (No. 1-6571)
*10.16	—	Merck & Co., Inc. 2010 Non-Employee Directors Stock Option Plan (amended and restated as of December 1, 2010) — Incorporated by reference to Exhibit 10.17 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2010 filed February 28, 2011 (No. 1-6571)
*10.17	—	Retirement Plan for the Directors of Merck & Co., Inc. (amended and restated June 21, 1996) — Incorporated by reference to Exhibit 10.C to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1996 filed August 13, 1996 (No. 1-3305)
*10.18	—	Merck & Co., Inc. Plan for Deferred Payment of Directors' Compensation (Amended and Restated effective as of January 1, 2020) - Incorporated by reference to Exhibit 10.18 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2019 filed February 26, 2020 (No. 1-6571)
10.19	—	Distribution agreement between Schering-Plough and Centocor, Inc., dated April 3, 1998 — Incorporated by reference to Exhibit 10(u) to Schering-Plough's Amended 10-K for the year ended December 31, 2003 filed May 3, 2004 (No. 1-6571)†
10.20	—	Amendment Agreement to the Distribution Agreement between Centocor, Inc., CAN Development, LLC, and Schering-Plough (Ireland) Company — Incorporated by reference to Exhibit 10.1 to Schering-Plough's Current Report on Form 8-K filed December 21, 2007 (No. 1-6571)†
10.21	—	Severance Agreement and General Release between Merck & Co., Inc. and Adam H. Schechter, dated December 1, 2018 - Incorporated by reference to Exhibit 10.27 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2018 filed February 27, 2019 (No. 1-6571)
10.22	—	Offer Letter between Merck & Co., Inc. and Jennifer Zachary, dated March 16, 2018 - Incorporated by reference to Exhibit 10.28 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2018 filed February 27, 2019 (No. 1-6571)
*10.23	—	Form of stock option terms for 2021 annual non-qualified option grants under the Merck & Co., Inc. 2019 Incentive Stock Plan.
*10.24	—	Form of restricted stock unit terms for 2021 annual grants under the Merck & Co., Inc. 2019 Incentive Stock Plan.
21	—	Subsidiaries of Merck & Co., Inc.
23	—	Consent of Independent Registered Public Accounting Firm
24.1	—	Power of Attorney
24.2	—	Certified Resolution of Board of Directors

31.1	—	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
31.2	—	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer
32.1	—	Section 1350 Certification of Chief Executive Officer
32.2	—	Section 1350 Certification of Chief Financial Officer

Exhibit Number		Description
101.INS	—	XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	—	XBRL Taxonomy Extension Schema Document.
101.CAL	—	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	—	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	—	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	—	XBRL Taxonomy Extension Presentation Linkbase Document.
104	—	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* *Management contract or compensatory plan or arrangement.*

† *Certain portions of the exhibit have been omitted pursuant to a request for confidential treatment. The non-public information has been filed separately with the Securities and Exchange Commission pursuant to rule 24b-2 under the Securities Exchange Act of 1934, as amended.*

Long-term debt instruments under which the total amount of securities authorized does not exceed 10% of Merck & Co., Inc.'s total consolidated assets are not filed as exhibits to this report. Merck & Co., Inc. will furnish a copy of these agreements to the Securities and Exchange Commission on request.

Item 16. Form 10-K Summary

Not applicable.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: February 25, 2021

MERCK & CO., INC.

By: KENNETH C. FRAZIER
(Chairman, President and Chief

By: /s/ JENNIFER ZACHA
Jennifer Zachary
(Attorney-in-Fact)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signatures	Title	Date
KENNETH C. FRAZIER	Chairman, President and Chief Executive Officer; Principal Executive Officer; Director	February 25, 2021
ROBERT M. DAVIS	Executive Vice President, Global Services, and Chief Financial Officer; Principal Financial Officer	February 25, 2021
RITA A. KARACHUN	Senior Vice President Finance-Global Controller; Principal Accounting Officer	February 25, 2021
LESLIE A. BRUN	Director	February 25, 2021
THOMAS R. CECH	Director	February 25, 2021
MARY ELLEN COE	Director	February 25, 2021
PAMELA J. CRAIG	Director	February 25, 2021
THOMAS H. GLOCER	Director	February 25, 2021
RISA J. LAVIZZO-MOUREY	Director	February 25, 2021
PAUL B. ROTHMAN	Director	February 25, 2021
PATRICIA F. RUSSO	Director	February 25, 2021
CHRISTINE E. SEIDMAN	Director	February 25, 2021
INGE G. THULIN	Director	February 25, 2021
KATHY J. WARDEN	Director	February 25, 2021
PETER C. WENDELL	Director	February 25, 2021

Jennifer Zachary, by signing her name hereto, does hereby sign this document pursuant to powers of attorney duly executed by the persons named, filed with the Securities and Exchange Commission as an exhibit to this document, on behalf of such persons, all in the capacities and on the date stated, such persons including a majority of the directors of the Company.

By: /S/ JENNIFER ZACHARY
Jennifer Zachary
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As filed with the Securities and Exchange Commission on February 26, 2020

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549

FORM 10-K

(MARK ONE)

☒ **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the Fiscal Year Ended December 31, 2019

OR

☐ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the transition period from _____ to _____

Commission File No. 1-6571

Merck & Co., Inc.

2000 Galloping Hill Road
Kenilworth New Jersey 07033
(908) 740-4000

New Jersey	**22-1918501**
(State or other jurisdiction of incorporation)	(I.R.S Employer Identification No.)

Securities Registered pursuant to Section 12(b) of the Act:

Title of Each Class	*Trading Symbol(s)*	*Name of Each Exchange on which Registered*
Common Stock ($0.50 par value)	MRK	New York Stock Exchange
1.125% Notes due 2021	MRK/21	New York Stock Exchange
0.500% Notes due 2024	MRK 24	New York Stock Exchange
1.875% Notes due 2026	MRK/26	New York Stock Exchange
2.500% Notes due 2034	MRK/34	New York Stock Exchange
1.375% Notes due 2036	MRK 36A	New York Stock Exchange

Number of shares of Common Stock ($0.50 par value) outstanding as of January 31, 2020: 2,536,268,760.

Aggregate market value of Common Stock ($0.50 par value) held by non-affiliates on June 30, 2019 based on closing price on June 30, 2019: $215,106,000,000.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. **Yes** ☒ **No** ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. **Yes** ☐ **No** ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. **Yes** ☒ **No** ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). **Yes** ☒ **No** ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check One):

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). **Yes** ☐ **No** ☒

Documents Incorporated by Reference:

Document	*Part of Form 10-K*
Proxy Statement for the Annual Meeting of Shareholders to be held May 26, 2020, to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this report	Part III

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PART I

Item 1. Business.

Merck & Co., Inc. (Merck or the Company) is a global health care company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies and animal health products. The Company's operations are principally managed on a products basis and include four operating segments, which are the Pharmaceutical, Animal Health, Healthcare Services and Alliances segments.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities.

The Animal Health segment discovers, develops, manufactures and markets a wide range of veterinary pharmaceutical and vaccine products, as well as health management solutions and services, for the prevention, treatment and control of disease in all major livestock and companion animal species. The Company also offers an extensive suite of digitally connected identification, traceability and monitoring products. The Company sells its products to veterinarians, distributors and animal producers.

The Healthcare Services segment provides services and solutions that focus on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company has recently sold certain businesses in the Healthcare Services segment and is in the process of divesting the remaining businesses. While the Company continues to look for investment opportunities in this area of health care, the approach to these investments has shifted toward venture capital investments in third parties as opposed to wholly-owned businesses.

The Alliances segment primarily includes activity from the Company's relationship with AstraZeneca LP related to sales of Nexium and Prilosec, which concluded in 2018.

The Company was incorporated in New Jersey in 1970.

All product or service marks appearing in type form different from that of the surrounding text are trademarks or service marks owned, licensed to, promoted or distributed by Merck, its subsidiaries or affiliates, except as noted. All other trademarks or services marks are those of their respective owners.

Planned Spin-Off of Women's Health, Legacy Brands and Biosimilars into a New Company

In February 2020, Merck announced its intention to spin-off (the Spin-Off) products from its women's health, trusted legacy brands and biosimilars businesses into a new, yet-to-be-named, independent, publicly traded company (NewCo) through a distribution of NewCo's publicly traded stock to Company shareholders. The distribution is expected to qualify as tax-free to the Company and its shareholders for U.S. federal income tax purposes. The legacy brands included in the transaction consist of dermatology, pain, respiratory, and select cardiovascular products including *Zetia* and *Vytorin*, as well as the rest of Merck's diversified brands franchise. Merck's existing research pipeline programs will continue to be owned and developed within Merck as planned. NewCo will have development capabilities initially focused on late-stage development and life-cycle management, and is expected over time to develop research capabilities in selected therapeutic areas. The Spin-Off is expected to be completed in the first half of 2021, subject to market and certain other conditions. See "Risk Factors - Risks Related to the Proposed Spin-Off of NewCo."

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Product Sales

Total Company sales, including sales of the Company's top pharmaceutical products, as well as sales of animal health products, were as follows:

($ in millions)	**2019**	**2018**	2017
Total Sales	**$ 46,840**	**$ 42,294**	$ 40,122
Pharmaceutical	**41,751**	**37,689**	35,390
Keytruda	**11,084**	**7,171**	3,809
Januvia/Janumet	**5,524**	**5,914**	5,896
Gardasil/Gardasil 9	**3,737**	**3,151**	2,308
ProQuad/M-M-R II/*Varivax*	**2,275**	**1,798**	1,676
Bridion	**1,131**	**917**	704
Isentress/Isentress HD	**975**	**1,140**	1,204
Pneumovax 23	**926**	**907**	821
NuvaRing	**879**	**902**	761
Zetia/Vytorin	**874**	**1,355**	2,095
Simponi	**830**	**893**	819
Animal Health	**4,393**	**4,212**	3,875
Livestock	**2,784**	**2,630**	2,484
Companion Animals	**1,609**	**1,582**	1,391
Other Revenues[(1)]	**696**	**393**	857

[(1)] *Other revenues are primarily comprised of Healthcare Services segment revenue, third-party manufacturing sales, and miscellaneous corporate revenues, including revenue hedging activities.*

Pharmaceutical

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. Certain of the products within the Company's franchises are as follows:

Oncology

Keytruda (pembrolizumab), the Company's anti-PD-1 (programmed death receptor-1) therapy, as monotherapy for the treatment of certain patients with melanoma, non-small-cell lung cancer (NSCLC), small-cell lung cancer (SCLC), head and neck squamous cell carcinoma (HNSCC), classical Hodgkin Lymphoma (cHL), primary mediastinal large B-cell lymphoma (PMBCL), urothelial carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient cancer, gastric or gastroesophageal junction adenocarcinoma, esophageal cancer, cervical cancer, hepatocellular carcinoma, and merkel cell carcinoma. *Keytruda* is also used for the treatment of certain patients in combination with chemotherapy for metastatic squamous and non-squamous NSCLC, in combination with chemotherapy for HNSCC, in combination with axitinib for renal cell carcinoma, and in combination with lenvatinib for endometrial carcinoma; and *Emend* (aprepitant) for the prevention of chemotherapy-induced and post-operative nausea and vomiting. In addition, the Company recognizes alliance revenue related to sales of Lynparza (olaparib), an oral poly (ADP-ribose) polymerase (PARP) inhibitor, for certain types of advanced ovarian, breast and pancreatic cancers; and Lenvima (lenvatinib) for certain types of thyroid cancer, hepatocellular carcinoma, in combination with everolimus for certain patients with renal cell carcinoma, and in combination with *Keytruda* for certain patients with endometrial carcinoma.

Vaccines

Gardasil (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant)/ *Gardasil* 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), vaccines to help prevent certain diseases caused by certain types of human papillomavirus (HPV); *ProQuad* (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella; *M-M-R* II (Measles, Mumps and Rubella Virus Vaccine Live), a vaccine to help prevent measles, mumps and rubella; *Varivax* (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox (varicella); *Pneumovax* 23 (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease; *RotaTeq* (Rotavirus Vaccine, Live Oral,

Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children; and *Vaqta* (hepatitis A vaccine, inactivated) indicated for the prevention of disease caused by hepatitis A virus in persons 12 months of age and older.

Hospital Acute Care

Bridion (sugammadex) Injection, a medication for the reversal of two types of neuromuscular blocking agents used during surgery; *Noxafil* (posaconazole) for the prevention of invasive fungal infections; *Primaxin* (imipenem and cilastatin sodium) an anti-bacterial product; *Invanz* (ertapenem sodium) for the treatment of certain infections; *Cubicin* (daptomycin for injection), an I.V. antibiotic for complicated skin and skin structure infections or bacteremia, when caused by designated susceptible organisms; *Cancidas* (caspofungin acetate), an anti-fungal product; and *Prevymis* (letermovir) for the prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant.

Immunology

Simponi (golimumab), a once-monthly subcutaneous treatment for certain inflammatory diseases; and *Remicade* (infliximab), a treatment for inflammatory diseases, which the Company markets in Europe, Russia and Turkey.

Neuroscience

Belsomra (suvorexant), an orexin receptor antagonist indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

Virology

Isentress/Isentress HD (raltegravir), an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection; and *Zepatier* (elbasvir and grazoprevir) for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype (GT) 1 or GT4 infection, with ribavirin in certain patient populations.

Cardiovascular

Zetia (ezetimibe) (marketed as *Ezetrol* in most countries outside the United States); *Vytorin* (ezetimibe/simvastatin) (marketed as *Inegy* outside the United States); *Atozet* (ezetimibe and atorvastatin) (marketed outside of the United States) and *Rosuzet* (ezetimibe and rosuvastatin) (marketed outside of the United States), cholesterol modifying medicines; and Adempas (riociguat), a cardiovascular drug for the treatment of pulmonary arterial hypertension.

Diabetes

Januvia (sitagliptin) and *Janumet* (sitagliptin/metformin HCl) for the treatment of type 2 diabetes.

Women's Health

NuvaRing (etonogestrel/ethinyl estradiol vaginal ring), a vaginal contraceptive product; and *Implanon* (etonogestrel implant), a single-rod subdermal contraceptive implant/*Nexplanon* (etonogestrel implant), a single, radiopaque, rod-shaped subdermal contraceptive implant.

Animal Health

The Animal Health segment discovers, develops, manufactures and markets a wide range of veterinary pharmaceuticals, vaccines and health management solutions and services, as well as an extensive suite of digitally connected identification, traceability and monitoring products. Principal products in this segment include:

Livestock Products

Nuflor (Florfenicol) antibiotic range for use in cattle and swine; *Bovilis*/*Vista* vaccine lines for infectious diseases in cattle; *Banamine* (Flunixin meglumine) bovine and swine anti-inflammatory; *Estrumate* (cloprostenol sodium) for the treatment of fertility disorders in cattle; *Matrix* (altrenogest) fertility management for swine; *Resflor* (florfenicol and flunixin meglumine), a combination broad-spectrum antibiotic and non-steroidal anti-inflammatory drug for bovine respiratory disease; *Zuprevo* (Tildipirosin) for bovine respiratory disease; *Zilmax* (zilpaterol hydrochloride) and *Revalor* (trenbolone acetate and estradiol) to improve production efficiencies in beef cattle; *Safe-Guard* (fenbendazole) de-wormer for cattle; *M+Pac* (Mycoplasma Hyopneumoniae Bacterin) swine pneumonia vaccine; *Porcilis* (Lawsonia intracellularis baterin) and *Circumvent* (Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector) vaccine lines for infectious diseases in swine; *Nobilis*/*Innovax* (Live Marek's Disease Vector), vaccine lines for poultry; *Paracox* and *Coccivac* coccidiosis vaccines; *Exzolt*, a systemic treatment for poultry red mite infestations; *Slice* (Emamectin benzoate) parasiticide for sea lice in salmon; *Aquavac* (Avirulent Live Culture)/*Norvax* vaccines against bacterial and viral disease in fish; *Compact PD* vaccine for salmon; *Aquaflor* (Florfenicol) antibiotic for farm-raised fish; and *Allflex Livestock Intelligence* solutions for animal identification, monitoring and traceability.

Companion Animal Products

Bravecto (fluralaner), a line of oral and topical parasitic control products for dogs and cats that last up to 12 weeks; *Nobivac* vaccine lines for flexible dog and cat vaccination; *Otomax* (Gentamicin sulfate, USP; Betamethasone valerate USP; and Clotrimazole USP ointment)/*Mometamax* (Gentamicin sulfate, USP, Mometasone Furoate Monohydrate and Clotrimazole, USP, Otic Suspension)/*Posatex* (Orbifloxacin, Mometasone Furoate Monohydrate and Posaconazole, Suspension) ear ointments for acute and chronic otitis; *Caninsulin*/*Vetsulin* (porcine insulin zinc suspension) diabetes mellitus treatment for dogs and cats; *Panacur* (fenbendazole)/*Safeguard* (fenbendazole) broad-spectrum anthelmintic (de-wormer) for use in many animals; *Regumate* (altrenogest) fertility management for horses; *Prestige* vaccine line for horses; and *Scalibor* (Deltamethrin)/*Exspot* for protecting against bites from fleas, ticks, mosquitoes and sandflies.

For a further discussion of sales of the Company's products, see Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" below.

2019 Product Approvals

Set forth below is a summary of significant product approvals received by the Company in 2019.

Product	Date	Approval
Ervebo	December 2019	The U.S. Food and Drug Administration (FDA) approved *Ervebo* for the prevention of disease caused by *Zaire ebolavirus* in individuals 18 years of age and older.
	November 2019	The European Commission (EC) granted a conditional marketing authorization for *Ervebo* for active immunization of individuals 18 years of age or older to protect against Ebola Virus Disease caused by Zaire Ebola virus.
Keytruda	December 2019	The Japanese Ministry of Health, Labour and Welfare (MHLW) approved *Keytruda* for three new first-line indications across advanced renal cell carcinoma (RCC) and recurrent or distant metastatic head and neck cancer.
	November 2019	EC approved two new regimens of *Keytruda* as first-line treatment for metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC).
	November 2019	The China National Medical Products Administration (NMPA) approved *Keytruda* for first-line treatment of metastatic squamous non-small cell lung cancer (NSCLC) in combination with chemotherapy.
	October 2019	NMPA approved *Keytruda* as monotherapy for first-line treatment of certain patients with advanced NSCLC whose tumors express PD-L1.
	September 2019	FDA approved *Keytruda* plus Lenvima combination treatment for patients with certain types of endometrial carcinoma.
	September 2019	EC approved *Keytruda* in combination with axitinib as first-line treatment for patients with advanced RCC.
	July 2019	FDA approved *Keytruda* for recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus in patients whose tumors express PD-L1 combined positive score [CPS] (CPS ≥10) with disease progression after one of more prior lines of systemic therapy.

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Keytruda	June 2019	FDA approved *Keytruda* as monotherapy for patients with metastatic small-cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy.
	June 2019	FDA approved two indications for *Keytruda* for first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC as monotherapy for patients whose tumors express PD-L1 CPS ≥1 or in combination with platinum and fluorouracil regardless of PD-L1 expression.
	April 2019	FDA approved *Keytruda* in combination with axitinib for first-line treatment of patients with advanced RCC.
	April 2019	FDA approved an expanded label for *Keytruda* as monotherapy for the first-line treatment of patients with stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC, and whose tumors express PD-L1 (tumor proportion score [TPS] ≥1%) as determined by an FDA-approved test, with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase positive (ALK) genomic tumor aberrations.
	April 2019	EC approved new extended dosing schedule for *Keytruda* for all approved monotherapy indications.
	April 2019	NMPA approved *Keytruda* for first-line treatment of metastatic nonsquamous NSCLC in combination with chemotherapy.
	March 2019	EC approved *Keytruda* in combination with chemotherapy for first-line treatment of adults with metastatic squamous NSCLC.
	February 2019	FDA approved *Keytruda* for the adjuvant treatment of patients with melanoma with involvement of lymph node(s) following complete resection.
	January 2019	MHLW approved *Keytruda* for five indications, including three expanded uses in advanced NSCLC, one in melanoma, as well as a new indication in advanced microsatellite instability-high tumors.
Lynparza[(1)]	December 2019	FDA approved Lynparza for first-line maintenance therapy for patients with germline *BRCA*-mutated (g*BRCA*-m) metastatic pancreatic cancer whose disease has not progressed for at least 16 weeks of a first-line, platinum-based chemotherapy regimen.
	December 2019	NMPA approved Lynparza as a first-line maintenance therapy in *BRCA*-m advanced ovarian cancer.
	July 2019	EC approved Lynparza as monotherapy for the maintenance treatment of adult patients with advanced *BRCA*-m, high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer.
	June 2019	MHLW approved Lynparza as first-line maintenance therapy in patients with *BRCA*-m advanced ovarian cancer.
	June 2019	EC approved Lynparza for use as first-line maintenance therapy in patients with *BRCA*-m advanced ovarian cancer.
	April 2019	EC approved Lynparza for the treatment of g*BRCA*-m HER2-negative advanced breast cancer.
Pifeltro and *Delstrigo*	September 2019	FDA approved supplemental New Drug Applications (sNDAs) for *Pifeltro* (doravirine) in combination with other antiretroviral agents, and *Delstrigo* (doravirine, lamivudine, and tenofovir disoproxil fumarate) as a complete regimen, for use in appropriate adults with HIV-1 infection who are virologically suppressed on a stable antiretroviral regimen.

Recarbrio	July 2019	FDA approved *Recarbrio* (imipenem, cilastatin, and relebactam) for the treatment of adults with complicated urinary tract and complicated intra-abdominal bacterial infections where limited or no alternative treatment options are available.
Zerbaxa	August 2019	EC approved *Zerbaxa* for the treatment of adults with hospital-acquired pneumonia, including ventilator-associated pneumonia (to be used in combination with an antibacterial agent active against Gram-positive pathogens when these are known or suspected to be contributing to the infectious process.)
	June 2019	FDA approved *Zerbaxa* 3g dose for the treatment of patients 18 years and older with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP).
Bravecto	November 2019	FDA approved *Bravecto Plus* topical solution for cats indicated for both external and internal parasite infestations.

(1) *In July 2017, Merck and AstraZeneca entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza.*

Competition and the Health Care Environment

Competition

The markets in which the Company conducts its business and the pharmaceutical industry in general are highly competitive and highly regulated. The Company's competitors include other worldwide research-based pharmaceutical companies, smaller research companies with more limited therapeutic focus, generic drug manufacturers and animal health care companies. The Company's operations may be adversely affected by generic and biosimilar competition as the Company's products mature, as well as technological advances of competitors, industry consolidation, patents granted to competitors, competitive combination products, new products of competitors, the generic availability of competitors' branded products, and new information from clinical trials of marketed products or post-marketing surveillance. In addition, patent rights are increasingly being challenged by competitors, and the outcome can be highly uncertain. An adverse result in a patent dispute can preclude commercialization of products or negatively affect sales of existing products and could result in the payment of royalties or in the recognition of an impairment charge with respect to intangible assets associated with certain products. Competitive pressures have intensified as pressures in the industry have grown.

Pharmaceutical competition involves a rigorous search for technological innovations and the ability to market these innovations effectively. With its long-standing emphasis on research and development, the Company is well-positioned to compete in the search for technological innovations. Additional resources required to meet market challenges include quality control, flexibility to meet customer specifications, an efficient distribution system and a strong technical information service. The Company is active in acquiring and marketing products through external alliances, such as licensing arrangements and collaborations, and has been refining its sales and marketing efforts to address changing industry conditions. However, the introduction of new products and processes by competitors may result in price reductions and product displacements, even for products protected by patents. For example, the number of compounds available to treat a particular disease typically increases over time and can result in slowed sales growth or reduced sales for the Company's products in that therapeutic category.

The highly competitive animal health business is affected by several factors including regulatory and legislative issues, scientific and technological advances, product innovation, the quality and price of the Company's products, effective promotional efforts and the frequent introduction of generic products by competitors.

Health Care Environment and Government Regulation

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access. In the United States, federal and state governments for many years also have pursued methods to reduce the cost of drugs and vaccines for which they pay. For example, federal laws require the Company to pay specified rebates for medicines reimbursed by Medicaid and to provide discounts for outpatient medicines purchased by certain Public Health Service entities and hospitals serving a disproportionate share of low income or uninsured patients.

Against this backdrop, the United States enacted major health care reform legislation in 2010 (the Patient Protection and Affordable Care Act (ACA)). Various insurance market reforms have since advanced and state and federal insurance exchanges were launched in 2014. With respect to the effect of the law on the pharmaceutical industry, the law increased the mandated Medicaid rebate from 15.1% to 23.1%, expanded the rebate to Medicaid managed care utilization, and increased the types of entities eligible for the federal 340B drug discount program. The law also required pharmaceutical manufacturers to pay a 50% point of service discount to Medicare Part D beneficiaries when they are in the Medicare Part D coverage gap (i.e., the so-called "donut hole"). As a result of the Balanced Budget Act of 2018 and effective at the beginning of 2019, the 50% point of service discount increased to a 70% point of service discount in the coverage gap. In addition, this point of service discount was extended to biosimilar products. Merck recorded a reduction to revenue of approximately $615 million, $365 million and $385 million in 2019, 2018 and 2017, respectively, related to the donut hole provision. Also, pharmaceutical manufacturers are required to pay an annual non-tax deductible health care reform fee. The total annual industry fee was $4.1 billion in 2018 and decreased to $2.8 billion in 2019 and is expected to remain at that amount for 2020. The fee is assessed on each company in proportion to its share of prior year branded pharmaceutical sales to certain government programs, such as Medicare and Medicaid. The Company recorded $112 million, $124 million and $210 million of costs within *Selling, general and administrative* expenses in 2019, 2018 and 2017, respectively, for the annual health care reform fee. In February 2016, the Centers for Medicare & Medicaid Services (CMS) issued the Medicaid rebate final rule that implements provisions of the ACA effective April 1, 2016. The rule provides comprehensive guidance on the calculation of Average Manufacturer Price and Best Price; two metrics utilized to determine the rebates drug manufacturers are required to pay to state Medicaid programs. The impact of changes resulting from the issuance of the rule is not material to Merck at this time. However, the Company is still awaiting guidance from CMS on two aspects of the rule that were deferred for later implementation. These include a definition of what constitutes a product 'line extension' and a delay in the participation of the U.S. Territories in the Medicaid Drug Rebate Program until April 1, 2022. The Company will evaluate the financial impact of these two elements when they become effective.

There is significant uncertainty about the future of the ACA in particular and health care laws in general in the United States. The Company is participating in the debate, and monitoring how any proposed changes could affect its business. The Company is unable to predict the likelihood of changes to the ACA. Depending on the nature of any repeal and replacement of the ACA, such actions could have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects.

A number of states have passed pharmaceutical price and cost transparency laws. These laws typically require manufacturers to report certain product price information or other financial data to the state. Some laws also require manufacturers to provide advance notification of price increases. The Company expects that states will continue their focus on pharmaceutical price transparency and that this focus will continue to exert pressure on product pricing.

The Company also faces increasing pricing pressure globally from managed care organizations, government agencies and programs that could negatively affect the Company's sales and profit margins. In the United States, these include (i) practices of managed care organizations, federal and state exchanges, and institutional and governmental purchasers, and (ii) U.S. federal laws and regulations related to Medicare and Medicaid, including the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and the ACA.

Changes to the health care system enacted as part of health care reform in the United States, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, could result in further pricing pressures. As an example, health care reform is contributing to an increase in the number of patients in the Medicaid program under which sales of pharmaceutical products are subject to substantial rebates.

The pharmaceutical industry could be considered a potential source of savings via legislative proposals that have been debated but not enacted. These types of revenue generating or cost saving proposals include additional direct price controls. In addition, Congress and/or the administration may again consider proposals to allow international reference pricing or, under certain conditions, the importation of medicines from other countries.

The administration has recently proposed a draft rule that would allow importation of certain lower-cost prescription drugs from Canada. If the rule is finalized as proposed, states or certain other non-federal governmental entities would be able to submit importation program proposals to the FDA for review and authorization of two-year programs (with the opportunity to extend for two more years). There will be a public comment period on the proposed rule which will expire on March 9, 2020. Following the comment period, the FDA will have to review and finalize its

proposal before any states or other parties can submit their plans to comply with the federal rule. If the proposed rule is adopted, it likely will be some time before states or other parties can actually implement importation plans.

In October 2018, the administration also issued an advance notice of proposed rulemaking to implement an "International Pricing Index" (IPI) model in the United States for products covered under Medicare Part B. The proposal would: (1) reduce Medicare Part B payments for drugs based on a market basket of international prices; (2) allow private sector vendors to negotiate prices for drugs, take title to drugs, and compete for physician and hospital business; and (3) change the physician reimbursement under Medicare Part B from the current model to eliminate the buy and bill system and instead pay physicians based on a flat fee that approximates the revenue they currently receive from drugs. Public comments on the IPI proposal were accepted through late 2018 and it is unclear when the agency may issue a proposed rule on the IPI model. Adoption of one or both of the proposed rules could have a material adverse effect on the Company's business, results of operations and financial condition.

It remains uncertain as to what proposals, if any, may be included as part of future federal legislative proposals that would directly or indirectly affect the Company.

In the U.S. private sector, consolidation and integration among health care providers is a major factor in the competitive marketplace for pharmaceutical products. Health plans and pharmacy benefit managers have been consolidating into fewer, larger entities, thus enhancing their purchasing strength and importance. Private third-party insurers, as well as governments, increasingly employ formularies to control costs by negotiating discounted prices in exchange for formulary inclusion. Failure to obtain timely or adequate pricing or formulary placement for Merck's products or obtaining such placement at unfavorable pricing could adversely impact revenue. In addition to formulary tier co-pay differentials, private health insurance companies and self-insured employers have been raising co-payments required from beneficiaries, particularly for branded pharmaceuticals and biotechnology products. Private health insurance companies also are increasingly imposing utilization management tools, such as clinical protocols, requiring prior authorization for a branded product if a generic product is available or requiring the patient to first fail on one or more generic products before permitting access to a branded medicine. These same management tools are also used in treatment areas in which the payer has taken the position that multiple branded products are therapeutically comparable. As the U.S. payer market concentrates further and as more drugs become available in generic form, pharmaceutical companies may face greater pricing pressure from private third-party payers.

In order to provide information about the Company's pricing practices, the Company annually posts on its website its Pricing Transparency Report for the United States. The report provides the Company's average annual list price, net price increases, and average discounts across the Company's U.S. portfolio dating back to 2010. In 2019, the Company's gross U.S. sales were reduced by approximately 44% as a result of rebates, discounts and returns.

Efforts toward health care cost containment also remain intense in European countries. The Company faces competitive pricing pressure resulting from generic and biosimilar drugs. In addition, a majority of countries in Europe attempt to contain drug costs by engaging in reference pricing in which authorities examine pre-determined markets for published prices of drugs by brand. The authorities then use price data from those markets to set new local prices for brand-name drugs, including the Company's drugs. Guidelines for examining reference pricing are usually set in local markets and can be changed pursuant to local regulations.

In addition, in Japan, the pharmaceutical industry is subject to government-mandated biennial price reductions of pharmaceutical products and certain vaccines, which occurred in 2018 and will occur again in 2020. Furthermore, the government can order re-pricings for specific products if it determines that use of such product will exceed certain thresholds defined under applicable re-pricing rules. Pursuant to those rules, the Japanese government reduced the price of *Keytruda* by 17.5% effective February 2020. Additionally, *Keytruda* will be subject to another significant price reduction in April 2020 under a provision of the Japanese pricing rules.

The Company's business in China has grown rapidly in the past few years, and the importance of China to the Company's overall pharmaceutical and vaccines business has increased accordingly. Continued growth of the Company's business in China is dependent upon ongoing development of a favorable environment for innovative pharmaceutical products and vaccines, sustained access for the Company's current in-line products, and the absence of trade impediments or adverse pricing controls. In recent years, the Chinese government has introduced and implemented a number of structural reforms to accelerate the shift to innovative products and reduce costs. Since 2017, there have been multiple new policies introduced by the government to improve access to new innovation, reduce the

complexity of regulatory filings, and accelerate the review and approval process. This has led to a significant increase in the number of new products being approved each year. Additionally, in 2017, the Chinese government updated the National Reimbursement Drug List for the first time in eight years. While the mechanism for drugs being added to the list evolves, inclusion may require a price negotiation which could impact the outlook in the market for selected brands. In 2019, drugs were added through two pathways, direct inclusion and price negotiations. For price negotiations, price reductions of approximately 60% on average were required for inclusion. While pricing pressure has always existed in China, health care reform has increased this pressure in part due to the acceleration of generic substitution through volume based procurement (VBP). In 2019, the government implemented the VBP program through a tendering process for mature products which have generic substitutes with a Generic Quality Consistency Evaluation approval. Mature products that have entered into the first two rounds of VBP have had, on average, a price reduction of 50%. The expansion of the VBP program remains to be seen.

The Company's focus on emerging markets, in addition to China, has continued. Governments in many emerging markets are also focused on constraining health care costs and have enacted price controls and related measures, such as compulsory licenses, that aim to put pressure on the price of pharmaceuticals and constrain market access. The Company anticipates that pricing pressures and market access challenges will continue in 2020 to varying degrees in the emerging markets, including China.

Certain markets outside of the United States have also implemented other cost management strategies, such as health technology assessments (HTA). Examples include the UK, France, Germany, Ireland, Italy and Sweden. The HTA process is the procedure according to which the assessment of the public health impact, therapeutic impact, and the economic and social impact of use of a given medicinal product in the national health care system of the individual country is conducted. HTAs generally focus on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual medicinal products as well as their potential implications for the health care system. Those elements of medicinal products are compared with other treatment options available on the market. The outcome of HTAs will often influence the pricing and reimbursement status granted to medicinal products by the regulatory authorities of individual European Union (EU) Member States. A negative HTA of one of the Company's products by a leading and recognized HTA body could undermine the Company's ability to obtain reimbursement for such product in the EU Member State in which such negative assessment was issued, and also in other EU Member States. HTA procedures require additional data, reviews and administrative processes, all of which increase the complexity, timing and costs of obtaining product reimbursement and exert downward pressure on available reimbursement. In the United States, HTAs are also being used by government and private payers.

Beyond pricing and market access challenges, other conditions in emerging market countries can affect the Company's efforts to continue to grow in these markets, including potential political instability, changes in trade sanctions and embargoes, significant currency fluctuation and controls, financial crises, limited or changing availability of funding for health care, and other developments that may adversely impact the business environment for the Company. Further, the Company may engage third-party agents to assist in operating in emerging market countries, which may affect its ability to realize continued growth and may also increase the Company's risk exposure.

In addressing cost containment pressures, the Company engages in public policy advocacy with policymakers and continues to work to demonstrate that its medicines provide value to patients and to those who pay for health care. The Company advocates with government policymakers to encourage a long-term approach to sustainable health care financing that ensures access to innovative medicines and does not disproportionately target pharmaceuticals as a source of budget savings. In markets with historically low rates of health care spending, the Company encourages those governments to increase their investments and adopt market reforms in order to improve their citizens' access to appropriate health care, including medicines.

Operating conditions have become more challenging under the global pressures of competition, industry regulation and cost containment efforts. Although no one can predict the effect of these and other factors on the Company's business, the Company continually takes measures to evaluate, adapt and improve the organization and its business practices to better meet customer needs and believes that it is well-positioned to respond to the evolving health care environment and market forces.

The pharmaceutical industry is also subject to regulation by regional, country, state and local agencies around the world focused on standards and processes for determining drug safety and effectiveness, as well as conditions for sale or reimbursement.

Of particular importance is the FDA in the United States, which administers requirements covering the testing, approval, safety, effectiveness, manufacturing, labeling, and marketing of prescription pharmaceuticals. In some cases, the FDA requirements and practices have increased the amount of time and resources necessary to develop new products and bring them to market in the United States. At the same time, the FDA has committed to expediting the development and review of products bearing the "breakthrough therapy" designation, which has accelerated the regulatory review process for medicines with this designation. The FDA has also undertaken efforts to bring generic competition to market more efficiently and in a more timely manner.

The EU has adopted directives and other legislation concerning the classification, labeling, advertising, wholesale distribution, integrity of the supply chain, enhanced pharmacovigilance monitoring and approval for marketing of medicinal products for human use. These provide mandatory standards throughout the EU, which may be supplemented or implemented with additional regulations by the EU member states. In particular, EU regulators may approve products subject to a number of post-authorization conditions. Examples of typical post-authorization commitments include additional pharmacovigilance, the conduct of clinical trials, the establishment of patient registries, physician or patient education and controlled distribution and prescribing arrangements. Non-compliance with post-authorization conditions, pharmacovigilance and other obligations can lead to regulatory action, including the variation, suspension or withdrawal of the marketing authorizations, or other enforcement or regulatory actions, including the imposition of financial penalties. The Company's policies and procedures are already consistent with the substance of these directives; consequently, it is believed that they will not have any material effect on the Company's business.

The Company believes that it will continue to be able to conduct its operations, including launching new drugs, in this regulatory environment. (See "Research and Development" below for a discussion of the regulatory approval process.)

Access to Medicines

As a global health care company, Merck's primary role is to discover and develop innovative medicines and vaccines. The Company also recognizes that it has an important role to play in helping to improve access to its medicines, vaccines, and to quality health care around the world. The Company's efforts in this regard are wide-ranging and include a set of principles that the Company strives to embed into its operations and business strategies to guide the Company's worldwide approach to expanding access to health care. In addition, through innovative social investments, including philanthropic programs and impact investing, Merck is also helping to strengthen health systems and build capacity, particularly in under-resourced communities. The Merck Patient Assistance Program provides medicines and adult vaccines for free to people in the United States who do not have prescription drug or health insurance coverage and who, without the Company's assistance, cannot afford their Merck medicines and vaccines. In 2011, Merck launched "Merck for Mothers," a long-term effort with global health partners to end preventable deaths from complications of pregnancy and childbirth. Merck has also provided funds to the Merck Foundation, an independent grantmaking organization, which has partnered with a variety of organizations dedicated to improving global health.

Privacy and Data Protection

The Company is subject to a significant number of privacy and data protection laws and regulations globally, many of which place restrictions on the Company's ability to transfer, access and use personal data across its business. The legislative and regulatory landscape for privacy and data protection continues to evolve. There has been increased attention to privacy and data protection issues in both developed and emerging markets with the potential to affect directly the Company's business, including both the EU General Data Protection Regulation, which went into effect on May 25, 2018 and imposes penalties of up to 4% of global revenue, and the California Consumer Privacy Act, which became effective January 1, 2020. Additional laws and regulations enacted in the United States, Europe, Asia and Latin America, increased enforcement and litigation activity in the United States and other developed markets, and increased regulatory cooperation among privacy authorities globally. The Company has adopted a comprehensive global privacy program to manage these evolving risks which has been certified as compliant with and approved by the Asia Pacific Economic Cooperation Cross-Border Privacy Rules System, the EU-U.S. and Swiss-U.S. Privacy Shield Programs, and the Binding Corporate Rules in the EU.

Distribution

The Company sells its human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers, such as health maintenance organizations, pharmacy

benefit managers and other institutions. Human health vaccines are sold primarily to physicians, wholesalers, physician distributors and government entities. The Company's professional representatives communicate the effectiveness, safety and value of the Company's pharmaceutical and vaccine products to health care professionals in private practice, group practices, hospitals and managed care organizations. The Company sells its animal health products to veterinarians, distributors and animal producers.

Raw Materials

Raw materials and supplies, which are generally available from multiple sources, are purchased worldwide and are normally available in quantities adequate to meet the needs of the Company's business.

Patents, Trademarks and Licenses

Patent protection is considered, in the aggregate, to be of material importance to the Company's marketing of its products in the United States and in most major foreign markets. Patents may cover products *per se*, pharmaceutical formulations, processes for, or intermediates useful in, the manufacture of products, or the uses of products. Protection for individual products extends for varying periods in accordance with the legal life of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent and its scope of coverage.

The Food and Drug Administration Modernization Act includes a Pediatric Exclusivity Provision that may provide an additional six months of market exclusivity in the United States for indications of new or currently marketed drugs if certain agreed upon pediatric studies are completed by the applicant. Current U.S. patent law provides additional patent term for periods when the patented product was under regulatory review by the FDA. The EU also provides an additional six months of pediatric market exclusivity attached to a product's Supplementary Protection Certificate (SPC). Japan provides the additional term for pediatric studies attached to market exclusivity unrelated to patent term.

Patent portfolios developed for products introduced by the Company normally provide market exclusivity. The Company has the following key patent protection in the United States, the EU, Japan and China (including the potential for patent term extensions (PTE) and SPCs where indicated) for the following marketed products:

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Product	Year of Expiration (U.S.)	Year of Expiration (EU)[1]	Year of Expiration (Japan)[2]	Year of Expiration (China)
Emend for Injection	Expired	2020[3]	2020	N/A
Januvia	2022[3]	2022[3]	2025-2026	2022
Janumet	2022[3]	2023	N/A	2022
Janumet XR	2022[3]	N/A	N/A	2022
Isentress	2024	2023[3]	2022-2026	2022
Simponi	N/A[4]	2024[5]	N/A[4]	N/A[4]
Lenvima[6]	2025[3] (with pending PTE)	2021 (patents), 2026[3] (SPCs)	2026	2021
Adempas[7]	2026[3]	2028[3]	2027-2028	2023
Bridion	2026[3] (with pending PTE)	2023	2024	2020
Nexplanon	2027 (device)	2025 (device)	Not Marketed	2025
Bravecto	2027 (with pending PTE)	2025 (patents), 2029 (SPCs)	2029	2033
Gardasil	2028	2021[3]	Expired	N/A
Gardasil 9	2028	2025 (patents), 2030[3] (SPCs)	N/A	2025
Keytruda	2028	2028 (patents), 2030[3] (SPCs)	2032-2033	2028
Lynparza[8]	2028[3] (with pending PTE)	2024 (patents), 2029[3] (SPCs)	2028-2029	2024
Zerbaxa	2028[3]	2023 (patents), 2028[3] (SPCs)	2028 (with pending PTE)	N/A
Belsomra	2029[3]	N/A	2031	N/A
Prevymis	2029[3] (with pending PTE)	2024 (patents), 2029[3] (SPCs)	2029	N/A
Steglatro[9]	2031[3] (with pending PTE)	2029 (patents), 2034[3] (SPCs)	N/A	2029
Steglujan[9]	2031 (with pending PTE)	2029 (patents), 2034 (SPCs)	N/A	2029
Segluromet[9]	2031 (with pending PTE)	2029 (patents), 2034 (SPCs)	N/A	2029
Delstrigo	2032 (with pending PTE)	2031 (patents), 2033 (SPCs)	N/A	N/A
Pifeltro	2032 (with pending PTE)	2031 (patents), 2033 (SPCs)	N/A	N/A
Recarbrio	2033[3] (with pending PTE)	N/A	N/A	N/A

Note: Compound patent unless otherwise noted. Certain of the products listed may be the subject of patent litigation. See Item 8. "Financial Statements and Supplementary Data," Note 10. "Contingencies and Environmental Liabilities" below.

N/A: Currently no marketing approval.

(1) *The EU date represents the expiration date for the following five countries: France, Germany, Italy, Spain and the United Kingdom (Major EU Markets). If SPC applications have been filed but have not been granted in all Major EU Markets, both the patent expiry date and the SPC expiry date are listed.*

(2) *The PTE system in Japan allows for a patent to be extended more than once provided the later approval is directed to a different indication from that of the previous approval. This may result in multiple PTE approvals for a given patent, each with its own expiration date.*

(3) *Eligible for 6 months Pediatric Exclusivity.*

(4) *The Company has no marketing rights in the U.S., Japan or China.*

(5) *Expiration of the distribution agreement with Janssen Pharmaceuticals, Inc.*

(6) *Part of a global strategic oncology collaboration with Eisai.*

(7) *Being commercialized in a worldwide collaboration with Bayer AG.*

(8) *Part of a global strategic oncology collaboration with AstraZeneca.*

(9) *Being commercialized and promoted in a worldwide, except Japan, collaboration with Pfizer Inc.*

The Company also has the following key U.S. patent protection for drug candidates in Phase 3 development:

Phase 3 Drug Candidate	Currently Anticipated Year of Expiration (in the U.S.)
MK-7264 (gefapixant)	2027
MK-1242 (vericiguat)[1]	2031
V114 (pneumoconjugate vaccine)	2031
MK-8591A (islatravir/doravirine)	2032

[1] *Being developed in a worldwide collaboration with Bayer AG.*

Unless otherwise noted, the patents in the above charts are compound patents. Each patent may be subject to a future patent term restoration of up to five years and six month pediatric market exclusivity, either or both of which may be available. In addition, depending on the circumstances surrounding any final regulatory approval of the compound, there may be other listed patents or patent applications pending that could have relevance to the product as finally approved; the relevance of any such application would depend upon the claims that ultimately may be granted and the nature of the final regulatory approval of the product. Also, regulatory exclusivity tied to the protection of clinical data is complementary to patent protection and, in some cases, may provide more effective or longer lasting marketing exclusivity than a compound's patent estate. In the United States, the data protection generally runs five years from first marketing approval of a new chemical entity, extended to seven years for an orphan drug indication and 12 years from first marketing approval of a biological product.

While the expiration of a product patent normally results in a loss of market exclusivity for the covered pharmaceutical product, commercial benefits may continue to be derived from: (i) later-granted patents on processes and intermediates related to the most economical method of manufacture of the active ingredient of such product; (ii) patents relating to the use of such product; (iii) patents relating to novel compositions and formulations; and (iv) in the United States and certain other countries, market exclusivity that may be available under relevant law. The effect of product patent expiration on pharmaceutical products also depends upon many other factors such as the nature of the market and the position of the product in it, the growth of the market, the complexities and economics of the process for manufacture of the active ingredient of the product and the requirements of new drug provisions of the Federal Food, Drug and Cosmetic Act or similar laws and regulations in other countries.

Additions to market exclusivity are sought in the United States and other countries through all relevant laws, including laws increasing patent life. Some of the benefits of increases in patent life have been partially offset by an increase in the number of incentives for and use of generic products. Additionally, improvements in intellectual property laws are sought in the United States and other countries through reform of patent and other relevant laws and implementation of international treaties.

For further information with respect to the Company's patents, see Item 1A. "Risk Factors" and Item 8. "Financial Statements and Supplementary Data," Note 10. "Contingencies and Environmental Liabilities" below.

Worldwide, all of the Company's important products are sold under trademarks that are considered in the aggregate to be of material importance. Trademark protection continues in some countries as long as used; in other countries, as long as registered. Registration is for fixed terms and can be renewed indefinitely.

Royalty income in 2019 on patent and know-how licenses and other rights amounted to $135 million. Merck also incurred royalty expenses amounting to $1.7 billion in 2019 under patent and know-how licenses it holds.

Research and Development

The Company's business is characterized by the introduction of new products or new uses for existing products through a strong research and development program. At December 31, 2019, approximately 15,600 people were employed in the Company's research activities. The Company prioritizes its research and development efforts and focuses on candidates that it believes represent breakthrough science that will make a difference for patients and payers.

The Company maintains a number of long-term exploratory and fundamental research programs in biology and chemistry as well as research programs directed toward product development. The Company's research and development model is designed to increase productivity and improve the probability of success by prioritizing the

Company's research and development resources on candidates the Company believes are capable of providing unambiguous, promotable advantages to patients and payers and delivering the maximum value of its approved medicines and vaccines through new indications and new formulations. Merck is pursuing emerging product opportunities independent of therapeutic area or modality (small molecule, biologics and vaccines) and is building its biologics capabilities. The Company is committed to ensuring that externally sourced programs remain an important component of its pipeline strategy, with a focus on supplementing its internal research with a licensing and external alliance strategy focused on the entire spectrum of collaborations from early research to late-stage compounds, as well as access to new technologies.

The Company's clinical pipeline includes candidates in multiple disease areas, including cancer, cardiovascular diseases, diabetes and other metabolic diseases, infectious diseases, neurosciences, pain, respiratory diseases, and vaccines.

In the development of human health products, industry practice and government regulations in the United States and most foreign countries provide for the determination of effectiveness and safety of new chemical compounds through pre-clinical tests and controlled clinical evaluation. Before a new drug or vaccine may be marketed in the United States, recorded data on pre-clinical and clinical experience are included in the NDA for a drug or the Biologics License Application (BLA) for a vaccine or biologic submitted to the FDA for the required approval.

Once the Company's scientists discover a new small molecule compound or biologic that they believe has promise to treat a medical condition, the Company commences pre-clinical testing with that compound. Pre-clinical testing includes laboratory testing and animal safety studies to gather data on chemistry, pharmacology, immunogenicity and toxicology. Pending acceptable pre-clinical data, the Company will initiate clinical testing in accordance with established regulatory requirements. The clinical testing begins with Phase 1 studies, which are designed to assess safety, tolerability, pharmacokinetics, and preliminary pharmacodynamic activity of the compound in humans. If favorable, additional, larger Phase 2 studies are initiated to determine the efficacy of the compound in the affected population, define appropriate dosing for the compound, as well as identify any adverse effects that could limit the compound's usefulness. In some situations, the clinical program incorporates adaptive design methodology to use accumulating data to decide how to modify aspects of the ongoing clinical study as it continues, without undermining the validity and integrity of the trial. One type of adaptive clinical trial is an adaptive Phase 2a/2b trial design, a two-stage trial design consisting of a Phase 2a proof-of-concept stage and a Phase 2b dose-optimization finding stage. If data from the Phase 2 trials are satisfactory, the Company commences large-scale Phase 3 trials to confirm the compound's efficacy and safety. Another type of adaptive clinical trial is an adaptive Phase 2/3 trial design, a study that includes an interim analysis and an adaptation that changes the trial from having features common in a Phase 2 study (e.g. multiple dose groups) to a design similar to a Phase 3 trial. An adaptive Phase 2/3 trial design reduces timelines by eliminating activities which would be required to start a separate study. Upon completion of Phase 3 trials, if satisfactory, the Company submits regulatory filings with the appropriate regulatory agencies around the world to have the product candidate approved for marketing. There can be no assurance that a compound that is the result of any particular program will obtain the regulatory approvals necessary for it to be marketed.

Vaccine development follows the same general pathway as for drugs. Pre-clinical testing focuses on the vaccine's safety and ability to elicit a protective immune response (immunogenicity). Pre-marketing vaccine clinical trials are typically done in three phases. Initial Phase 1 clinical studies are conducted in normal subjects to evaluate the safety, tolerability and immunogenicity of the vaccine candidate. Phase 2 studies are dose-ranging studies. Finally, Phase 3 trials provide the necessary data on effectiveness and safety. If successful, the Company submits regulatory filings with the appropriate regulatory agencies.

In the United States, the FDA review process begins once a complete NDA or BLA is submitted, received and accepted for review by the agency. Within 60 days after receipt, the FDA determines if the application is sufficiently complete to permit a substantive review. The FDA also assesses, at that time, whether the application will be granted a priority review or standard review. Pursuant to the Prescription Drug User Fee Act V (PDUFA), the FDA review period target for NDAs or original BLAs is either six months, for priority review, or ten months, for a standard review, from the time the application is deemed sufficiently complete. Once the review timelines are determined, the FDA will generally act upon the application within those timelines, unless a major amendment has been submitted (either at the Company's own initiative or the FDA's request) to the pending application. If this occurs, the FDA may extend the review period to allow for review of the new information, but by no more than three months. Extensions to the review period are communicated to the Company. The FDA can act on an application either by issuing an approval letter or by issuing a Complete Response Letter (CRL) stating that the application will

not be approved in its present form and describing all deficiencies that the FDA has identified. Should the Company wish to pursue an application after receiving a CRL, it can resubmit the application with information that addresses the questions or issues identified by the FDA in

order to support approval. Resubmissions are subject to review period targets, which vary depending on the underlying submission type and the content of the resubmission.

The FDA has four program designations — Fast Track, Breakthrough Therapy, Accelerated Approval, and Priority Review — to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening conditions. The Fast Track designation provides pharmaceutical manufacturers with opportunities for frequent interactions with FDA reviewers during the product's development and the ability for the manufacturer to do a rolling submission of the NDA/BLA. A rolling submission allows completed portions of the application to be submitted and reviewed by the FDA on an ongoing basis. The Breakthrough Therapy designation provides manufacturers with all of the features of the Fast Track designation as well as intensive guidance on implementing an efficient development program for the product and a commitment by the FDA to involve senior managers and experienced staff in the review. The Accelerated Approval designation allows the FDA to approve a product based on an effect on a surrogate or intermediate endpoint that is reasonably likely to predict a product's clinical benefit and generally requires the manufacturer to conduct required post-approval confirmatory trials to verify the clinical benefit. The Priority Review designation means that the FDA's goal is to take action on the NDA/BLA within six months, compared to ten months under standard review.

In addition, under the Generating Antibiotic Incentives Now Act, the FDA may grant Qualified Infectious Disease Product (QIDP) status to antibacterial or antifungal drugs intended to treat serious or life threatening infections including those caused by antibiotic or antifungal resistant pathogens, novel or emerging infectious pathogens, or other qualifying pathogens. QIDP designation offers certain incentives for development of qualifying drugs, including Priority Review of the NDA when filed, eligibility for Fast Track designation, and a five-year extension of applicable exclusivity provisions under the Food, Drug and Cosmetic Act.

The primary method the Company uses to obtain marketing authorization of pharmaceutical products in the EU is through the "centralized procedure." This procedure is compulsory for certain pharmaceutical products, in particular those using biotechnological processes, and is also available for certain new chemical compounds and products. A company seeking to market an innovative pharmaceutical product through the centralized procedure must file a complete set of safety data and efficacy data as part of a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA). After the EMA evaluates the MAA, it provides a recommendation to the EC and the EC then approves or denies the MAA. It is also possible for new chemical products to obtain marketing authorization in the EU through a "mutual recognition procedure" in which an application is made to a single member state and, if the member state approves the pharmaceutical product under a national procedure, the applicant may submit that approval to the mutual recognition procedure of some or all other member states.

Outside of the United States and the EU, the Company submits marketing applications to national regulatory authorities. Examples of such are the Ministry of Health, Labour and Welfare in Japan, Health Canada, Agência Nacional de Vigilância Sanatária in Brazil, Korea Food and Drug Administration in South Korea, Therapeutic Goods Administration in Australia and the National Medical Products Administration in China. Each country has a separate and independent review process and timeline. In many markets, approval times can be longer as the regulatory authority requires approval in a major market, such as the United States or the EU, and issuance of a Certificate of Pharmaceutical Product from that market before initiating their local review process.

Research and Development Update

The Company currently has several candidates under regulatory review in the United States and internationally.

Keytruda is an anti-PD-1 therapy approved for the treatment of many cancers that is in clinical development for expanded indications. These approvals were the result of a broad clinical development program that currently consists of more than 1,000 clinical trials, including more than 600 trials that combine *Keytruda* with other cancer treatments. These studies encompass more than 30 cancer types including: biliary tract, cervical, colorectal, cutaneous squamous cell, endometrial, gastric, head and neck, hepatocellular, Hodgkin lymphoma, non-Hodgkin lymphoma, melanoma, mesothelioma, nasopharyngeal, non-small-cell lung, ovarian, PMBCL, prostate, renal, small-cell lung, triple-negative breast, and urothelial, many of which are currently in Phase 3 clinical development. Further trials are being planned for other cancers.

Keytruda is under review in the EU as monotherapy for the first-line treatment of patients with stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC, and whose tumors express PD-L1 (TPS ≥1%) with no EGFR or ALK genomic tumor aberrations based on results from the Phase 3 KEYNOTE-042 trial.

Keytruda is under review in Japan as monotherapy and in combination with chemotherapy for the first-line treatment of advanced gastric or gastroesophageal junction adenocarcinoma based on results from the pivotal Phase 3 KEYNOTE-062 trial.

Keytruda is also under review in Japan as monotherapy for the second-line treatment of advanced or metastatic esophageal or esophagogastric junction carcinoma based on the results of the Phase 3 KEYNOTE-181 trial. Merck has made the decision to withdraw its Type II variation application for *Keytruda* for this indication in the EU.

In October 2019, the FDA accepted a supplemental BLA seeking use of *Keytruda* for the treatment of patients with recurrent and/or metastatic cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation based on the results of the KEYNOTE-629 trial. The FDA set a PDUFA date of June 29, 2020.

In February 2020, Merck announced the FDA issued a Complete Response Letter (CRL) regarding Merck's supplemental BLAs seeking to update the dosing frequency for *Keytruda* to include a 400 mg dose infused over 30 minutes every-six-weeks (Q6W) option in multiple indications. The submitted applications are based on pharmacokinetic modeling and simulation data presented at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting. These data supported the EC approval of 400 mg Q6W dosing for *Keytruda* monotherapy indications in March 2019. Merck is reviewing the letter and will discuss next steps with the FDA.

Additionally, *Keytruda* has received Breakthrough Therapy designation from the FDA in combination with neoadjuvant chemotherapy for the treatment of high-risk early-stage triple-negative breast cancer (TNBC) and in combination with enfortumab vedotin, in the first-line setting for the treatment of patients with unresectable locally advanced or metastatic urothelial cancer who are not eligible for cisplatin-containing chemotherapy. The FDA's Breakthrough Therapy designation is intended to expedite the development and review of a candidate that is planned for use, alone or in combination, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

In September 2019, Merck announced results from the pivotal neoadjuvant/adjuvant Phase 3 KEYNOTE-522 trial in patients with early-stage TNBC. The trial investigated a regimen of neoadjuvant *Keytruda* plus chemotherapy, followed by adjuvant *Keytruda* as monotherapy (the *Keytruda* regimen) compared with a regimen of neoadjuvant chemotherapy followed by adjuvant placebo (the chemotherapy-placebo regimen). Interim findings were presented at the European Society for Medical Oncology (ESMO) 2019 Congress. In the neoadjuvant phase, *Keytruda* plus chemotherapy resulted in a statistically significant increase in pathological complete response (pCR) versus chemotherapy in patients with early-stage TNBC. The improvement seen when adding *Keytruda* to neoadjuvant chemotherapy was observed regardless of PD-L1 expression. In the other dual primary endpoint of event-free-survival (EFS), with a median follow-up of 15.5 months, the *Keytruda* regimen reduced the risk of progression in the neoadjuvant phase and recurrence in the adjuvant phase compared with the chemotherapy-placebo regimen. Merck continues to discuss interim analysis data from KEYNOTE-522 with regulatory authorities. The *Keytruda* breast cancer clinical development program encompasses several internal and external collaborative studies.

In February 2020, Merck announced that the pivotal Phase 3 KEYNOTE-355 trial investigating *Keytruda* in combination with chemotherapy met one of its dual primary endpoints of progression-free survival (PFS) in patients with metastatic triple-negative breast cancer (mTNBC) whose tumors expressed PD-L1 (CPS ≥10). Based on an interim analysis conducted by an independent Data Monitoring Committee (DMC), first-line treatment with *Keytruda* in combination with chemotherapy (nab-paclitaxel, paclitaxel or gemcitabine/carboplatin) demonstrated a statistically significant and clinically meaningful improvement in PFS compared to chemotherapy alone in these patients. Based on the recommendation of the DMC, the trial will continue without changes to evaluate the other dual primary endpoint of overall survival (OS).

In May 2019, Merck announced that the Phase 3 KEYNOTE-119 trial evaluating *Keytruda* as monotherapy for the second- or third-line treatment of patients with metastatic TNBC did not meet its pre-specified primary endpoint of superior OS compared to chemotherapy. Other endpoints were not formally tested per the study protocol because the primary endpoint of OS was not met.

In June 2019, Merck announced full results from the pivotal Phase 3 KEYNOTE-062 trial evaluating *Keytruda* as monotherapy and in combination with chemotherapy for the first-line treatment of advanced gastric or gastroesophageal junction adenocarcinoma. In the monotherapy arm of the study, *Keytruda* met a primary endpoint by demonstrating noninferiority to chemotherapy, the current standard of care, for OS in patients whose tumors expressed PD-L1 (CPS ≥1). In the combination arm of KEYNOTE-062, *Keytruda* plus chemotherapy was not found

to be statistically superior for OS (CPS ≥1 or CPS ≥10) or PFS (CPS ≥1) compared with chemotherapy alone. Results were presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting. In September 2017, the FDA

approved *Keytruda* as a third-line treatment for previously treated patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction cancer whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test. KEYNOTE-062 was a potential confirmatory trial for this accelerated, third-line approval. In addition to KEYNOTE-062, additional first-line, Phase 3 studies in Merck's gastric clinical program include KEYNOTE-811 and KEYNOTE-859, as well as KEYNOTE-585 in the neoadjuvant and adjuvant treatment setting.

In January 2020, Merck announced that the Phase 3 KEYNOTE-604 trial investigating *Keytruda* in combination with chemotherapy met one of its dual primary endpoints of PFS in the first-line treatment of patients with extensive stage SCLC. At the final analysis of the study, there was also an improvement in OS for patients treated with *Keytruda* in combination with chemotherapy compared to chemotherapy alone; however, these OS results did not meet statistical significance per the pre-specified statistical plan. Results will be presented at an upcoming medical meeting and discussed with regulatory authorities.

Lynparza, is an oral PARP inhibitor currently approved for certain types of advanced ovarian, breast and pancreatic cancers being co-developed for multiple cancer types as part of a collaboration with AstraZeneca.

Lynparza is under review in the EU as a first-line maintenance monotherapy for patients with g*BRCA*m metastatic pancreatic cancer whose disease has not progressed following first-line platinum-based chemotherapy. Lynparza was approved for this indication by the FDA in December 2019 based on results from the Phase 3 POLO trial. A decision from the EMA is expected in the second half of 2020.

In January 2020, the FDA accepted a supplemental NDA for Lynparza in combination with bevacizumab for the maintenance treatment of women with advanced ovarian cancer whose disease showed a complete or partial response to first-line treatment with platinum-based chemotherapy and bevacizumab based on the results from the pivotal Phase 3 PAOLA-1 trial. A PDUFA date is set for the second quarter of 2020. This indication is also under review in the EU.

In January 2020, the FDA accepted for Priority Review a supplemental NDA for Lynparza for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) and deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutations, who have progressed following prior treatment with a new hormonal agent based on positive results from the Phase 3 PROfound trial. A PDUFA date is set for the second quarter of 2020. This indication is also under review in the EU.

In June 2019, Merck and AstraZeneca presented full results from the Phase 3 SOLO-3 trial which evaluated Lynparza, compared to chemotherapy, for the treatment of platinum-sensitive relapsed patients with g*BRCA*m advanced ovarian cancer, who have received two or more prior lines of chemotherapy. The results from the trial showed a statistically-significant and clinically-meaningful improvement in objective response rate (ORR) in the Lynparza arm compared to the chemotherapy arm. The key secondary endpoint of PFS was also significantly increased in the Lynparza arm compared to the chemotherapy arm. The results were presented at the 2019 ASCO Annual Meeting.

MK-5618, selumetinib, is a MEK 1/2 inhibitor being co-developed as part of a strategic collaboration with AstraZeneca. Selumetinib is under Priority Review with the FDA as a potential new medicine for pediatric patients aged three years and older with neurofibromatosis type 1 (NF1) and symptomatic, inoperable plexiform neurofibromas. This regulatory submission was based on positive results from the National Cancer Institute Cancer Therapy Evaluation Program-sponsored SPRINT Phase 2 Stratum 1 trial. A PDUFA date is set for the second quarter of 2020.

V503 is under review in Japan for an initial indication in females for the prevention of certain HPV-related diseases and precursors.

In February 2020, the FDA accepted for Priority Review a supplemental BLA for *Gardasil* 9 for the prevention of certain head and neck cancers caused by vaccine-type HPV in females and males 9 through 45 years of age. The FDA set a PDUFA date of June 2020.

In addition to the candidates under regulatory review, the Company has several drug candidates in Phase 3 clinical development in addition to the *Keytruda* programs discussed above.

Lynparza, in addition to the indications under review discussed above, is in Phase 3 development in combination with *Keytruda* for the treatment of NSCLC.

Lenvima is an orally available tyrosine kinase inhibitor currently approved for certain types of thyroid cancer, HCC, and in combination for certain patients with RCC being co-developed as part of a strategic

collaboration with Eisai. Pursuant to the agreement, the companies will jointly initiate clinical studies evaluating the *Keytruda*/Lenvima combination in six types of cancer (endometrial cancer, NSCLC, HCC, HNSCC, bladder cancer and melanoma), as well as a basket trial targeting multiple cancer types. The FDA granted Breakthrough Therapy designation

for *Keytruda* in combination with Lenvima both for the potential treatment of patients with advanced and/or metastatic RCC and for the potential treatment of patients with unresectable HCC not amenable to locoregional treatment.

MK-7264, gefapixant, is a selective, non-narcotic, orally-administered P2X3-receptor antagonist being investigated in Phase 3 trials for the treatment of refractory, chronic cough and in a Phase 2 trial for the treatment of women with endometriosis-related pain.

MK-1242, vericiguat, is a sGC stimulator for the potential treatment of patients with worsening chronic heart failure being developed as part of a worldwide strategic collaboration between Merck and Bayer. Vericiguat is being studied in patients suffering from chronic heart failure with reduced ejection fraction (Phase 3 clinical trial) and from chronic heart failure with preserved ejection fraction (Phase 2 clinical trial). In November 2019, Merck announced that the Phase 3 VICTORIA study evaluating the efficacy and safety of vericiguat met the primary efficacy endpoint. Vericiguat reduced the risk of the composite endpoint of heart failure hospitalization or cardiovascular death in patients with worsening chronic heart failure with reduced ejection fraction compared to placebo when given in combination with available heart failure therapies. The results of the VICTORIA study will be presented at an upcoming medical meeting in 2020.

V114 is an investigational polyvalent conjugate vaccine for the prevention of pneumococcal disease. In June 2018, Merck initiated the first Phase 3 study in the adult population for the prevention of invasive pneumococcal disease. Currently six Phase 3 adult studies are ongoing, including studies in healthy adults 50 years of age or older, adults with risk factors for pneumococcal disease, those infected with HIV, and those who are recipients of allogeneic hematopoietic stem cell transplant. In October 2018, Merck began the first Phase 3 study in the pediatric population. Currently, eight studies are ongoing, including studies in healthy infants and in children afflicted with sickle cell disease. V114 has received Breakthrough Therapy designation from the FDA for the prevention of invasive pneumococcal disease caused by the vaccine serotypes in pediatric patients (6 weeks to 18 years of age) and in adults.

The chart below reflects the Company's research pipeline as of February 21, 2020. Candidates shown in Phase 3 include specific products and the date such candidate entered into Phase 3 development. Candidates shown in Phase 2 include the most advanced compound with a specific mechanism or, if listed compounds have the same mechanism, they are each currently intended for commercialization in a given therapeutic area. Small molecules and biologics are given MK-number designations and vaccine candidates are given V-number designations. Except as otherwise noted, candidates in Phase 1, additional indications in the same therapeutic area (other than with respect to cancer) and additional claims, line extensions or formulations for in-line products are not shown.

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Phase 2	Phase 3 (Phase 3 Entry Date)	Under Review
Cancer	**Cancer**	**New Molecular Entities/Vaccines**
MK-3475 *Keytruda*	MK-3475 *Keytruda*	**Pediatric Neurofibromatosis Type-1**
Advanced Solid Tumors	Biliary Tract (September 2019)	MK-5618 (selumetinib)*(1)* (U.S.)
MK-6482	Breast (October 2015)	**HPV Vaccine**
Renal Cell Carcinoma	Cervical (October 2018) (EU)	V503 Human Papillomavirus 9-valent Vaccine, Recombinant (JPN)
MK-7123*(2)*	Colorectal (November 2015)	**Certain Supplemental Filings**
Solid Tumors	Cutaneous Squamous Cell Carcinoma (August 2019) (EU)	**Cancer**
MK-7339 Lynparza*(1)*	Endometrial (August 2019) (EU)	MK-3475 *Keytruda*
Advanced Solid Tumors	Esophageal (December 2015) (EU)	● First-Line Metastatic Non-Small-Cell Lung Cancer (KEYNOTE-042) (EU)
MK-7690 (vicriviroc)*(2)*	Gastric (May 2015) (EU)	● First-Line Metastatic Gastric Cancer (KEYNOTE-062) (JPN)
Colorectal	Hepatocellular (May 2016) (EU)	● Recurrent Locally Advanced or Metastatic Esophageal Cancer (KEYNOTE-180/181) (JPN)
MK-7902 Lenvima*(1)*	Mesothelioma (May 2018)	● Recurrent and/or Metastatic Cutaneous Squamous Cell Carcinoma (KEYNOTE-629) (U.S.)
Biliary Tract	Nasopharyngeal (April 2016)	● Alternative Dosing Regimen*(3)* (Q6W) (U.S.)
V937	Ovarian (December 2018)	MK-7339 Lynparza*(1)*
Melanoma	Prostate (May 2019)	● First-Line g*BRCA*m Pancreatic Cancer (POLO) (EU)
MK-7684*(2)*	Small-Cell Lung (May 2017) (EU)	● First-Line Maintenance Newly Diagnosed Advanced Ovarian Cancer (PAOLA) (U.S.) (EU)
Non-Small-Cell Lung	MK-7339 Lynparza*(1,2)*	● Metastatic Prostate Cancer (PROfound) (U.S.) (EU)
MK-1026	Non-Small-Cell Lung (June 2019)	**Footnotes:**
Hematological Malignancies	MK-7902 Lenvima*(1,2)*	*(1)* Being developed in a collaboration.
MK-4280*(2)*	Bladder (May 2019)	*(2)* Being developed in combination with *Keytruda.*
Hematological Malignancies	Endometrial (June 2018) (EU)	*(3)* The Company received a CRL in February 2020. Merck is reviewing the letter and will discuss next steps with the FDA.
Non-Small-Cell Lung	Head and Neck Squamous Cell Carcinoma (February 2020)	
MK-1308*(2)*	Melanoma (March 2019)	
Non-Small-Cell Lung	Non-Small-Cell Lung (March 2019)	
MK-5890*(2)*	**Cough**	
Non-Small-Cell Lung	MK-7264 (gefapixant) (March 2018)	
Cytomegalovirus	**Heart Failure**	
V160	MK-1242 (vericiguat) (September 2016)*(1)*	
HIV-1 Infection	**HIV-1 Infection**	
MK-8591 (islatravir)	MK-8591A (islatravir/doravirine) (February 2020)	
Overgrowth Syndrome	**Pneumoconjugate Vaccine**	
MK-7075	V114 (June 2018)	
Pediatric Neurofibromatosis Type-1		
MK-5618 (selumetinib)*(1)* (EU)		
Respiratory Syncytial Virus		
MK-1654		
Schizophrenia		
MK-8189		

Employees

As of December 31, 2019, the Company had approximately 71,000 employees worldwide, with approximately 26,000 employed in the United States, including Puerto Rico. Approximately 30% of worldwide employees of the Company are represented by various collective bargaining groups.

Restructuring Activities

In early 2019, Merck approved a new global restructuring program (Restructuring Program) as part of a worldwide initiative focused on further optimizing the Company's manufacturing and supply network, as well as reducing its global real estate footprint. This program is a continuation of the Company's plant rationalization, builds on prior restructuring programs and does not include any actions associated with the planned spin-off of NewCo. As the Company continues to evaluate its global footprint and overall operating model, it has subsequently identified additional actions under the Restructuring Program, and could identify further actions over time. The actions currently contemplated under the Restructuring Program are expected to be substantially completed by the end of 2023. Actions under previous global restructuring programs have been substantially completed.

Environmental Matters

The Company believes that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on the Company. The Company is also remediating environmental contamination resulting from past industrial activity at certain of its sites. Expenditures for remediation and environmental liabilities were $19 million in 2019 and are estimated at $47 million in the aggregate for the years 2020 through 2024. These amounts do not consider potential recoveries from other parties. The Company has taken an active role in identifying and accruing for these costs and, in management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $67 million and $71 million at December 31, 2019 and 2018, respectively. Although it is not possible to predict with certainty the outcome

of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed $58 million in the aggregate. Management also does not believe that these expenditures should have a material adverse effect on the Company's financial condition, results of operations, liquidity or capital resources for any year.

Merck believes that climate change could present risks to its business. Some of the potential impacts of climate change to its business include increased operating costs due to additional regulatory requirements, physical risks to the Company's facilities, water limitations and disruptions to its supply chain. These potential risks are integrated into the Company's business planning including investment in reducing energy, water use and greenhouse gas emissions. The Company does not believe these risks are material to its business at this time.

Geographic Area Information

The Company's operations outside the United States are conducted primarily through subsidiaries. Sales worldwide by subsidiaries outside the United States as a percentage of total Company sales were 57% of sales in each of 2019, 2018 and 2017.

The Company's worldwide business is subject to risks of currency fluctuations, governmental actions and other governmental proceedings abroad. The Company does not regard these risks as a deterrent to further expansion of its operations abroad. However, the Company closely reviews its methods of operations and adopts strategies responsive to changing economic and political conditions.

Merck has operations in countries located in Latin America, the Middle East, Africa, Eastern Europe and Asia Pacific. Business in these developing areas, while sometimes less stable, offers important opportunities for growth over time.

Available Information

The Company's Internet website address is *www.merck.com*. The Company will make available, free of charge at the "Investors" portion of its website, its Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after such reports are electronically filed with, or furnished to, the U.S. Securities and Exchange Commission (SEC). The address of that website is www.sec.gov. In addition, the Company will provide without charge a copy of its Annual Report on Form 10-K, including financial statements and schedules, upon the written request of any shareholder to the Office of the Secretary, Merck & Co., Inc., 2000 Galloping Hill Road, K1-4157, Kenilworth, NJ 07033 U.S.A.

The Company's corporate governance guidelines and the charters of the Board of Directors' four standing committees are available on the Company's website at *www.merck.com/about/leadership* and all such information is available in print to any shareholder who requests it from the Company.

Item 1A. Risk Factors.

Investors should carefully consider all of the information set forth in this Form 10-K, including the following risk factors, before deciding to invest in any of the Company's securities. The risks below are not the only ones the Company faces. Additional risks not currently known to the Company or that the Company presently deems immaterial may also impair its business operations. The Company's business, financial condition, results of operations or prospects could be materially adversely affected by any of these risks. This Form 10-K also contains forward-looking statements that involve risks and uncertainties. The Company's results could materially differ from those anticipated in these forward-looking statements as a result of certain factors, including the risks it faces described below and elsewhere. See "Cautionary Factors that May Affect Future Results" below.

The Company is dependent on its patent rights, and if its patent rights are invalidated or circumvented, its business could be materially adversely affected.

Patent protection is considered, in the aggregate, to be of material importance to the Company's marketing of human health and animal health products in the United States and in most major foreign markets. Patents covering products that it has introduced normally provide market exclusivity, which is important for the successful marketing

and sale of its products. The Company seeks patents covering each of its products in each of the markets where it intends to sell the products and where meaningful patent protection is available.

Even if the Company succeeds in obtaining patents covering its products, third parties or government authorities may challenge or seek to invalidate or circumvent its patents and patent applications. It is important for the Company's business to defend successfully the patent rights that provide market exclusivity for its products. The Company is often involved in patent disputes relating to challenges to its patents or claims by third parties of infringement against the Company. The Company defends its patents both within and outside the United States, including by filing claims of infringement against other parties. See Item 8. "Financial Statements and Supplementary Data," Note 10. "Contingencies and Environmental Liabilities" below. In particular, manufacturers of generic pharmaceutical products from time to time file abbreviated NDAs with the FDA seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned or licensed by the Company. The Company normally responds by defending its patent, including by filing lawsuits alleging patent infringement. Patent litigation and other challenges to the Company's patents are costly and unpredictable and may deprive the Company of market exclusivity for a patented product or, in some cases, third-party patents may prevent the Company from marketing and selling a product in a particular geographic area.

Additionally, certain foreign governments have indicated that compulsory licenses to patents may be granted in the case of national emergencies or in other circumstances, which could diminish or eliminate sales and profits from those regions and negatively affect the Company's results of operations. Further, court decisions relating to other companies' patents, potential legislation in both the U.S. and certain foreign markets relating to patents, as well as regulatory initiatives may result in a more general weakening of intellectual property protection.

If one or more important products lose patent protection in profitable markets, sales of those products are likely to decline significantly as a result of generic versions of those products becoming available. The Company's results of operations may be adversely affected by the lost sales unless and until the Company has launched commercially successful products that replace the lost sales. In addition, if products that were measured at fair value and capitalized in connection with acquisitions experience difficulties in the market that negatively affect product cash flows, the Company may recognize material non-cash impairment charges with respect to the value of those products.

A chart listing the patent protection for certain of the Company's marketed products, and U.S. patent protection for candidates in Phase 3 clinical development is set forth above in Item 1. "Business — Patents, Trademarks and Licenses."

As the Company's products lose market exclusivity, the Company generally experiences a significant and rapid loss of sales from those products.

The Company depends upon patents to provide it with exclusive marketing rights for its products for some period of time. Loss of patent protection for one of the Company's products typically leads to a significant and rapid loss of sales for that product as lower priced generic versions of that drug become available. In the case of products that contribute significantly to the Company's sales, the loss of market exclusivity can have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects. For example, the patents that provided U.S. and EU market exclusivity for certain forms of *Noxafil* expired in July 2019 and December 2019, respectively, and the Company anticipates a significant decline in U.S. and EU *Noxafil* sales. Also, the patent that provided U.S. market exclusivity for *NuvaRing* expired in April 2018 and generic competition began in December 2019. The Company anticipates a rapid and substantial decline in U.S. *NuvaRing* sales in 2020 as a result of this generic competition. In addition, the patents that provide market exclusivity for *Januvia* and *Janumet* in the U.S. expire in July 2022 (although six-month pediatric exclusivity may extend this date). The patent that provides market exclusivity for *Januvia* in the EU expires in July 2022 (although pediatric exclusivity may extend this date to September 2022). Finally, the SPC that provides market exclusivity for *Janumet* in the EU expires in April 2023. The Company anticipates sales of *Januvia* and *Janumet* in these markets will decline substantially after these patent expiries.

Key products generate a significant amount of the Company's profits and cash flows, and any events that adversely affect the markets for its leading products could have a material adverse effect on the Company's results of operations and financial condition.

The Company's ability to generate profits and operating cash flow depends largely upon the continued profitability of the Company's key products, such as *Keytruda, Gardasil/Gardasil* 9, *Januvia*, *Janumet*, and *Bridion*. In particular, in 2019, the Company's oncology portfolio, led by *Keytruda,* represented the majority of the Company's revenue and earnings growth. As a result of the Company's dependence on key products, any event that adversely affects any of these products or the markets for any of these products could have a significant adverse impact on results of operations and cash flows. These events could include loss of patent protection, increased costs associated with manufacturing, generic or over-the-counter availability of the Company's product or a competitive product, the discovery of previously unknown side effects, results of post-approval trials, increased competition from the introduction of new, more effective treatments and discontinuation or removal from the market of the product for any reason. Such events could have a material adverse effect on the sales of any such products.

The Company's research and development efforts may not succeed in developing commercially successful products and the Company may not be able to acquire commercially successful products in other ways; in consequence, the Company may not be able to replace sales of successful products that have lost patent protection.

Like other major pharmaceutical companies, in order to remain competitive, the Company must continue to launch new products. Expected declines in sales of products after the loss of market exclusivity mean that the Company's future success is dependent on its pipeline of new products, including new products that it may develop through collaborations and joint ventures and products that it is able to obtain through license or acquisition. To accomplish this, the Company commits substantial effort, funds and other resources to research and development, both through its own dedicated resources and through various collaborations with third parties. There is a high rate of failure inherent in the research and development process for new drugs. As a result, there is a high risk that funds invested by the Company in research programs will not generate financial returns. This risk profile is compounded by the fact that this research has a long investment cycle. To bring a pharmaceutical compound from the discovery phase to market may take a decade or more and failure can occur at any point in the process, including later in the process after significant funds have been invested.

For a description of the research and development process, see Item 1. "Business — Research and Development" above. Each phase of testing is highly regulated and during each phase there is a substantial risk that the Company will encounter serious obstacles or will not achieve its goals. Therefore, the Company may abandon a product in which it has invested substantial amounts of time and resources. Some of the risks encountered in the research and development process include the following: pre-clinical testing of a new compound may yield disappointing results; competing products from other manufacturers may reach the market first; clinical trials of a new drug may not be successful; a new drug may not be effective or may have harmful side effects; a new drug may not be approved by the regulators for its intended use; it may not be possible to obtain a patent for a new drug; payers may refuse to cover or reimburse the new product; or sales of a new product may be disappointing.

The Company cannot state with certainty when or whether any of its products now under development will be approved or launched; whether it will be able to develop, license or otherwise acquire compounds, product candidates or products; or whether any products, once launched, will be commercially successful. The Company must maintain a continuous flow of successful new products and successful new indications or brand extensions for existing products sufficient both to cover its substantial research and development costs and to replace sales that are lost as profitable products lose market exclusivity or are displaced by competing products or therapies. Failure to do so in the short term or long term would have a material adverse effect on the Company's business, results of operations, cash flow, financial condition and prospects.

The Company's success is dependent on the successful development and marketing of new products, which are subject to substantial risks.

Products that appear promising in development may fail to reach the market or fail to succeed for numerous reasons, including the following:

- findings of ineffectiveness, superior safety or efficacy of competing products, or harmful side effects in clinical or pre-clinical testing;
- failure to receive the necessary regulatory approvals, including delays in the approval of new products and new indications, or the anticipated labeling, and uncertainties about the time required to obtain regulatory approvals and the benefit/risk standards applied by regulatory agencies in determining whether to grant approvals;
- failure in certain markets to obtain reimbursement commensurate with the level of innovation and clinical benefit presented by the product;
- lack of economic feasibility due to manufacturing costs or other factors; and
- preclusion from commercialization by the proprietary rights of others.

In the future, if certain pipeline programs are cancelled or if the Company believes that their commercial prospects have been reduced, the Company may recognize material non-cash impairment charges for those programs that were measured at fair value and capitalized in connection with acquisitions or certain collaborations.

Failure to successfully develop and market new products in the short term or long term would have a material adverse effect on the Company's business, results of operations, cash flow, financial condition and prospects.

The Company's products, including products in development, cannot be marketed unless the Company obtains and maintains regulatory approval.

The Company's activities, including research, pre-clinical testing, clinical trials and the manufacturing and marketing of its products, are subject to extensive regulation by numerous federal, state and local governmental authorities in the United States, including the FDA, and by foreign regulatory authorities, including in the EU, Japan and China. In the United States, the FDA administers requirements covering the testing, approval, safety, effectiveness, manufacturing, labeling and marketing of prescription pharmaceuticals. In many cases, the FDA requirements have increased the amount of time and money necessary to develop new products and bring them to market in the United States. Regulation outside the United States also is primarily focused on drug safety and effectiveness and, in many cases, reduction in the cost of drugs. The FDA and foreign regulatory authorities, including in Japan and China, have substantial discretion to require additional testing, to delay or withhold registration and marketing approval and to otherwise preclude distribution and sale of a product.

Even if the Company is successful in developing new products, it will not be able to market any of those products unless and until it has obtained all required regulatory approvals in each jurisdiction where it proposes to market the new products. Once obtained, the Company must maintain approval as long as it plans to market its new products in each jurisdiction where approval is required. The Company's failure to obtain approval, significant delays in the approval process, or its failure to maintain approval in any jurisdiction will prevent it from selling the products in that jurisdiction. The Company would not be able to realize revenues for those new products in any jurisdiction where it does not have approval.

Developments following regulatory approval may adversely affect sales of the Company's products.

Even after a product reaches the market, certain developments following regulatory approval may decrease demand for the Company's products, including the following:

- results in post-approval Phase 4 trials or other studies;
- the re-review of products that are already marketed;
- the recall or loss of marketing approval of products that are already marketed;
- changing government standards or public expectations regarding safety, efficacy, quality or labeling changes; and

- scrutiny of advertising and promotion.

In the past several years, clinical trials and post-marketing surveillance of certain marketed drugs of the Company and of competitors within the industry have raised concerns that have led to recalls, withdrawals or adverse

labeling of marketed products. Clinical trials and post-marketing surveillance of certain marketed drugs also have raised concerns among some prescribers and patients relating to the safety or efficacy of pharmaceutical products in general that have negatively affected the sales of such products. In addition, increased scrutiny of the outcomes of clinical trials has led to increased volatility in market reaction. Further, these matters often attract litigation and, even where the basis for the litigation is groundless, considerable resources may be needed to respond.

In addition, following in the wake of product withdrawals and other significant safety issues, health authorities such as the FDA, the EMA, Japan's PMDA and China's NMPA have increased their focus on safety when assessing the benefit/risk balance of drugs. Some health authorities appear to have become more cautious when making decisions about approvability of new products or indications.

If previously unknown side effects are discovered or if there is an increase in negative publicity regarding known side effects of any of the Company's products, it could significantly reduce demand for the product or require the Company to take actions that could negatively affect sales, including removing the product from the market, restricting its distribution or applying for labeling changes. Further, in the current environment in which all pharmaceutical companies operate, the Company is at risk for product liability and consumer protection claims and civil and criminal governmental actions related to its products, research and/or marketing activities. In addition, dissemination of promotional materials through evolving digital channels serves to increase visibility and scrutiny in the marketplace.

The Company faces intense competition from lower cost generic products.

In general, the Company faces increasing competition from lower-cost generic products. The patent rights that protect its products are of varying strengths and durations. In addition, in some countries, patent protection is significantly weaker than in the United States or in the EU. In the United States and the EU, political pressure to reduce spending on prescription drugs has led to legislation and other measures that encourage the use of generic and biosimilar products. Although it is the Company's policy to actively protect its patent rights, generic challenges to the Company's products can arise at any time, and the Company's patents may not prevent the emergence of generic competition for its products.

Loss of patent protection for a product typically is followed promptly by generic substitutes, reducing the Company's sales of that product. Availability of generic substitutes for the Company's drugs may adversely affect its results of operations and cash flow. In addition, proposals emerge from time to time in the United States and other countries for legislation to further encourage the early and rapid approval of generic drugs. Any such proposal that is enacted into law could worsen this substantial negative effect on the Company's sales and, potentially, its business, cash flow, results of operations, financial condition and prospects.

The Company faces intense competition from competitors' products.

The Company's products face intense competition from competitors' products. This competition may increase as new products enter the market. In such an event, the competitors' products may be safer or more effective, more convenient to use, have better insurance coverage or reimbursement levels or be more effectively marketed and sold than the Company's products. Alternatively, in the case of generic competition, including the generic availability of competitors' branded products, they may be equally safe and effective products that are sold at a substantially lower price than the Company's products. As a result, if the Company fails to maintain its competitive position, this could have a material adverse effect on its business, cash flow, results of operations, financial condition and prospects. In addition, if products that were measured at fair value and capitalized in connection with acquisitions experience difficulties in the market that negatively impact product cash flows, the Company may recognize material non-cash impairment charges with respect to the value of those products.

The Company faces continued pricing pressure with respect to its products.

The Company faces continued pricing pressure globally and, particularly in mature markets, from managed care organizations, government agencies and programs that could negatively affect the Company's sales and profit margins. In the United States, these include (i) practices of managed care groups and institutional and governmental purchasers, (ii) U.S. federal laws and regulations related to Medicare and Medicaid, including the Medicare Prescription Drug Improvement and Modernization Act of 2003 and the ACA, and (iii) state activities aimed at increasing price transparency, including new laws as noted above in Item 1. "Competition and the Health Care Environment — Health

Care Environment and Government Regulations." Changes to the health care system enacted as part of health care reform in the United States, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, could result in further pricing pressures. In addition, in the United States, larger customers have received higher rebates on drugs in certain highly competitive categories. The Company must also compete to be placed on formularies of managed care organizations. Exclusion of a product from a formulary can lead to reduced usage in the managed care organization.

In order to provide information about the Company's pricing practices, the Company annually posts on its website its Pricing Transparency Report for the United States. The report provides the Company's average annual list price and net price increases across the Company's U.S. portfolio dating back to 2010. In 2019, the Company's gross U.S. sales were reduced by approximately 44% as a result of rebates, discounts and returns.

Outside the United States, numerous major markets, including the EU, Japan and China have pervasive government involvement in funding health care and, in that regard, fix the pricing and reimbursement of pharmaceutical and vaccine products. Consequently, in those markets, the Company is subject to government decision making and budgetary actions with respect to its products. In Japan, the pharmaceutical industry is subject to government-mandated biennial price reductions of pharmaceutical products and certain vaccines, which will occur again in 2020. Furthermore, the government can order re-pricing for specific products if it determines that use of such product will exceed certain thresholds defined under applicable re-pricing rules. For example, pursuant to a re-pricing rule, the Japanese government reduced the price of *Keytruda* by 17.5%, effective February 2020. Additionally, *Keytruda* will be subject to another significant price reduction in April 2020 under a provision of the Japanese pricing rules.

The Company expects pricing pressures to continue in the future.

The health care industry in the United States has been, and will continue to be, subject to increasing regulation and political action.

The Company believes that the health care industry will continue to be subject to increasing regulation as well as political and legal action, as future proposals to reform the health care system are considered by the Executive branch, Congress and state legislatures.

In 2010, the United States enacted major health care reform legislation in the form of the ACA. Various insurance market reforms have advanced and state and federal insurance exchanges were launched in 2014. The ACA increased the mandated Medicaid rebate from 15.1% to 23.1%, expanded the rebate to Medicaid managed care utilization, and increased the types of entities eligible for the federal 340B drug discount program.

The ACA also requires pharmaceutical manufacturers to pay a point of service discount to Medicare Part D beneficiaries when they are in the Medicare Part D coverage gap (i.e., the so-called "donut hole") which increased to 70% in 2019 and was extended to biosimilar products. In 2019, the Company's revenue was reduced by approximately $615 million due to this requirement. Also, pharmaceutical manufacturers are required to pay an annual non-tax deductible health care reform fee. In 2019, the Company recorded $112 million of costs for this annual fee.

In 2016, the Centers for Medicare & Medicaid Services (CMS) issued the Medicaid rebate final rule that implements provisions of the ACA effective April 1, 2016. The rule provides comprehensive guidance on the calculation of Average Manufacturer Price and Best Price; two metrics utilized to determine the rebates drug manufacturers are required to pay to state Medicaid programs. The impact of changes resulting from the issuance of the rule is not material to Merck at this time. However, the Company is still awaiting guidance from CMS on two aspects of the rule that were deferred for later implementation. These include a definition of what constitutes a product 'line extension' and a delay in the participation of the U.S. Territories in the Medicaid Drug Rebate Program until April 1, 2022. The Company will evaluate the financial impact of these two elements when they become effective.

In addition, as discussed above in "Competition and the Health Care Environment," the administration has recently proposed a draft rule that would allow importation of certain lower-cost prescription drugs from Canada. If the rule is finalized as proposed, states or certain other non-federal governmental entities would be able to submit importation program proposals to the FDA for review and authorization of two-year programs (with the opportunity to extend for two more years). There will be a public comment period on the proposed rule which will expire on March 9, 2020. Following the comment period, the FDA will have to review and finalize its proposal before any states or other

parties can submit their plans to comply with the federal rule. If the proposed rule is adopted, it likely will be some time before states or other parties can actually implement importation plans.

Also, in October 2018, the administration issued an advance notice of proposed rulemaking to implement an “International Pricing Index” (IPI) model in the United States for products covered under Medicare Part B. The proposal would: (1) reduce Medicare Part B payments for drugs based on a market basket of international prices; (2) allow private sector vendors to negotiate prices for drugs, take title to drugs, and compete for physician and hospital business; and (3) change the physician reimbursement under Medicare Part B from the current model to eliminate the buy and bill system and instead pay physicians based on a flat fee that approximates the revenue they currently receive from drugs. Public comments on the IPI proposal were accepted through late 2018 and it is unclear when the agency may issue a proposed rule on the IPI model. Adoption of one or both of the proposed rules could have a material adverse effect on the Company’s business, results of operations and financial condition.

The Company cannot predict the likelihood of additional future changes in the health care industry in general, or the pharmaceutical industry in particular, or what impact they may have on the Company’s business, cash flow, results of operations, financial condition and prospects.

The Company is increasingly dependent on sophisticated software applications and computing infrastructure. In 2017, the Company experienced a network cyber-attack that led to a disruption of its worldwide operations, including manufacturing, research and sales operations. The Company could be a target of future cyber-attacks.

The Company is increasingly dependent on sophisticated software applications and complex information technology systems and computing infrastructure (collectively, IT systems) to conduct critical operations. Certain of these systems are managed, hosted, provided or used by third parties to assist in conducting the Company’s business. Disruption, degradation, or manipulation of these IT systems through intentional or accidental means by the Company’s employees, third parties with authorized access or unauthorized third parties could adversely affect key business processes. Cyber-attacks against the Company’s IT systems or third-party providers’ IT systems, such as cloud-based systems, could result in exposure of confidential information, the modification of critical data, and/or the failure of critical operations. Misuse of any of these IT systems could result in the disclosure of sensitive personal information or the theft of trade secrets, intellectual property, or other confidential business information. The Company continues to leverage new and innovative technologies across the enterprise to improve the efficacy and efficiency of its business processes; the use of which can create new risks.

In 2017, the Company experienced a network cyber-attack that led to a disruption of its worldwide operations, including manufacturing, research and sales operations, and resulting losses.

The Company has insurance coverage insuring against losses resulting from cyber-attacks and has received proceeds in connection with the 2017 cyber-attack. However, there are disputes with certain of the insurers about the availability of some of the insurance coverage for claims related to the 2017 cyber-attack.

The Company has implemented a variety of measures to further enhance and modernize its systems to guard against similar attacks in the future, and also is pursuing an enterprise-wide effort to enhance the Company's resiliency against future cyber-attacks, including incidents similar to the 2017 attack. The objective of these efforts is not only to protect against future cyber-attacks, but also to improve the speed of the Company’s recovery from such attacks and enable continued business operations to the greatest extent possible during any recovery period.

Although the aggregate impact of cyber-attacks and network disruptions, including the 2017 cyber-attack, on the Company’s operations and financial condition has not been material to date, the Company continues to be a target of events of this nature and expects them to continue. The Company monitors its data, information technology and personnel usage of Company IT systems to reduce these risks and continues to do so on an ongoing basis for any current or potential threats. There can be no assurance that the Company’s efforts to protect its data and IT systems or the efforts of third-party providers to protect their IT systems will be successful in preventing disruptions to the Company’s operations, including its manufacturing, research and sales operations. Such disruptions have in the past and could in the future result in loss of revenue, or the loss of critical or sensitive information from the Company’s or the Company’s third-party providers’ databases or IT systems and have in the past and could in the future also result in financial, legal, business or reputational harm to the Company and substantial remediation costs.

The Company is subject to a variety of U.S. and international laws and regulations.

The Company is currently subject to a number of government laws and regulations and, in the future, could become subject to new government laws and regulations. The costs of compliance with such laws and regulations, or the negative results of non-compliance, could adversely affect the business, cash flow, results of operations, financial condition and prospects of the Company; these laws and regulations include (i) additional healthcare reform initiatives in the United States or in other countries, including additional mandatory discounts or fees; (ii) the U.S. Foreign Corrupt Practices Act or other anti-bribery and corruption laws; (iii) new laws, regulations and judicial or other governmental decisions affecting pricing, drug reimbursement, and access or marketing within or across jurisdictions; (iv) changes in intellectual property laws; (v) changes in accounting standards; (vi) new and increasing data privacy regulations and enforcement, particularly in the EU and the United States; (vii) legislative mandates or preferences for local manufacturing of pharmaceutical or vaccine products; (viii) emerging and new global regulatory requirements for reporting payments and other value transfers to healthcare professionals; (ix) environmental regulations; and (x) the potential impact of importation restrictions, embargoes, trade sanctions and legislative and/or other regulatory changes.

The uncertainty in global economic conditions together with cost-reduction measures being taken by certain governments could negatively affect the Company's operating results.

Uncertainty in global economic and geopolitical conditions may result in a slowdown to the global economy that could affect the Company's business by reducing the prices that drug wholesalers and retailers, hospitals, government agencies and managed health care providers may be able or willing to pay for the Company's products or by reducing the demand for the Company's products, which could in turn negatively impact the Company's sales and result in a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects.

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. Changes to the U.S. health care system as part of health care reform, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, have contributed to pricing pressure. In several international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. In addition, the Company's revenue performance in 2019 was negatively affected by other cost-reduction measures taken by governments and other third-parties to lower health care costs. The Company anticipates all of these actions, and additional actions in the future, will continue to negatively affect revenue performance.

If credit and economic conditions worsen, the resulting economic and currency impacts in the affected markets and globally could have a material adverse effect on the Company's results.

The Company has significant global operations, which expose it to additional risks, and any adverse event could have a material adverse effect on the Company's results of operations and financial condition.

The extent of the Company's operations outside the United States is significant. Risks inherent in conducting a global business include:

- changes in medical reimbursement policies and programs and pricing restrictions in key markets;
- multiple regulatory requirements that could restrict the Company's ability to manufacture and sell its products in key markets;
- trade protection measures and import or export licensing requirements, including the imposition of trade sanctions or similar restrictions by the United States or other governments;
- foreign exchange fluctuations;
- diminished protection of intellectual property in some countries; and
- possible nationalization and expropriation.

In addition, there may be changes to the Company's business and political position if there is instability, disruption or destruction in a significant geographic region, regardless of cause, including war, terrorism, riot, civil

insurrection or social unrest; and natural or man-made disasters, including famine, flood, fire, earthquake, storm or disease.

In 2016, the United Kingdom (UK) held a referendum in which voters approved an exit from the EU, commonly referred to as "Brexit." As a result of that referendum and subsequent negotiations, the UK left the EU on January 31, 2020. A transitional period will apply from January 31, 2020 until December 31, 2020, and during this period the EU will treat the UK as if it were an EU Member State, and the UK will continue to participate in the EU Customs Union allowing for the freedom of movement for people and goods. During the transitional period the EU and the UK will continue to negotiate a trade agreement to formalize the terms of the UK's future relationship with the EU. The Company has taken actions and made certain contingency plans for scenarios in which the UK and the EU do not reach a mutually satisfactory understanding as to a future trade agreement. It is not possible at this time to predict whether there will be any such understanding before the end of 2020, or if such an understanding is reached, whether its terms will vary in ways that result in greater restrictions on imports and exports between the UK and EU countries, increased regulatory complexities, and/or cross border labor issues that could materially adversely impact the Company's business operations in the UK.

Failure to attract and retain highly qualified personnel could affect the Company's ability to successfully develop and commercialize products.

The Company's success is largely dependent on its continued ability to attract and retain highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical research and development, governmental regulation and commercialization. Competition for qualified personnel in the pharmaceutical industry is intense. The Company cannot be sure that it will be able to attract and retain quality personnel or that the costs of doing so will not materially increase.

In the past, the Company has experienced difficulties and delays in manufacturing certain of its products, including vaccines.

Merck has, in the past, experienced difficulties in manufacturing certain of its products, including vaccines. In addition, the network cyber-attack experienced by the Company in June 2017 led to a disruption of the Company's operations, including its manufacturing operations. The Company may, in the future, experience difficulties and delays inherent in manufacturing its products, such as (i) failure of the Company or any of its vendors or suppliers to comply with Current Good Manufacturing Practices and other applicable regulations and quality assurance guidelines that could lead to manufacturing shutdowns, product shortages and delays in product manufacturing; (ii) delays related to the construction of new facilities or the expansion of existing facilities, including those intended to support future demand for the Company's products; and (iii) other manufacturing or distribution problems including changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, changes in types of products produced, or physical limitations that could impact continuous supply. In addition, the Company could experience difficulties or delays in manufacturing its products caused by natural disasters, such as hurricanes. For example, in 2017, the Company's lone manufacturing plant in Puerto Rico was negatively affected by Hurricane Maria. Manufacturing difficulties can result in product shortages, leading to lost sales and reputational harm to the Company.

The Company may not be able to realize the expected benefits of its investments in emerging markets.

The Company has been taking steps to increase its sales in emerging markets. However, there is no guarantee that the Company's efforts to expand sales in these markets will succeed. Some countries within emerging markets may be especially vulnerable to periods of global financial instability or may have very limited resources to spend on health care. In order for the Company to successfully implement its emerging markets strategy, it must attract and retain qualified personnel. The Company may also be required to increase its reliance on third-party agents within less developed markets. In addition, many of these countries have currencies that fluctuate substantially and, if such currencies devalue and the Company cannot offset the devaluations, the Company's financial performance within such countries could be adversely affected.

The Company's business in China has grown rapidly in the past few years, and the importance of China to the Company's overall pharmaceutical and vaccines business outside the United States has increased accordingly. Continued growth of the Company's business in China is dependent upon ongoing development of a favorable environment for innovative pharmaceutical products and vaccines, sustained access for the Company's currently marketed products, and the absence of trade impediments or adverse pricing controls. As noted above in "*Health Care Environment and Government Regulation*," pricing pressure in China has increased as the Chinese government has been taking steps to reduce costs, including implementing healthcare reform that has led to the acceleration of generic

substitution, where available. While pricing pressure has always existed in China, health care reform has increased this pressure in part due to the acceleration of generic substitution through the government's VBP program. In 2019, the government implemented the VBP program through a tendering process for mature products which have generic substitutes with a Generic Quality Consistency Evaluation approval. Mature products that have entered into the first two rounds of VBP had, on average, a price reduction of 50%. The expansion of the VBP program remains to be seen. In addition, the Company anticipates that the reported inquiries made by various governmental authorities involving multinational pharmaceutical companies in China may continue.

Also, in December 2019, a new Coronavirus, now known as COVID-19, which has proved to be highly contagious, emerged in Wuhan, China. The outbreak of the virus has caused material disruptions to the Chinese economy, including its health care system, which will have a negative effect on the Company's first quarter 2020 results which, at this time, is not expected to be material. Since the future course and duration of the COVID-19 outbreak are unknown, the Company is currently unable to determine whether the outbreak will have a further negative effect on the Company's results in 2020. The outbreak of COVID-19 currently has also had a limited effect on the Company's supply chain of drugs into and raw materials out of China. The outbreak has also negatively affected certain of the Company's clinical trials.

For all these reasons, sales within emerging markets carry significant risks. However, a failure to maintain the Company's presence in emerging markets could have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects.

The Company is exposed to market risk from fluctuations in currency exchange rates and interest rates.

The Company operates in multiple jurisdictions and virtually all sales are denominated in currencies of the local jurisdiction. Additionally, the Company has entered and will enter into business development transactions, borrowings or other financial transactions that may give rise to currency and interest rate exposure.

Since the Company cannot, with certainty, foresee and mitigate against such adverse fluctuations, fluctuations in currency exchange rates, interest rates and inflation could negatively affect the Company's business, cash flow, results of operations, financial condition and prospects.

In order to mitigate against the adverse impact of these market fluctuations, the Company will from time to time enter into hedging agreements. While hedging agreements, such as currency options and forwards and interest rate swaps, may limit some of the exposure to exchange rate and interest rate fluctuations, such attempts to mitigate these risks may be costly and not always successful.

Certain of the Company's interest rate derivatives and investments are based on the London Interbank Offered Rate (LIBOR), and a portion of Merck's indebtedness bears interest at variable interest rates, primarily based on LIBOR. LIBOR is the subject of recent national, international and other regulatory guidance and proposals for reform, which may cause LIBOR to cease to exist entirely after 2021. While the Company expects that reasonable alternatives to LIBOR will be implemented prior to the 2021 target date, the Company cannot predict the consequences and timing of these developments, which could include an increase in interest expense and may also require the amendment of contracts that reference LIBOR.

The Company is subject to evolving and complex tax laws, which may result in additional liabilities that may affect results of operations and financial condition.

The Company is subject to evolving and complex tax laws in the jurisdictions in which it operates. Significant judgment is required for determining the Company's tax liabilities, and the Company's tax returns are periodically examined by various tax authorities. The Company believes that its accrual for tax contingencies is adequate for all open years based on past experience, interpretations of tax law, and judgments about potential actions by tax authorities; however, due to the complexity of tax contingencies, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued. In addition, the Company may be negatively affected by changes in tax laws, or new tax laws, affecting, for example, tax rates, and/or revised tax law interpretations in domestic or foreign jurisdictions.

Pharmaceutical products can develop unexpected safety or efficacy concerns.

Unexpected safety or efficacy concerns can arise with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals, or declining sales, as well as product liability, consumer fraud and/or other claims, including potential civil or criminal governmental actions.

Reliance on third-party relationships and outsourcing arrangements could materially adversely affect the Company's business.

The Company depends on third parties, including suppliers, alliances with other pharmaceutical and biotechnology companies, and third-party service providers, for key aspects of its business including development, manufacture and commercialization of its products and support for its IT systems. Failure of these third parties to meet their contractual, regulatory and other obligations to the Company or the development of factors that materially disrupt the relationships between the Company and these third parties could have a material adverse effect on the Company's business.

Negative events in the animal health industry could have a material adverse effect on future results of operations and financial condition.

Future sales of key animal health products could be adversely affected by a number of risk factors including certain risks that are specific to the animal health business. For example, the outbreak of disease carried by animals, such as African Swine Fever, could lead to their widespread death and precautionary destruction as well as the reduced consumption and demand for animals, which could adversely affect the Company's results of operations. Also, the outbreak of any highly contagious diseases near the Company's main production sites could require the Company to immediately halt production of vaccines at such sites or force the Company to incur substantial expenses in procuring raw materials or vaccines elsewhere. Other risks specific to animal health include epidemics and pandemics, government procurement and pricing practices, weather and global agribusiness economic events. As the Animal Health segment of the Company's business becomes more significant, the impact of any such events on future results of operations would also become more significant.

Biologics and vaccines carry unique risks and uncertainties, which could have a material adverse effect on the Company's future results of operations and financial condition.

The successful development, testing, manufacturing and commercialization of biologics and vaccines, particularly human and animal health vaccines, is a long, complex, expensive and uncertain process. There are unique risks and uncertainties related to biologics and vaccines, including:

- There may be limited access to, and supply of, normal and diseased tissue samples, cell lines, pathogens, bacteria, viral strains and other biological materials. In addition, government regulations in multiple jurisdictions, such as the United States and the EU, could result in restricted access to, or transport or use of, such materials. If the Company loses access to sufficient sources of such materials, or if tighter restrictions are imposed on the use of such materials, the Company may not be able to conduct research activities as planned and may incur additional development costs.

- The development, manufacturing and marketing of biologics and vaccines are subject to regulation by the FDA, the EMA and other regulatory bodies. These regulations are often more complex and extensive than the regulations applicable to other pharmaceutical products. For example, in the United States, a BLA, including both pre-clinical and clinical trial data and extensive data regarding the manufacturing procedures, is required for human vaccine candidates, and FDA approval is generally required for the release of each manufactured commercial lot.

- Manufacturing biologics and vaccines, especially in large quantities, is often complex and may require the use of innovative technologies to handle living micro-organisms. Each lot of an approved biologic and vaccine must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to

the manufacturing process, the Company may be required to provide pre-clinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes.

- Biologics and vaccines are frequently costly to manufacture because production ingredients are derived from living animal or plant material, and most biologics and vaccines cannot be made synthetically. In particular, keeping up with the demand for vaccines may be difficult due to the complexity of producing vaccines.

- The use of biologically derived ingredients can lead to variability in the manufacturing process and could lead to allegations of harm, including infections or allergic reactions, which allegations would be reviewed through a standard investigation process that could lead to closure of product facilities due to possible contamination. Any of these events could result in substantial costs.

Product liability insurance for products may be limited, cost prohibitive or unavailable.

As a result of a number of factors, product liability insurance has become less available while the cost of such insurance has increased significantly. The Company is subject to a substantial number of product liability claims. See Item 8. “Financial Statements and Supplementary Data,” Note 10. “Contingencies and Environmental Liabilities” below for more information on the Company’s current product liability litigation. With respect to product liability, the Company self-insures substantially all of its risk, as the availability of commercial insurance has become more restrictive. The Company has evaluated its risks and has determined that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and, as such, has no insurance for most product liabilities. The Company will continually assess the most efficient means to address its risk; however, there can be no guarantee that insurance coverage will be obtained or, if obtained, will be sufficient to fully cover product liabilities that may arise.

Social media platforms present risks and challenges.

The inappropriate and/or unauthorized use of certain social media channels could cause brand damage or information leakage or could lead to legal implications, including from the improper collection and/or dissemination of personally identifiable information. In addition, negative or inaccurate posts or comments about the Company or its products on any social networking platforms could damage the Company’s reputation, brand image and goodwill. Further, the disclosure of non-public Company-sensitive information by the Company’s workforce or others through external media channels could lead to information loss. Although there is an internal Company Social Media Policy that guides employees on appropriate personal and professional use of social media about the Company, the processes in place may not completely secure and protect information. Identifying new points of entry as social media continues to expand also presents new challenges.

Risks Related to the Proposed Spin-Off of NewCo.

The proposed Spin-Off of NewCo may not be completed on the terms or timeline currently contemplated, if at all, and may not achieve the expected results.

In February 2020, the Company announced its intention to Spin-Off products from its women’s health, trusted legacy brands and biosimilars businesses into a new, yet-to-be-named, independent, publicly traded company (NewCo) through a distribution of NewCo’s publicly traded stock to Company shareholders. The distribution is expected to qualify as tax-free to the Company and its shareholders for U.S. federal income tax purposes. The transaction is expected to be completed in the first half of 2021. Completion of the Spin-Off will be subject to a number of factors and conditions, and there can be no assurances that the Company will be able to complete the Spin-Off on the terms or on the timeline that was announced, if at all. Unanticipated developments could delay, prevent or otherwise adversely affect the proposed Spin-Off, including but not limited to disruptions in general or financial market conditions or potential problems or delays in obtaining various regulatory and tax approvals or clearances. In addition, consummation of the proposed Spin-Off will require final approval from the Company’s Board of Directors.

The costs to complete the proposed Spin-Off will be significant. In addition, the Company may be unable to achieve some or all of the strategic and financial benefits that it expects to achieve from the Spin-Off of NewCo.

The Company will incur significant expenses in connection with the Spin-Off. In addition, the Company may not be able to achieve the full strategic and financial benefits that are expected to result from the Spin-Off. The anticipated benefits of the Spin-Off are based on a number of assumptions, some of which may prove incorrect.

Following the Spin-Off, the price of shares of the Company's common stock may fluctuate significantly.

The Company cannot predict the effect of the Spin-Off on the trading price of shares of its common stock, and the market value of shares of its common stock may be less than, equal to or greater than the market value of shares of its common stock prior to the Spin-Off. In addition, the price of Merck's common stock may be more volatile around the time of the Spin-Off.

There could be significant income tax liability if the Spin-Off or certain related transactions are determined to be taxable for U.S. federal income tax purposes.

The Company expects that prior to completion of the Spin-Off it will receive an opinion from its U.S. tax counsel that concludes, among other things, that the Spin-Off of all of the outstanding NewCo shares to Merck shareholders and certain related transactions will qualify as tax-free to Merck and its shareholders under Sections 355, 361 and 368 of the U.S. Internal Revenue Code, except to the extent of any cash received in lieu of fractional shares of NewCo common stock. Any such opinion is not binding on the Internal Revenue Service (IRS). Accordingly, while the Company believes the risk is low, the IRS may reach conclusions with respect to the Spin-Off that are different from the conclusions reached in the opinion. The opinion will rely on certain facts, assumptions, representations and undertakings from Merck and NewCo regarding the past and future conduct of the companies' respective businesses and other matters, which, if incomplete, incorrect or not satisfied, could alter the conclusions of the party giving such opinion.

If the proposed Spin-Off ultimately is determined to be taxable, which the Company believes is unlikely, the Spin-Off could be treated as a taxable dividend to Merck's shareholders for U.S. federal income tax purposes, and Merck's shareholders could incur significant U.S. federal income tax liabilities. In addition, Merck would recognize a taxable gain to the extent that the fair market value of NewCo common stock exceeds Merck's tax basis in such stock on the date of the Spin-Off.

Cautionary Factors that May Affect Future Results

(Cautionary Statements Under the Private Securities Litigation Reform Act of 1995)

This report and other written reports and oral statements made from time to time by the Company may contain so-called "forward-looking statements," all of which are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially from those set forth in the statements. One can identify these forward-looking statements by their use of words such as "anticipates," "expects," "plans," "will," "estimates," "forecasts," "projects" and other words of similar meaning, or negative variations of any of the foregoing. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address the Company's growth strategy, financial results, product development, product approvals, product potential, and development programs. One must carefully consider any such statement and should understand that many factors could cause actual results to differ materially from the Company's forward-looking statements. These factors include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. No forward-looking statement can be guaranteed and actual future results may vary materially. The Company does not assume the obligation to update any forward-looking statement. The Company cautions you not to place undue reliance on these forward-looking statements. Although it is not possible to predict or identify all such factors, they may include the following:

- Competition from generic and/or biosimilar products as the Company's products lose patent protection.

- Increased "brand" competition in therapeutic areas important to the Company's long-term business performance.

- The difficulties and uncertainties inherent in new product development. The outcome of the lengthy and complex process of new product development is inherently uncertain. A drug candidate can fail at any stage of the process and one or more late-stage product candidates could fail to receive regulatory approval. New product candidates may appear promising in development but fail to reach the market because of efficacy or safety concerns, the inability to obtain necessary regulatory approvals, the difficulty or excessive cost to manufacture and/or the infringement of patents or intellectual property rights of others. Furthermore, the sales of new products may prove to be disappointing and fail to reach anticipated levels.

- Pricing pressures, both in the United States and abroad, including rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and health care reform, pharmaceutical reimbursement and pricing in general.

- Changes in government laws and regulations, including laws governing intellectual property, and the enforcement thereof affecting the Company's business.

- Efficacy or safety concerns with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales.

- Significant changes in customer relationships or changes in the behavior and spending patterns of purchasers of health care products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing health care insurance coverage.

- Legal factors, including product liability claims, antitrust litigation and governmental investigations, including tax disputes, environmental concerns and patent disputes with branded and generic competitors, any of which could preclude commercialization of products or negatively affect the profitability of existing products.

- Cyber-attacks on the Company's or third-party providers' information technology systems, which could disrupt the Company's operations.

- Lost market opportunity resulting from delays and uncertainties in the approval process of the FDA and foreign regulatory authorities.

- Increased focus on privacy issues in countries around the world, including the United States and the EU. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect directly the Company's business, including recently enacted laws in a majority of states in the United States requiring security breach notification.

- Changes in tax laws including changes related to the taxation of foreign earnings.

- Changes in accounting pronouncements promulgated by standard-setting or regulatory bodies, including the Financial Accounting Standards Board and the SEC, that are adverse to the Company.

- Economic factors over which the Company has no control, including changes in inflation, interest rates and foreign currency exchange rates.

- The proposed Spin-Off might be delayed or the costs to complete the Spin-Off might be more significant than expected.

This list should not be considered an exhaustive statement of all potential risks and uncertainties. See "Risk Factors" above.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

The Company's corporate headquarters is located in Kenilworth, New Jersey. The Company also maintains operational or divisional headquarters in Kenilworth, New Jersey, Madison, New Jersey and Upper Gwynedd, Pennsylvania. Principal U.S. research facilities are located in Rahway and Kenilworth, New Jersey, West Point, Pennsylvania, Palo Alto, California, Boston, Massachusetts, South San Francisco, California and Elkhorn, Nebraska (Animal Health). Principal research facilities outside the United States are located in the United Kingdom, Switzerland

and China. Merck's manufacturing operations are headquartered in Whitehouse Station, New Jersey. The Company also has production facilities for human health products at nine locations in the United States and Puerto Rico. Outside the United States, through subsidiaries, the Company owns or has an interest in manufacturing plants or other properties in Japan, Singapore, South Africa, and other countries in Western Europe, Central and South America, and Asia.

Capital expenditures were $3.5 billion in 2019, $2.6 billion in 2018 and $1.9 billion in 2017. In the United States, these amounted to $1.9 billion in 2019, $1.5 billion in 2018 and $1.2 billion in 2017. Abroad, such expenditures amounted to $1.6 billion in 2019, $1.1 billion in 2018 and $728 million in 2017.

The Company and its subsidiaries own their principal facilities and manufacturing plants under titles that they consider to be satisfactory. The Company believes that its properties are in good operating condition and that its machinery and equipment have been well maintained. The Company believes that its plants for the manufacture of products are suitable for their intended purposes and have capacities and projected capacities, including previously-disclosed capital expansion projects, that will be adequate for current and projected needs for existing Company products. Some capacity of the plants is being converted, with any needed modification, to the requirements of newly introduced and future products.

Item 3. Legal Proceedings.

The information called for by this Item is incorporated herein by reference to Item 8. "Financial Statements and Supplementary Data," Note 10. "Contingencies and Environmental Liabilities".

Item 4. Mine Safety Disclosures.

Not Applicable.

Executive Officers of the Registrant (ages as of February 1, 2020)

All officers listed below serve at the pleasure of the Board of Directors. None of these officers was elected pursuant to any arrangement or understanding between the officer and any other person(s).

Name	Age	Offices and Business Experience
Kenneth C. Frazier	65	Chairman, President and Chief Executive Officer (since December 2011)
Sanat Chattopadhyay	60	Executive Vice President and President, Merck Manufacturing Division (since March 2016); Senior Vice President, Operations, Merck Manufacturing Division (November 2009-March 2016)
Frank Clyburn	55	Executive Vice President, Chief Commercial Officer (since January 2019); President, Global Oncology Business Unit (October 2013-December 2018)
Robert M. Davis	53	Executive Vice President, Global Services, and Chief Financial Officer (since April 2016); Executive Vice President and Chief Financial Officer (April 2014-April 2016)
Richard R. DeLuca, Jr.	57	Executive Vice President and President, Merck Animal Health (since September 2011)
Michael W. Fleming	61	Senior Vice President, Chief Ethics and Compliance Officer (since March 2019); Senior Vice President, International Legal and Compliance (January 2017-March 2019); Vice President, International Legal and Compliance (July 2008-January 2017)
Julie L. Gerberding	64	Executive Vice President and Chief Patient Officer, Strategic Communications, Global Public Policy and Population Health (since July 2016); Executive Vice President for Strategic Communications, Global Public Policy and Population Health (January 2015-July 2016)
Rita A. Karachun	56	Senior Vice President Finance - Global Controller (since March 2014)
Steven C. Mizell	59	Executive Vice President, Chief Human Resources Officer (since October 2018); Executive Vice President, Chief Human Resources Officer (December 2016-October 2018) and Executive Vice President, Human Resources, Monsanto Company (August 2011-December 2016)
Michael T. Nally	44	Executive Vice President, Chief Marketing Officer (since January 2019); President, Global Vaccines, Global Human Health (September 2016-January 2019); Managing Director, United Kingdom and Ireland, Global Human Health (January 2014-September 2016)
Roger M. Perlmutter, M.D., Ph.D.	67	Executive Vice President and President, Merck Research Laboratories (since April 2013)
Jennifer Zachary	42	Executive Vice President, General Counsel and Corporate Secretary (since January 2020); Executive Vice President and General Counsel (April 2018-January 2020); Partner, Covington & Burling LLP (January 2013-March 2018)

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

The principal market for trading of the Company's Common Stock is the New York Stock Exchange (NYSE) under the symbol MRK.

As of January 31, 2020, there were approximately 109,500 shareholders of record of the Company's Common Stock.

Issuer purchases of equity securities for the three months ended December 31, 2019 were as follows:

Issuer Purchases of Equity Securities

			($ in millions)
Period	Total Number of Shares Purchased[1]	Average Price Paid Per Share	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs[1]
October 1 — October 31	5,064,526	$83.63	$7,796
November 1 — November 30	4,182,277	$84.72	$7,441
December 1 — December 31	3,053,800	$89.16	$7,169
Total	12,300,603	$85.37	$7,169

[1] *All shares purchased during the period were made as part of a plan approved by the Board of Directors in October 2018 to purchase up to $10 billion in Merck shares for its treasury.*

Performance Graph

The following graph assumes a $100 investment on December 31, 2014, and reinvestment of all dividends, in each of the Company's Common Shares, the S&P 500 Index, and a composite peer group of major U.S. and European-based pharmaceutical companies, which are: AbbVie Inc., Amgen Inc., AstraZeneca plc, Bristol-Myers Squibb Company, Johnson & Johnson, Eli Lilly and Company, GlaxoSmithKline plc, Novartis AG, Pfizer Inc., Roche Holding AG, and Sanofi SA.

Comparison of Five-Year Cumulative Total Return*

Merck & Co., Inc., Composite Peer Group and S&P 500 Index

	End of Period Value	2019/2014 CAGR*
MERCK	$187	13%
PEER GRP.**	152	9%
S&P 500	174	12%

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	2014	2015	2016	2017	2018	2019
MERCK	100.0	96.0	110.5	108.8	152.5	186.5
PEER GRP.	100.0	103.0	99.9	119.6	127.8	151.6
S&P 500	100.0	101.4	113.5	138.3	132.2	173.8

* *Compound Annual Growth Rate*

** *Peer group average was calculated on a market cap weighted basis.*

This Performance Graph will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that the Company specifically incorporates it by reference. In addition, the Performance Graph will not be deemed to be "soliciting material" or to be "filed" with the SEC or subject to Regulation 14A or 14C, other than as provided in Regulation S-K, or to the liabilities of section 18 of the Securities Exchange Act of 1934, except to the extent that the Company specifically requests that such information be treated as soliciting material or specifically incorporates it by reference into a filing under the Securities Act or the Exchange Act.

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Item 6. Selected Financial Data.

The following selected financial data should be read in conjunction with Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and consolidated financial statements and notes thereto contained in Item 8. "Financial Statements and Supplementary Data" of this report.

Merck & Co., Inc. and Subsidiaries
($ in millions except per share amounts)

	2019 [1]	2018 [2]	2017 [3]	2016 [4]	2015 [5]
Results for Year:					
Sales	**$ 46,840**	$ 42,294	$ 40,122	$ 39,807	$ 39,498
Cost of sales	**14,112**	13,509	12,912	14,030	15,043
Selling, general and administrative	**10,615**	10,102	10,074	10,017	10,508
Research and development	**9,872**	9,752	10,339	10,261	6,796
Restructuring costs	**638**	632	776	651	619
Other (income) expense, net	**139**	(402)	(500)	189	1,131
Income before taxes	**11,464**	8,701	6,521	4,659	5,401
Taxes on income	**1,687**	2,508	4,103	718	942
Net income	**9,777**	6,193	2,418	3,941	4,459
Less: Net (loss) income attributable to noncontrolling interests	**(66)**	(27)	24	21	17
Net income attributable to Merck & Co., Inc.	**9,843**	6,220	2,394	3,920	4,442
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	**$ 3.84**	$ 2.34	$ 0.88	$ 1.42	$ 1.58
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	**$ 3.81**	$ 2.32	$ 0.87	$ 1.41	$ 1.56
Cash dividends declared	**5,820**	5,313	5,177	5,135	5,115
Cash dividends declared per common share	**$ 2.26**	$ 1.99	$ 1.89	$ 1.85	$ 1.81
Capital expenditures	**3,473**	2,615	1,888	1,614	1,283
Depreciation	**1,679**	1,416	1,455	1,611	1,593
Average common shares outstanding (millions)	**2,565**	2,664	2,730	2,766	2,816
Average common shares outstanding assuming dilution (millions)	**2,580**	2,679	2,748	2,787	2,841
Year-End Position:					
Working capital	**$ 5,263**	$ 3,669	$ 6,152	$ 13,410	$ 10,550
Property, plant and equipment, net	**15,053**	13,291	12,439	12,026	12,507
Total assets	**84,397**	82,637	87,872	95,377	101,677
Long-term debt	**22,736**	19,806	21,353	24,274	23,829
Total equity	**26,001**	26,882	34,569	40,308	44,767
Year-End Statistics:					
Number of stockholders of record	**110,023**	115,800	121,700	129,500	135,500
Number of employees	**71,000**	69,000	69,000	68,000	68,000

[1] *Amounts for 2019 include a charge for the acquisition of Peloton Therapeutics, Inc.*

[2] *Amounts for 2018 include a charge related to the formation of a collaboration with Eisai Co., Ltd.*

[3] *Amounts for 2017 include a provisional net tax charge related to the enactment of U.S. tax legislation and a charge related to the formation of a collaboration with AstraZeneca PLC.*

[4] *Amounts for 2016 include a charge related to the settlement of worldwide patent litigation related to* Keytruda.

[5] *Amounts for 2015 include a net charge related to the settlement of* Vioxx *shareholder class action litigation, foreign exchange losses related to Venezuela, gains on the dispositions of businesses and other assets, and the favorable benefit of certain tax items.*

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following section of this Form 10-K generally discusses 2019 and 2018 results and year-to-year comparisons between 2019 and 2018. Discussion of 2017 results and year-to-year comparisons between 2018 and 2017 that are not included in this Form 10-K can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 filed on February 27, 2019.

Description of Merck's Business

Merck & Co., Inc. (Merck or the Company) is a global health care company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies and animal health products. The Company's operations are principally managed on a products basis and include four operating segments, which are the Pharmaceutical, Animal Health, Healthcare Services and Alliances segments. The Pharmaceutical and Animal Health segments are the only reportable segments.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities.

The Animal Health segment discovers, develops, manufactures and markets a wide range of veterinary pharmaceutical and vaccine products, as well as health management solutions and services, for the prevention, treatment and control of disease in all major livestock and companion animal species. The Company also offers an extensive suite of digitally connected identification, traceability and monitoring products. The Company sells its products to veterinarians, distributors and animal producers.

The Healthcare Services segment provides services and solutions that focus on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company has recently sold certain businesses in the Healthcare Services segment and is in the process of divesting the remaining businesses. While the Company continues to look for investment opportunities in this area of health care, the approach to these investments has shifted toward venture capital investments in third parties as opposed to wholly-owned businesses.

The Alliances segment primarily includes activity from the Company's relationship with AstraZeneca LP related to sales of Nexium and Prilosec, which concluded in 2018.

Planned Spin-Off of Women's Health, Legacy Brands and Biosimilars into New Company

In February 2020, Merck announced its intention to spin-off products from its women's health, trusted legacy brands and biosimilars businesses into a new, yet-to-be-named, independent, publicly traded company (NewCo) through a distribution of NewCo's publicly traded stock to Company shareholders. The distribution is expected to qualify as tax-free to the Company and its shareholders for U.S. federal income tax purposes. The legacy brands included in the transaction consist of dermatology, pain, respiratory, and select cardiovascular products including *Zetia* and *Vytorin*, as well as the rest of Merck's diversified brands franchise. Merck's existing research pipeline programs will continue to be owned and developed within Merck as planned. NewCo will have development capabilities initially focused on late-stage development and life-cycle management, and is expected over time to develop research capabilities in selected therapeutic areas. The spin-off is expected to be completed in the first half of 2021, subject to market and certain other conditions.

Overview

Merck's performance during 2019 demonstrates execution in both commercial and research operations driven by a focus on key growth drivers and innovative pipeline investment reinforcing the Company's science-led strategy. In 2019, Merck enhanced its portfolio and pipeline with external innovation, increased investment in new capital projects focused primarily on expanding manufacturing capacity across Merck's key businesses, and returned capital to shareholders.

Worldwide sales were $46.8 billion in 2019, an increase of 11% compared with 2018, including a 2% unfavorable effect from foreign exchange. The sales increase was driven primarily by Merck's growth pillars of oncology, human health vaccines, certain hospital acute care products, and animal health. Growth in these areas was partially offset by the ongoing effects of generic competition, particularly in the diversified brands and cardiovascular franchises, as well as by competitive pressure, particularly in the diabetes and virology franchises.

Merck continued to prioritize business development aimed at enhancing its portfolio and strengthening its pipeline by executing several business development transactions in 2019. To expand its oncology presence, Merck completed the acquisitions of Peloton Therapeutics, Inc. (Peloton), a clinical-stage biopharmaceutical company focused on the development of novel small molecule therapeutic candidates for the treatment of cancer and other diseases, and Immune Design, a late-stage immunotherapy company employing next-generation *in vivo* approaches to enable the body's immune system to fight disease. Merck also announced an agreement to acquire ArQule, Inc. (ArQule), a biopharmaceutical company focused on kinase inhibitor discovery and development for the treatment of cancer and other diseases; the acquisition closed in January 2020. To augment Merck's animal health business, the Company acquired Antelliq Group (Antelliq), a leader in digital animal identification, traceability and monitoring solutions.

During 2019, the Company received numerous regulatory approvals and progressed many important pipeline candidates through clinical development. Within oncology, *Keytruda* received multiple additional approvals in the United States, European Union (EU), China and Japan as monotherapy in the therapeutic areas of non-small-cell lung cancer (NSCLC), small-cell lung cancer (SCLC), esophageal cancer and in combination with axitinib for the treatment of renal cell carcinoma (RCC), in combination with chemotherapy for head and neck squamous cell carcinoma (HNSCC), and in combination with Lenvima for endometrial carcinoma. Lynparza, which is being developed in collaboration with AstraZeneca PLC (AstraZeneca), received U.S. Food and Drug Administration (FDA) approval for the treatment of appropriate patients with germline *BRCA*-mutated (g*BRCA*m) pancreatic cancer and European Commission (EC) approval for use in certain patients with advanced ovarian cancer and advanced or metastatic breast cancer.

In addition to oncology, the Company received regulatory approvals in the hospital acute care and vaccines therapeutic areas. The FDA approved *Recarbrio* (imipenem, cilastatin, and relebactam) for injection, a new combination antibacterial for the treatment of certain patients with complicated urinary tract infections caused by certain Gram-negative microorganisms. *Recarbrio* was approved by the EC in February 2020. The FDA and EC also approved expanded indications for *Zerbaxa* for the treatment of patients with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by certain susceptible Gram-negative microorganisms. Additionally, *Ervebo* (Ebola Zaire Vaccine, Live), a vaccine for the prevention of disease caused by *Zaire ebolavirus* in adults, was approved in the United States and received conditional approval in the EU.

In addition to the recent regulatory approvals discussed above, the Company advanced its late-stage pipeline, particularly in oncology, with several regulatory submissions for *Keytruda*, Lynparza and Lenvima in the United States and internationally. The Company's Phase 3 oncology programs include *Keytruda* in the therapeutic areas of biliary tract, breast, cervical, colorectal, cutaneous squamous cell, endometrial, esophageal, gastric, hepatocellular, mesothelioma, nasopharyngeal, ovarian, prostate and small-cell lung cancers; Lynparza in combination with *Keytruda* for non-small cell lung cancer; and Lenvima in combination with *Keytruda* for bladder, endometrial, head and neck, melanoma and non-small-cell lung cancers. Additionally, the Company has candidates in Phase 3 clinical development in several other therapeutic areas, including V114, an investigational polyvalent conjugate vaccine for the prevention of pneumococcal disease that received Breakthrough Therapy designation from the FDA for the prevention of invasive pneumococcal disease caused by the vaccine serotypes in pediatric patients (6 weeks to 18 years of age) and in adults; MK-7264, gefapixant, a selective, non-narcotic, orally-administered P2X3-receptor antagonist being developed for the treatment of refractory, chronic cough; MK-8591A, islatravir, an investigational nucleoside reverse transcriptase translocation inhibitor (NRTTI) in combination with doravirine for the treatment of HIV-1 infection; and MK-1242, vericiguat, an investigational treatment for heart failure being developed in a collaboration (see "Research and Development" below).

The Company is allocating resources to effectively support its commercial opportunities in the near term while making the necessary investments to support long-term growth. Research and development expenses in 2019 reflect higher clinical development spending and increased investment in discovery research and early drug development.

In November 2019, Merck's Board of Directors approved an increase to the Company's quarterly dividend, raising it to $0.61 per share from $0.55 per share on the Company's outstanding common stock. During 2019, the Company returned $10.5 billion to shareholders through dividends and share repurchases.

Earnings per common share assuming dilution attributable to common shareholders (EPS) for 2019 were $3.81 compared with $2.32 in 2018. EPS in both years reflects the impact of acquisition and divestiture-related costs, as well as restructuring costs and certain other items. Certain other items in 2019 include a charge related to the acquisition of Peloton and in 2018 include a charge related to the formation of a collaboration with Eisai Co., Ltd. (Eisai). Non-GAAP EPS, which excludes these items, was $5.19 in 2019 and $4.34 in 2018 (see "Non-GAAP Income and Non-GAAP EPS" below).

Pricing

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. Changes to the U.S. health care system as part of health care reform, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, have contributed to pricing pressure. In several international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. In addition, the Company's revenue performance in 2019 was negatively affected by other cost-reduction measures taken by governments and other third-parties to lower health care costs. The Company anticipates all of these actions and additional actions in the future will continue to negatively affect revenue performance.

Operating Results

Sales

($ in millions)	**2019**	**% Change**	**% Change Excluding Exchange**	2018	% Change	% Change Excluding Exchange	2017
United States	**$ 20,325**	**12 %**	**12 %**	$ 18,212	5 %	5 %	$ 17,424
International	**26,515**	**10 %**	**13 %**	24,083	6 %	6 %	22,698
Total	**$ 46,840**	**11 %**	**13 %**	$ 42,294	5 %	5 %	$ 40,122

U.S. plus international may not equal total due to rounding.

Worldwide sales grew 11% in 2019 driven primarily by higher sales in the oncology franchise reflecting strong growth of *Keytruda*, as well as increased alliance revenue related to Lynparza and Lenvima. Also contributing to revenue growth were higher sales of vaccines, including *Gardasil/Gardasil* 9, *Varivax*, *ProQuad* and *M-M-R* II, as well as increased sales of certain hospital acute care products, including *Bridion.* Higher sales of animal health products also drove revenue growth in 2019.

Sales growth in 2019 was partially offset by the effects of generic competition for cardiovascular products *Zetia* and *Vytorin*, hospital acute care products *Invanz*, *Cubicin* and *Noxafil*, oncology product *Emend*, and products within the diversified brands franchise, as well as biosimilar competition for immunology product *Remicade.* The diversified brands franchise includes certain products that are approaching the expiration of their marketing exclusivity or that are no longer protected by patents in developed markets. Lower sales of diabetes products *Januvia* and *Janumet* and HIV products *Isentress/Isentress HD* also partially offset revenue growth in 2019.

Sales in the United States grew 12% in 2019 driven primarily by higher sales of *Keytruda*, combined sales of *ProQuad*, *M-M-R* II and *Varivax*, and *Bridion*, as well as higher alliance revenue from Lenvima and Lynparza. Revenue growth was partially offset by lower sales of *Januvia, Janumet*, *Invanz*, *Emend*, *Isentress/Isentress HD*, *Cubicin* and *Noxafil*.

International sales grew 10% in 2019. Performance in international markets was led by China, which had total sales of $3.2 billion in 2019, representing growth of 47% compared with 2018, including a 7% unfavorable effect from foreign exchange. The increase in international sales primarily reflects growth in *Keytruda*, *Gardasil/ Gardasil* 9, combined sales of *ProQuad*, *M-M-R* II and *Varivax*, as well as higher alliance revenue from Lynparza and Lenvima. Sales growth was partially offset by lower sales of *Zetia*, *Vytorin*, *Zepatier, Remicade*, and products within the diversified brands franchise. International sales represented 57% of total sales in both 2019 and 2018.

See Note 18 to the consolidated financial statements for details on sales of the Company's products. A discussion of performance for select products in the franchises follows.

Pharmaceutical Segment

Oncology

($ in millions)	**2019**	**% Change**	**% Change Excluding Exchange**	2018	% Change	% Change Excluding Exchange	2017
Keytruda	**$ 11,084**	**55 %**	**58 %**	$ 7,171	88 %	88 %	$ 3,809
Alliance Revenue - Lynparza [1]	**444**	**137 %**	**141 %**	187	*	*	20
Alliance Revenue - Lenvima [1]	**404**	**171 %**	**173 %**	149	N/A	N/A	—
Emend	**388**	**(26 %)**	**(24 %)**	522	(6 %)	(7 %)	556

** Calculation not meaningful.*

[1] *Alliance revenue represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs (see Note 4 to the consolidated financial statements).*

Keytruda is an anti-PD-1 therapy that has been approved for the treatment of multiple malignancies including cervical cancer, classical Hodgkin lymphoma (cHL), esophageal cancer, gastric or gastroesophageal junction adenocarcinoma, HNSCC, hepatocellular carcinoma (HCC), NSCLC, SCLC, melanoma, Merkel cell carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient cancer, primary mediastinal large B-cell lymphoma (PMBCL), RCC and urothelial carcinoma. The *Keytruda* clinical development program includes studies across a broad range of cancer types (see "Research and Development" below).

In January 2020, the FDA approved *Keytruda* as monotherapy for the treatment of certain patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) based on the results of the KEYNOTE-057 trial.

In July 2019, the FDA approved *Keytruda* as monotherapy for the treatment of certain patients with recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus whose tumors express PD-L1 (Combined Positive Score [CPS] ≥10) as determined by an FDA-approved test, based on the results of the KEYNOTE-181 and KEYNOTE-180 trials.

In June 2019, the FDA approved *Keytruda* as monotherapy or in combination with chemotherapy for the first-line treatment of patients with metastatic or unresectable, recurrent HNSCC based on results from the pivotal Phase 3 KEYNOTE-048 trial. *Keytruda* was initially approved for HNSCC under the FDA's accelerated approval process based on data from the Phase 1b KEYNOTE-012 trial. In accordance with the accelerated approval process, continued approval was contingent upon verification and description of clinical benefit, which has now been demonstrated in KEYNOTE-048 and has resulted in the FDA converting the accelerated approval to a full (regular) approval. *Keytruda* was approved for these indications by the EC in November 2019 and by Japan's Ministry of Health, Labour and Welfare (MHLW) in December 2019.

Also in June 2019, the FDA approved *Keytruda* as monotherapy for the treatment of certain patients with metastatic SCLC based on pooled data from the KEYNOTE-158 (cohort G) and KEYNOTE-028 (cohort C1) clinical trials.

In April 2019, the FDA approved *Keytruda* in combination with Inlyta (axitinib), a tyrosine kinase inhibitor, for the first-line treatment of patients with advanced RCC, the most common type of kidney cancer, based on findings from the pivotal Phase 3 KEYNOTE-426 trial. *Keytruda* was approved for this indication by the EC in September 2019 and by Japan's MHLW in December 2019.

Also in April 2019, the FDA approved an expanded label for *Keytruda* as monotherapy for the first-line treatment of patients with NSCLC expressing PD-L1 (Tumor Proportion Score [TPS] ≥1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations, in stage III disease where patients are not candidates for surgical resection or definitive chemoradiation, and in metastatic disease. The approval was based on results from the Phase 3 KEYNOTE-042 trial.

In September 2019, the FDA approved the combination of *Keytruda* plus Lenvima for the treatment of certain patients with advanced endometrial carcinoma that is not MSI-H or mismatch repair deficient.

In March 2019, the EC approved *Keytruda* in combination with carboplatin and either paclitaxel or nab-paclitaxel for the first-line treatment of adults with metastatic squamous NSCLC based on data from the Phase 3 KEYNOTE-407 trial. *Keytruda* was approved for this indication by the FDA in October 2018.

In April 2019, the EC approved a new extended dosing schedule of 400 mg every six weeks (Q6W) delivered as an intravenous infusion over 30 minutes for all approved monotherapy indications in the EU. The Q6W dose is available in addition to the formerly approved dose of *Keytruda* 200 mg every three weeks (Q3W) infused over 30 minutes.

Additionally, in 2019, *Keytruda* received the following approvals from China's National Medical Products Administration (NMPA): in combination with pemetrexed and platinum chemotherapy for the first-line treatment of patients with metastatic nonsquamous NSCLC, with no EGFR or ALK genomic tumor aberrations, based on data from the pivotal Phase 3 KEYNOTE-189 trial; as monotherapy for the first-line treatment of patients with locally advanced or metastatic NSCLC whose tumors express PD-L1 as determined by a NMPA-approved test, with no EGFR or ALK genomic tumor aberrations, based on the results from the Phase 3 KEYNOTE-042 trial; and in combination with carboplatin and paclitaxel for the first-line treatment of patients with metastatic squamous NSCLC based on findings from the pivotal Phase 3 KEYNOTE-407 trial.

Global sales of *Keytruda* grew 55% in 2019 driven by higher demand as the Company continues to launch *Keytruda* with multiple new indications globally. Sales in the United States continue to build across the multiple approved indications, in particular for the treatment of NSCLC as monotherapy and in combination with chemotherapy for both nonsquamous and squamous metastatic NSCLC, along with uptake in the recently launched RCC and adjuvant melanoma indications. Other indications contributing to U.S. sales growth include HNSCC, urothelial carcinoma, melanoma, and MSI-H cancer. *Keytruda* sales growth in international markets was driven primarily by performance in Europe, Japan and China reflecting increased use in the treatment of NSCLC, as well as for the more recently approved indications as described above.

The Company is a party to certain third-party license agreements pursuant to which the Company pays royalties on sales of *Keytruda*. Under the terms of the more significant of these agreements, Merck pays a royalty of 6.5% on worldwide sales of *Keytruda* through 2023 to one third party; this royalty will decline to 2.5% for 2024 through 2026 and will terminate thereafter. The Company pays an additional 2% royalty on worldwide sales of *Keytruda* to another third party, the termination date of which varies by country; this royalty will expire in the United States in 2024 and in major European markets in 2025. The royalties are included in *Cost of sales*.

Pursuant to a re-pricing rule, the Japanese government reduced the price of *Keytruda* by 17.5% effective February 2020. Additionally, *Keytruda* will be subject to another significant price reduction in April 2020 under a provision of the Japanese pricing rules.

Lynparza, an oral poly (ADP-ribose) polymerase (PARP) inhibitor being developed as part of a collaboration with AstraZeneca entered into in July 2017 (see Note 4 to the consolidated financial statements), is approved for the treatment of certain types of advanced ovarian, breast and pancreatic cancers. The increase in alliance revenue related to Lynparza in 2019 was driven primarily by expanded use in the United States, the EU, Japan and China reflecting in part the ongoing launch of new indications. Lynparza received approval for the treatment of certain types of advanced ovarian cancer in the United States in December 2018, in the EU and in Japan in June 2019, and in China in December 2019 based on the results of the Phase 3 SOLO-1 trial. Also, in April 2019, the EC approved Lynparza for the treatment of certain adult patients with advanced breast cancer based on the results of the Phase 3 OlympiAD trial. Additionally, in December 2019, the FDA approved Lynparza for the maintenance treatment of certain adult patients with advanced pancreatic cancer based on the results of the Phase 3 POLO trial.

Lenvima, an oral receptor tyrosine kinase inhibitor being developed as part of a collaboration with Eisai entered into in March 2018 (see Note 4 to the consolidated financial statements), is approved for the treatment of certain types of thyroid cancer, HCC, and in combination with evorolimus for certain patients with RCC. Additionally, in September 2019, the FDA approved the combination of *Keytruda* plus Lenvima for the treatment of certain patients with advanced endometrial carcinoma that is not MSI-H or mismatch repair deficient. This marks the first U.S. approval for the combination of *Keytruda* plus Lenvima. The increase in alliance revenue related to Lenvima in 2019 reflects strong performance in the treatment of HCC following recent worldwide launches, as well as a full year of collaboration activity in 2019.

Global sales of *Emend*, for the prevention of chemotherapy-induced and post-operative nausea and vomiting, declined 26% in 2019 driven primarily by lower demand and pricing in the United States due to competition, including recent generic competition for *Emend* for Injection following U.S. patent expiry in September 2019. The patent that provided U.S. market exclusivity for *Emend* expired in 2015 and the patent that provided market exclusivity in most major European markets expired in May 2019. Additionally, *Emend* for Injection will lose market exclusivity in major European markets in August 2020. The Company anticipates that sales of *Emend* for Injection in these markets will decline significantly thereafter.

Vaccines

($ in millions)	**2019**	**% Change**	**% Change Excluding Exchange**	2018	% Change	% Change Excluding Exchange	2017
Gardasil/Gardasil 9	**$ 3,737**	**19 %**	**21 %**	$ 3,151	37 %	36 %	$ 2,308
ProQuad	**756**	**27 %**	**29 %**	593	12 %	12 %	528
M-M-R II	**549**	**28 %**	**29 %**	430	13 %	12 %	382
Varivax	**970**	**25 %**	**28 %**	774	1 %	1 %	767
RotaTeq	**791**	**9 %**	**10 %**	728	6 %	6 %	686

Worldwide sales of *Gardasil/Gardasil* 9, vaccines to help prevent certain cancers and other diseases caused by certain types of HPV, grew 19% in 2019 driven primarily by higher demand in the Asia Pacific region, particularly in China, and higher demand in certain European markets reflecting increased vaccination rates for both boys and girls. Growth was partially offset by lower sales in the United States. The U.S. sales decline was driven by the borrowing of *Gardasil* 9 doses from the U.S. Centers for Disease and Control Prevention (CDC) Pediatric Vaccine Stockpile, offset in part by higher demand and pricing.

In 2019, the Company borrowed doses of *Gardasil* 9 from the CDC Pediatric Vaccine Stockpile. The borrowing reduced sales in 2019 by approximately $120 million and the Company recognized a corresponding liability. During 2018, the Company replenished doses borrowed from the CDC Pediatric Vaccine Stockpile in 2017 resulting in the recognition of sales of $125 million in 2018 and a reversal of the liability related to that borrowing.

The decision of Japan's MHLW to suspend the active recommendation for HPV vaccination is still under review.

The Company is a party to certain third-party license agreements pursuant to which the Company pays royalties on sales of *Gardasil/Gardasil* 9. Under the terms of the more significant of these agreements, Merck pays a 7% royalty on worldwide sales of *Gardasil/Gardasil* 9 to one third party (this agreement expires in December 2023) and an additional 7% royalty on sales of *Gardasil/Gardasil* 9 in the United States to another third party (this agreement expires in December 2028). The royalties are included in *Cost of sales*.

Global sales of *ProQuad*, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, grew 27% in 2019 driven primarily by higher volumes and pricing in the United States, as well as volume growth in the EU largely reflecting a competitor supply issue.

Worldwide sales of *M-M-R* II, a vaccine to help protect against measles, mumps and rubella, grew 28% in 2019 driven primarily by higher sales in the United Sates reflecting increased demand due to measles outbreaks, as well as higher pricing. The Company anticipates that U.S. sales of *M-M-R* II will decline in 2020 driven by lower expected demand related to fewer measles outbreaks.

Global sales of *Varivax,* a vaccine to help prevent chickenpox (varicella), grew 25% in 2019 driven primarily by government tenders in Latin America, as well as higher pricing and volume growth in the United States. *Varivax* sales are expected to decline in 2020 due in part to the timing of government tenders and competition in select Latin American markets.

Global sales of *RotaTeq,* a vaccine to help protect against rotavirus gastroenteritis in infants and children, grew 9% in 2019 driven primarily by continued uptake from the launch in China and higher volumes in the United States, partially offset by lower volumes in Latin America.

In December 2019, the FDA approved *Ervebo* for the prevention of disease caused by *Zaire ebolavirus* in individuals 18 years of age and older. As previously announced, Merck is working to initiate manufacturing of licensed doses and expects these doses to start becoming available in approximately the third quarter of 2020. Merck is working closely with the U.S. government, the World Health Organization (WHO), UNICEF, and Gavi (the Vaccine Alliance) to plan for how eventual, licensed doses will support future public health preparedness and response efforts against *Zaire ebolavirus* disease. Merck is not seeking to profit from sales of this vaccine; rather, to ensure the vaccine is sustainable by recovering manufacturing and operational costs associated with the program. Ervebo was also granted a conditional marking authorization by the EC. Additionally, Merck has made submissions to African country national regulatory authorities in collaboration with the African Vaccine Regulatory Forum that will allow the vaccine to be registered in African countries considered to be at-risk for Ebola outbreaks by the WHO. In February 2020, Merck confirmed that four African countries have approved *Ervebo*. Approvals in additional countries in Africa are anticipated in the near future.

Hospital Acute Care

($ in millions)	**2019**	**% Change**	**% Change Excluding Exchange**	2018	% Change	% Change Excluding Exchange	2017
Bridion	**$ 1,131**	**23 %**	**26 %**	$ 917	30 %	30 %	$ 704
Noxafil	**662**	**(11 %)**	**(7 %)**	742	17 %	15 %	636
Invanz	**263**	**(47 %)**	**(44 %)**	496	(18 %)	(17 %)	602
Cubicin	**257**	**(30 %)**	**(28 %)**	367	(4 %)	(5 %)	382

Global sales of *Bridion*, for the reversal of two types of neuromuscular blocking agents used during surgery, grew 23% in 2019 driven by higher demand globally, particularly in the United States.

Worldwide sales of *Noxafil*, for the prevention of invasive fungal infections, declined 11% in 2019 driven primarily by generic competition in the United States. The patent that provided U.S. market exclusivity for certain forms of *Noxafil* representing the majority of U.S. *Noxafil* sales expired in July 2019. Accordingly, the Company is experiencing a decline in U.S. *Noxafil* sales as a result of generic competition and expects the decline to continue. Additionally, the patent for *Noxafil* expired in a number of major European markets in December 2019. As a result, the Company anticipates sales of *Noxafil* in these markets will decline significantly in future periods.

Global sales of *Invanz*, for the treatment of certain infections, declined 47% in 2019 driven by generic competition in the United States. The patent that provided U.S. market exclusivity for *Invanz* expired in November 2017 and generic competition began in the second half of 2018. The Company subsequently experienced a significant decline in *Invanz* sales in the United States as a result of this generic competition and has since lost most of its U.S. *Invanz* sales.

Global sales of *Cubicin*, an I.V. antibiotic for complicated skin and skin structure infections or bacteremia when caused by designated susceptible organisms, declined 30% in 2019 resulting primarily from ongoing generic competition in the United States following expiration of the U.S. composition patent for *Cubicin* in 2016.

In 2019, the FDA and EC approved expanded indications for *Zerbaxa* for the treatment of HABP/VABP caused by certain susceptible Gram-negative microorganisms based on the results of the pivotal Phase 3 ASPECT-NP trial. *Zerbaxa* was previously approved in the United States and EU for the treatment of adults with certain complicated urinary tract and intra-abdominal infections.

In July 2019, the FDA approved *Recarbrio* for injection, a new combination antibacterial for the treatment of adults who have limited or no alternative treatment options with complicated urinary tract infections and complicated intra-abdominal infections caused by certain susceptible Gram-negative microorganisms. *Recarbrio* was approved by the EC in February 2020. Merck anticipates making *Recarbrio* available in the first half of 2020.

In January 2020, the FDA approved *Dificid* (fidaxomicin) for oral suspension and *Dificid* tablets for the treatment of *Clostridioides* (formerly *Clostridium*) *difficile*-associated diarrhea in children aged six months and older.

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Immunology

($ in millions)	2019	% Change	% Change Excluding Exchange	2018	% Change	% Change Excluding Exchange	2017
Simponi	**$ 830**	**(7 %)**	**(2 %)**	$ 893	9 %	5 %	$ 819
Remicade	**411**	**(29 %)**	**(25 %)**	582	(31 %)	(33 %)	837

Sales of *Simponi*, a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), declined 7% in 2019 driven by the unfavorable effect of foreign exchange and lower pricing in Europe. Sales of *Simponi* are being unfavorably affected by the launch of biosimilars for a competing product. The Company expects this competition will continue to unfavorably affect sales of *Simponi*.

Sales of *Remicade,* a treatment for inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), declined 29% in 2019 driven by ongoing biosimilar competition in the Company's marketing territories. The Company lost market exclusivity for *Remicade* in major European markets in 2015 and no longer has market exclusivity in any of its marketing territories. The Company is experiencing pricing and volume declines in these markets as a result of biosimilar competition and expects the declines to continue.

Virology

($ in millions)	2019	% Change	% Change Excluding Exchange	2018	% Change	% Change Excluding Exchange	2017
Isentress/Isentress HD	**$ 975**	**(15 %)**	**(10 %)**	$ 1,140	(5 %)	(5 %)	$ 1,204

Worldwide sales of *Isentress/Isentress HD*, an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, declined 15% in 2019 primarily reflecting lower demand in the United States and in the EU due to competitive pressure.

In September 2019, the FDA approved supplemental New Drug Applications (NDA) for *Pifeltro* (doravirine) in combination with other antiretroviral agents, and for *Delstrigo* (doravirine/lamivudine/tenofovir disoproxil fumarate) as a complete regimen, that expand their indications to include adult patients with HIV-1 infection who are virologically suppressed on a stable antiretroviral regimen.

Cardiovascular

($ in millions)	2019	% Change	% Change Excluding Exchange	2018	% Change	% Change Excluding Exchange	2017
Zetia/Vytorin	**$ 874**	**(35 %)**	**(34 %)**	$ 1,355	(35 %)	(38 %)	$ 2,095
Atozet	**391**	**13 %**	**18 %**	347	54 %	48 %	225
Rosuzet	**120**	**107 %**	**115 %**	58	12 %	9 %	52
Adempas	**419**	**27 %**	**30 %**	329	10 %	7 %	300

Combined global sales of *Zetia* (marketed in most countries outside the United States as *Ezetrol*) and *Vytorin* (marketed outside the United States as *Inegy*), medicines for lowering LDL cholesterol, declined 35% in 2019 driven primarily by lower sales in the EU. The EU patents for *Ezetrol* and *Inegy* expired in April 2018 and April 2019, respectively. Accordingly, the Company is experiencing sales declines in these markets as a result of generic competition and expects the declines to continue. The sales decline was also attributable to loss of exclusivity in Australia. Merck lost market exclusivity in the United States for *Zetia* in 2016 and *Vytorin* in 2017 and subsequently lost nearly all U.S. sales of these products as a result of generic competition.

Sales of *Atozet* (marketed outside of the United States), a medicine for lowering LDL cholesterol, grew 13% in 2019, primarily driven by higher demand in the EU and in Korea.

Sales of *Rosuzet* (marketed outside of the United States), a medicine for lowering LDL cholesterol, more than doubled in 2019, primarily driven by the launch in Japan, as well as higher demand in Korea.

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Adempas, a cardiovascular drug for the treatment of pulmonary arterial hypertension, is part of a worldwide clinical development collaboration with Bayer AG (Bayer) to market and develop soluble guanylate cyclase (sGC) modulators including Adempas (see Note 4 to the consolidated financial statements). The increase in alliance revenue of 27% in 2019 was driven both by higher profits from Bayer and higher sales of Adempas in Merck's marketing territories.

Diabetes

($ in millions)	**2019**	**% Change**	**% Change Excluding Exchange**	2018	% Change	% Change Excluding Exchange	2017
Januvia/Janumet	**$ 5,524**	**(7 %)**	**(4 %)**	$ 5,914	— %	(1 %)	$ 5,896

Worldwide combined sales of *Januvia* and *Janumet*, medicines that help lower blood sugar levels in adults with type 2 diabetes, declined 7% in 2019 as a result of continued pricing pressure in the United States, partially offset by higher demand in most international markets. The Company expects U.S. pricing pressure to continue. The patents that provide market exclusivity for *Januvia* and *Janumet* in the United States expire in July 2022 (although six-month pediatric exclusivity may extend this date). The patent that provides market exclusivity for *Januvia* in the EU expires in July 2022 (although pediatric exclusivity may extend this date to September 2022). The supplementary patent certificate that provides market exclusivity for *Janumet* in the EU expires in April 2023. The Company anticipates sales of *Januvia* and *Janumet* in these markets will decline substantially after these patent expiries.

Women's Health

($ in millions)	**2019**	**% Change**	**% Change Excluding Exchange**	2018	% Change	% Change Excluding Exchange	2017
NuvaRing	**$ 879**	**(3 %)**	**(2 %)**	$ 902	19 %	18 %	$ 761
Implanon/Nexplanon	**787**	12 %	**14 %**	703	2 %	3 %	686

Worldwide sales of *NuvaRing*, a vaginal contraceptive product, declined 3% in 2019 driven primarily by lower demand in the EU due to generic competition, largely offset by higher sales in the United States reflecting higher pricing that was partially offset by lower demand. The patent that provided U.S. market exclusivity for *NuvaRing* expired in April 2018 and generic competition began in December 2019. The Company anticipates a rapid and substantial decline in U.S. *NuvaRing* sales in 2020 as a result of this generic competition.

Worldwide sales of *Implanon/Nexplanon*, a single-rod subdermal contraceptive implant, grew 12% in 2019, primarily driven by higher demand and pricing in the United States.

Biosimilars

($ in millions)	**2019**	**% Change**	**% Change Excluding Exchange**	2018	% Change	% Change Excluding Exchange	2017
Biosimilars	$ 252	*	*	$ 64	*	*	$ 5

** Calculation not meaningful.*

Biosimilar products are marketed by the Company pursuant to an agreement with Samsung Bioepis Co., Ltd. (Samsung) to develop and commercialize multiple pre-specified biosimilar candidates. Currently, the Company markets Renflexis (infliximab-abda), a tumor necrosis factor (TNF) antagonist biosimilar to Remicade (infliximab) for the treatment of certain inflammatory diseases; Ontruzant (trastuzumab-dttb), a human epidermal growth factor receptor 2 (HER2)/ neu receptor antagonist biosimilar to Herceptin (trastuzumab) for the treatment of HER2-positive breast cancer and HER2 overexpressing gastric cancer; and Brenzys (etanercept biosimilar), a TNF antagonist biosimilar to Enbrel for the treatment of certain inflammatory diseases. Merck's commercialization territories under the agreement vary by product. Sale growth of biosimilars in 2019 was driven by continued uptake of Renflexis in United States since launch in 2017, continued uptake of Ontruzant in the EU since launch in 2018, and the launch of Brenzys in Brazil in 2019.

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Animal Health Segment

($ in millions)	2019	% Change	% Change Excluding Exchange	2018	% Change	% Change Excluding Exchange	2017
Livestock	**$ 2,784**	**6 %**	**11 %**	$ 2,630	6 %	7 %	$ 2,484
Companion Animal	**1,609**	**2 %**	**5 %**	1,582	14 %	13 %	1,391

Sales of livestock products grew 6% in 2019 predominantly due to products obtained in the April 2019 acquisition of Antelliq, a leader in digital animal identification, traceability and monitoring solutions (see Note 3 to the consolidated financial statements). Growth in sales of livestock products was also driven by higher demand for aqua and swine products. Sales of companion animal products grew 2% in 2019 driven primarily by higher demand for the *Bravecto* line of products for parasitic control.

Costs, Expenses and Other

($ in millions)	2019	Change	2018	Change	2017
Cost of sales	**$ 14,112**	**4 %**	$ 13,509	5 %	$ 12,912
Selling, general and administrative	**10,615**	**5 %**	10,102	— %	10,074
Research and development	**9,872**	**1 %**	9,752	-6 %	10,339
Restructuring costs	**638**	**1 %**	632	-19 %	776
Other (income) expense, net	**139**	*****	(402)	-20 %	(500)
	$ 35,376	**5 %**	$ 33,593	— %	$ 33,601

** Greater than 100%.*

Cost of Sales

Cost of sales was $14.1 billion in 2019 compared with $13.5 billion in 2018. Cost of sales includes the amortization of intangible assets recorded in connection with business acquisitions, which totaled $1.4 billion in 2019 compared with $2.7 billion in 2018. Cost of sales also includes the amortization of amounts capitalized in connection with collaborations of $464 million in 2019 compared with $347 million in 2018 (see Note 8 to the consolidated financial statements). Additionally, costs in 2019 include intangible asset impairment charges of $705 million related to marketed products recorded in connection with business acquisitions (see Note 8 to the consolidated financial statements). The Company may recognize additional non-cash impairment charges in the future related to intangible assets that were measured at fair value and capitalized in connection with business acquisitions and such charges could be material. Costs in 2018 include a $423 million charge related to the termination of a collaboration agreement with Samsung for insulin glargine (see Note 3 to the consolidated financial statements). Also included in cost of sales are expenses associated with restructuring activities which amounted to $251 million in 2019 compared with $21 million in 2018, primarily reflecting accelerated depreciation and asset write-offs related to the planned sale or closure of manufacturing facilities. Separation costs associated with manufacturing-related headcount reductions have been incurred and are reflected in *Restructuring costs* as discussed below.

Gross margin was 69.9% in 2019 compared with 68.1% in 2018. The gross margin improvement in 2019 reflects the charge recorded in 2018 in connection with the termination of the collaboration agreement with Samsung (noted above), favorable product mix, and lower amortization of intangible assets (noted above). These improvements in gross margin were partially offset by unfavorable manufacturing variances, inventory write-offs, pricing pressure, and higher restructuring costs.

Selling, General and Administrative

Selling, general and administrative (SG&A) expenses were $10.6 billion in 2019, an increase of 5% compared with 2018, driven primarily by higher administrative costs, acquisition and divestiture-related costs (largely related to the acquisition of Antelliq), promotional expenses primarily in support of strategic brands, and restructuring costs, partially offset by the favorable effect of foreign exchange and lower selling costs. SG&A expenses in 2019 include restructuring costs of $34 million related primarily to accelerated depreciation for facilities to be closed or divested. Separation costs associated with sales force reductions have been incurred and are reflected

in *Restructuring costs* as discussed below. SG&A expenses include acquisition and divestiture-related costs of $126 million in 2019 compared

with $32 million in 2018, consisting of integration, transaction, and certain other costs related to business acquisitions and divestitures.

Research and Development

Research and development (R&D) expenses were $9.9 billion in 2019, an increase of 1% compared with 2018. The increase was driven primarily by a $993 million charge in 2019 for the acquisition of Peloton (see Note 3 to the consolidated financial statements), as well as higher expenses related to clinical development and increased investment in discovery research and early drug development. The increase in R&D expenses in 2019 was partially offset by a $1.4 billion charge in 2018 related to the formation of an oncology collaboration with Eisai (see Note 4 to the consolidated financial statements), a $344 million charge in 2018 related to the acquisition of Viralytics Limited (Viralytics) (see Note 3 to the consolidated financial statements), and the favorable effect of foreign exchange.

R&D expenses are comprised of the costs directly incurred by Merck Research Laboratories (MRL), the Company's research and development division that focuses on human health-related activities, which were $6.1 billion in 2019 compared with $5.6 billion in 2018. Also included in R&D expenses are Animal Health research costs, licensing costs and costs incurred by other divisions in support of R&D activities, including depreciation, production and general and administrative, which in the aggregate were $2.6 billion in 2019 and $2.3 billion in 2018. R&D expenses also include in-process research and development (IPR&D) impairment charges of $172 million and $152 million in 2019 and 2018, respectively (see Note 8 to the consolidated financial statements). The Company may recognize additional non-cash impairment charges in the future related to the cancellation or delay of other pipeline programs that were measured at fair value and capitalized in connection with business acquisitions and such charges could be material. In addition, R&D expenses include expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration recorded in connection with business acquisitions. During 2019 and 2018, the Company recorded a net reduction in expenses of $39 million and $54 million, respectively, related to changes in these estimates.

Restructuring Costs

In early 2019, Merck approved a new global restructuring program (Restructuring Program) as part of a worldwide initiative focused on further optimizing the Company's manufacturing and supply network, as well as reducing its global real estate footprint. This program is a continuation of the Company's plant rationalization, builds on prior restructuring programs and does not include any actions associated with the planned spin-off of NewCo. As the Company continues to evaluate its global footprint and overall operating model, it has subsequently identified additional actions under the Restructuring Program, and could identify further actions over time. The actions currently contemplated under the Restructuring Program are expected to be substantially completed by the end of 2023, with the cumulative pretax costs to be incurred by the Company to implement the program now estimated to be approximately $2.5 billion. The Company expects to record charges of approximately $800 million in 2020 related to the Restructuring Program. The Company anticipates the actions under the Restructuring Program to result in annual net cost savings of approximately $900 million by the end of 2023. Actions under previous global restructuring programs have been substantially completed.

Restructuring costs, primarily representing separation and other related costs associated with these restructuring activities, were $638 million in 2019 and $632 million in 2018. Separation costs incurred were associated with actual headcount reductions, as well as estimated expenses under existing severance programs for headcount reductions that were probable and could be reasonably estimated. Also included in restructuring costs are asset abandonment, facility shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation plan costs. For segment reporting, restructuring costs are unallocated expenses.

Additional costs associated with the Company's restructuring activities are included in *Cost of sales*, *Selling, general and administrative* and *Research and development*. The Company recorded aggregate pretax costs of $927 million in 2019 and $658 million in 2018 related to restructuring program activities (see Note 5 to the consolidated financial statements).

Other (Income) Expense, Net

For details on the components of Other (income) expense, net, see Note 14 to the consolidated financial statements.

Segment Profits

($ in millions)	**2019**	2018	2017
Pharmaceutical segment profits	**$ 28,324**	$ 24,871	$ 23,018
Animal Health segment profits	**1,609**	1,659	1,552
Other non-reportable segment profits	**(7)**	103	275
Other	**(18,462)**	(17,932)	(18,324)
Income Before Taxes	**$ 11,464**	$ 8,701	$ 6,521

Pharmaceutical segment profits are comprised of segment sales less standard costs, as well as SG&A expenses directly incurred by the segment. Animal Health segment profits are comprised of segment sales, less all cost of sales, as well as SG&A and R&D expenses directly incurred by the segment. For internal management reporting presented to the chief operating decision maker, Merck does not allocate the remaining cost of sales not included in segment profits as described above, research and development expenses incurred by MRL, or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. Also excluded from the determination of segment profits are costs related to restructuring activities and acquisition and divestiture-related costs, including amortization of purchase accounting adjustments, intangible asset impairment charges and changes in the estimated fair value measurement of liabilities for contingent consideration. Additionally, segment profits do not reflect other expenses from corporate and manufacturing cost centers and other miscellaneous income or expense. These unallocated items are reflected in "Other" in the above table. Also included in "Other" are miscellaneous corporate profits (losses), as well as operating profits (losses) related to third-party manufacturing sales. During 2019, as a result of changes to the Company's internal reporting structure, certain costs that were previously included in the Pharmaceutical segment are now being included as part of non-segment expenses within MRL. Prior period Pharmaceutical segment profits have been recast to reflect these changes on a comparable basis.

Pharmaceutical segment profits grew 14% in 2019 compared with 2018 driven primarily by higher sales, as well as lower selling costs. Animal Health segment profits declined 3% in 2019 driven primarily by unfavorable product mix, higher investments in selling and product development, and the unfavorable effect of foreign exchange, partially offset by higher sales.

Taxes on Income

The effective income tax rates of 14.7% in 2019 and 28.8% in 2018 reflect the impacts of acquisition and divestiture-related costs, restructuring costs and the beneficial impact of foreign earnings, including product mix. The effective income tax rate in 2019 also reflects the favorable impact of a $364 million net tax benefit related to the settlement of certain federal income tax matters (see Note 15 to the consolidated financial statements) and the reversal of tax reserves established in connection with the 2014 divestiture of Merck's Consumer Care (MCC) business due to the lapse in the statute of limitations. In addition, the effective income tax rate in 2019 reflects the unfavorable impacts of a charge for the acquisition of Peloton for which no tax benefit was recognized and charges of $117 million related to the finalization of treasury regulations for the transition tax associated with the 2017 enactment of U.S. tax legislation known as the Tax Cuts and Jobs Act (TCJA) (see Note 15 to the consolidated financial statements). The effective income tax rate in 2018 includes measurement-period adjustments to the provisional amounts recorded in 2017 associated with the enactment of the TCJA, including $124 million related to the transition tax. In addition, the effective income tax rate for 2018 reflects the unfavorable impacts of a charge recorded in connection with the formation of a collaboration with Eisai and a charge related to the termination of a collaboration agreement with Samsung for which no tax benefit was recognized.

Net (Loss) Income Attributable to Noncontrolling Interests

Net (loss) income attributable to noncontrolling interests was $(66) million in 2019 compared with $(27) million in 2018. The losses in 2019 and 2018 were driven primarily by the portion of goodwill impairment charges related to certain business in the Healthcare Services segment that are attributable to noncontrolling interests.

Net Income and Earnings per Common Share

Net income attributable to Merck & Co., Inc. was $9.8 billion in 2019 and $6.2 billion in 2018. EPS was $3.81 in 2019 and $2.32 in 2018.

Non-GAAP Income and Non-GAAP EPS

Non-GAAP income and non-GAAP EPS are alternative views of the Company's performance that Merck is providing because management believes this information enhances investors' understanding of the Company's results as it permits investors to understand how management assesses performance. Non-GAAP income and non-GAAP EPS exclude certain items because of the nature of these items and the impact that they have on the analysis of underlying business performance and trends. The excluded items (which should not be considered non-recurring) consist of acquisition and divestiture-related costs, restructuring costs and certain other items. These excluded items are significant components in understanding and assessing financial performance.

Non-GAAP income and non-GAAP EPS are important internal measures for the Company. Senior management receives a monthly analysis of operating results that includes non-GAAP EPS. Management uses these measures internally for planning and forecasting purposes and to measure the performance of the Company along with other metrics. In addition, senior management's annual compensation is derived in part using non-GAAP pretax income. Since non-GAAP income and non-GAAP EPS are not measures determined in accordance with GAAP, they have no standardized meaning prescribed by GAAP and, therefore, may not be comparable to the calculation of similar measures of other companies. The information on non-GAAP income and non-GAAP EPS should be considered in addition to, but not as a substitute for or superior to, net income and EPS prepared in accordance with generally accepted accounting principles in the United States (GAAP).

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A reconciliation between GAAP financial measures and non-GAAP financial measures is as follows:

($ in millions except per share amounts)	**2019**	2018	2017
Income before taxes as reported under GAAP	**$ 11,464**	$ 8,701	$ 6,521
Increase (decrease) for excluded items:			
Acquisition and divestiture-related costs	**2,681**	3,066	3,760
Restructuring costs	**927**	658	927
Other items:			
Charge for the acquisition of Peloton	**993**	—	—
Charge related to the formation of an oncology collaboration with Eisai	**—**	1,400	—
Charge related to the termination of a collaboration with Samsung	**—**	423	—
Charge for the acquisition of Viralytics	**—**	344	—
Charge related to the formation of an oncology collaboration with AstraZeneca	**—**	—	2,350
Other	**55**	(57)	(16)
Non-GAAP income before taxes	**16,120**	14,535	13,542
Taxes on income as reported under GAAP	**1,687**	2,508	4,103
Estimated tax benefit on excluded items [1]	**695**	535	785
Net tax charge related to the enactment of the TCJA and subsequent finalization of related treasury regulations [2]	**(117)**	(160)	(2,625)
Net tax benefit from the settlement of certain federal income tax matters	**364**	—	234
Tax benefit from the reversal of tax reserves related to the divestiture of MCC	**86**	—	—
Tax benefit related to the settlement of a state income tax matter	**—**	—	88
Non-GAAP taxes on income	**2,715**	2,883	2,585
Non-GAAP net income	**13,405**	11,652	10,957
Less: Net (loss) income attributable to noncontrolling interests as reported under GAAP	**(66)**	(27)	24
Acquisition and divestiture-related costs attributable to noncontrolling interests	**(89)**	(58)	—
Non-GAAP net income attributable to noncontrolling interests	**23**	31	24
Non-GAAP net income attributable to Merck & Co., Inc.	**$ 13,382**	$ 11,621	$ 10,933
EPS assuming dilution as reported under GAAP	**$ 3.81**	$ 2.32	$ 0.87
EPS difference	**1.38**	2.02	3.11
Non-GAAP EPS assuming dilution	**$ 5.19**	$ 4.34	$ 3.98

[1] *The estimated tax impact on the excluded items is determined by applying the statutory rate of the originating territory of the non-GAAP adjustments.*

[2] *Amount in 2017 was provisional (see Note 15 to the consolidated financial statements).*

Acquisition and Divestiture-Related Costs

Non-GAAP income and non-GAAP EPS exclude the impact of certain amounts recorded in connection with business acquisitions and divestitures. These amounts include the amortization of intangible assets and amortization of purchase accounting adjustments to inventories, as well as intangible asset impairment charges and expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration. Also excluded are integration, transaction, and certain other costs associated with business acquisitions and divestitures.

Restructuring Costs

Non-GAAP income and non-GAAP EPS exclude costs related to restructuring actions (see Note 5 to the consolidated financial statements). These amounts include employee separation costs and accelerated depreciation associated with facilities to be closed or divested. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the asset, based upon the anticipated date the site

will be closed or divested or the equipment disposed of, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. Restructuring costs also include asset abandonment, facility shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation costs.

Certain Other Items

These items are adjusted for after they are evaluated on an individual basis considering their quantitative and qualitative aspects. Typically, these consist of items that are unusual in nature, significant to the results of a particular period or not indicative of future operating results. Excluded from non-GAAP income and non-GAAP EPS in 2019 is a charge for the acquisition of Peloton (see Note 3 to the consolidated financial statements), tax charges related to the finalization of U.S. treasury regulations related to the TCJA, a net tax benefit related to the settlement of certain federal income tax matters, and a tax benefit related to the reversal of tax reserves established in connection with the 2014 divestiture of MCC (see Note 15 to the consolidated financial statements). Excluded from non-GAAP income and non-GAAP EPS in 2018 is a charge related to the formation of a collaboration with Eisai (see Note 4 to the consolidated financial statements), a charge related to the termination of a collaboration agreement with Samsung for insulin glargine (see Note 3 to the consolidated financial statements), a charge for the acquisition of Viralytics (see Note 3 to the consolidated financial statements), and measurement-period adjustments related to the provisional amounts recorded for the TCJA (see Note 15 to the consolidated financial statements). Excluded from non-GAAP income and non-GAAP EPS in 2017 is a charge related to the formation of a collaboration with AstraZeneca (see Note 4 to the consolidated financial statements), as well as a provisional net tax charge related to the enactment of the TCJA, a net tax benefit related to the settlement of certain federal income tax matters and a tax benefit related to the settlement of a state income tax matter (see Note 15 to the consolidated financial statements).

Research and Development

A chart reflecting the Company's current research pipeline as of February 21, 2020 is set forth in Item 1. "Business — Research and Development" above.

Research and Development Update

The Company currently has several candidates under regulatory review in the United States and internationally.

Keytruda is an anti-PD-1 therapy approved for the treatment of many cancers that is in clinical development for expanded indications. These approvals were the result of a broad clinical development program that currently consists of more than 1,000 clinical trials, including more than 600 trials that combine *Keytruda* with other cancer treatments. These studies encompass more than 30 cancer types including: biliary tract, cervical, colorectal, cutaneous squamous cell, endometrial, gastric, head and neck, hepatocellular, Hodgkin lymphoma, non-Hodgkin lymphoma, melanoma, mesothelioma, nasopharyngeal, non-small-cell lung, ovarian, PMBCL, prostate, renal, small-cell lung, triple-negative breast and urothelial, many of which are currently in Phase 3 clinical development. Further trials are being planned for other cancers.

Keytruda is under review in the EU as monotherapy for the first-line treatment of patients with stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC, and whose tumors express PD-L1 (TPS ≥1%) with no EGFR or ALK genomic tumor aberrations based on results from the Phase 3 KEYNOTE-042 trial.

Keytruda is under review in Japan as monotherapy and in combination with chemotherapy for the first-line treatment of advanced gastric or gastroesophageal junction adenocarcinoma based on results from the pivotal Phase 3 KEYNOTE-062 trial.

Keytruda is also under review in Japan as monotherapy for the second-line treatment of advanced or metastatic esophageal or esophagogastric junction carcinoma based on the results of the Phase 3 KEYNOTE-181 trial. Merck has made the decision to withdraw its Type II variation application for *Keytruda* for this indication in the EU.

In October 2019, the FDA accepted a supplemental Biologics License Application (BLA) seeking use of *Keytruda* for the treatment of patients with recurrent and/or metastatic cutaneous squamous cell carcinoma (cSCC) that

is not curable by surgery or radiation based on the results of the KEYNOTE-629 trial. The FDA set a Prescription Drug User Fee Act (PDUFA) date of June 29, 2020.

In February 2020, Merck announced the FDA issued a Complete Response Letter regarding Merck's supplemental BLAs seeking to update the dosing frequency for *Keytruda* to include a 400 mg dose infused over 30 minutes every-six-weeks (Q6W) option in multiple indications. The submitted applications are based on pharmacokinetic modeling and simulation data presented at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting. These data supported the EC approval of 400 mg Q6W dosing for *Keytruda* monotherapy indications in March 2019. Merck is reviewing the letter and will discuss next steps with the FDA.

Additionally, *Keytruda* has received Breakthrough Therapy designation from the FDA in combination with neoadjuvant chemotherapy for the treatment of high-risk, early-stage triple-negative breast cancer (TNBC) and in combination with enfortumab vedotin, in the first-line setting for the treatment of patients with unresectable locally advanced or metastatic urothelial cancer who are not eligible for cisplatin-containing chemotherapy. The FDA's Breakthrough Therapy designation is intended to expedite the development and review of a candidate that is planned for use, alone or in combination, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

In September 2019, Merck announced results from the pivotal neoadjuvant/adjuvant Phase 3 KEYNOTE-522 trial in patients with early-stage TNBC. The trial investigated a regimen of neoadjuvant *Keytruda* plus chemotherapy, followed by adjuvant *Keytruda* as monotherapy (the *Keytruda* regimen) compared with a regimen of neoadjuvant chemotherapy followed by adjuvant placebo (the chemotherapy-placebo regimen). Interim findings were presented at the European Society for Medical Oncology (ESMO) 2019 Congress. In the neoadjuvant phase, *Keytruda* plus chemotherapy resulted in a statistically significant increase in pathological complete response (pCR) versus chemotherapy in patients with early-stage TNBC. The improvement seen when adding *Keytruda* to neoadjuvant chemotherapy was observed regardless of PD-L1 expression. In the other dual primary endpoint of event-free-survival (EFS), with a median follow-up of 15.5 months, the *Keytruda* regimen reduced the risk of progression in the neoadjuvant phase and recurrence in the adjuvant phase compared with the chemotherapy-placebo regimen. Merck continues to discuss interim analysis data from KEYNOTE-522 with regulatory authorities. The *Keytruda* breast cancer clinical development program encompasses several internal and external collaborative studies.

In February 2020, Merck announced that the pivotal Phase 3 KEYNOTE-355 trial investigating *Keytruda* in combination with chemotherapy met one of its dual primary endpoints of progression-free survival (PFS) in patients with metastatic triple-negative breast cancer (mTNBC) whose tumors expressed PD-L1 (CPS ≥10). Based on an interim analysis conducted by an independent Data Monitoring Committee (DMC), first-line treatment with *Keytruda* in combination with chemotherapy (nab-paclitaxel, paclitaxel or gemcitabine/carboplatin) demonstrated a statistically significant and clinically meaningful improvement in PFS compared to chemotherapy alone in these patients. Based on the recommendation of the DMC, the trial will continue without changes to evaluate the other dual primary endpoint of overall survival (OS).

In May 2019, Merck announced that the Phase 3 KEYNOTE-119 trial evaluating *Keytruda* as monotherapy for the second- or third-line treatment of patients with metastatic TNBC did not meet its pre-specified primary endpoint of superior OS compared to chemotherapy. Other endpoints were not formally tested per the study protocol because the primary endpoint of OS was not met.

In June 2019, Merck announced full results from the pivotal Phase 3 KEYNOTE-062 trial evaluating *Keytruda* as monotherapy and in combination with chemotherapy for the first-line treatment of advanced gastric or gastroesophageal junction adenocarcinoma. In the monotherapy arm of the study, *Keytruda* met a primary endpoint by demonstrating noninferiority to chemotherapy, the current standard of care, for OS in patients whose tumors expressed PD-L1 (CPS ≥1). In the combination arm of KEYNOTE-062, *Keytruda* plus chemotherapy was not found to be statistically superior for OS (CPS ≥1 or CPS ≥10) or PFS (CPS ≥1) compared with chemotherapy alone. Results were presented at the 2019 ASCO Annual Meeting. In September 2017, the FDA approved *Keytruda* as a third-line treatment for previously treated patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction cancer whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test. KEYNOTE-062 was a potential confirmatory trial for this accelerated, third-line approval. In addition to KEYNOTE-062, additional first-line, Phase

3 studies in Merck's gastric clinical program include KEYNOTE-811 and KEYNOTE-859, as well as KEYNOTE-585 in the neoadjuvant and adjuvant treatment setting.

In January 2020, Merck announced that the Phase 3 KEYNOTE-604 trial investigating *Keytruda* in combination with chemotherapy met one of its dual primary endpoints of PFS in the first-line treatment of patients with extensive stage SCLC. At the final analysis of the study, there was also an improvement in OS for patients treated with *Keytruda* in combination with chemotherapy compared to chemotherapy alone; however, these OS results did not meet statistical significance per the pre-specified statistical plan. Results will be presented at an upcoming medical meeting and discussed with regulatory authorities.

Lynparza is an oral PARP inhibitor currently approved for certain types of advanced ovarian, breast and pancreatic cancers being co-developed for multiple cancer types as part of a collaboration with AstraZeneca (see Note 4 to the consolidated financial statements).

Lynparza is under review in the EU as a first-line maintenance monotherapy for patients with g*BRCA*m metastatic pancreatic cancer whose disease has not progressed following first-line platinum-based chemotherapy. Lynparza was approved for this indication by the FDA in December 2019 based on results from the Phase 3 POLO trial. A decision from the European Medicines Agency (EMA) is expected in the second half of 2020.

In January 2020, the FDA accepted a supplemental NDA for Lynparza in combination with bevacizumab for the maintenance treatment of women with advanced ovarian cancer whose disease showed a complete or partial response to first-line treatment with platinum-based chemotherapy and bevacizumab based on the results from the pivotal Phase 3 PAOLA-1 trial. A PDUFA date is set for the second quarter of 2020. This indication is also under review in the EU.

In January 2020, the FDA accepted for Priority Review a supplemental NDA for Lynparza for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) and deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutations, who have progressed following prior treatment with a new hormonal agent based on positive results from the Phase 3 PROfound trial. A PDUFA date is set for the second quarter of 2020. This indication is also under review in the EU.

In June 2019, Merck and AstraZeneca presented full results from the Phase 3 SOLO-3 trial which evaluated Lynparza, compared to chemotherapy, for the treatment of platinum-sensitive relapsed patients with g*BRCA*m advanced ovarian cancer, who have received two or more prior lines of chemotherapy. The results from the trial showed a statistically-significant and clinically-meaningful improvement in objective response rate (ORR) in the Lynparza arm compared to the chemotherapy arm. The key secondary endpoint of PFS was also significantly increased in the Lynparza arm compared to the chemotherapy arm. The results were presented at the 2019 ASCO Annual Meeting.

MK-5618, selumetinib, is a MEK 1/2 inhibitor being co-developed as part of a strategic collaboration with AstraZeneca (see Note 4 to the consolidated financial statements). Selumetinib is under Priority Review with the FDA as a potential new medicine for pediatric patients aged three years and older with neurofibromatosis type 1 (NF1) and symptomatic, inoperable plexiform neurofibromas. This regulatory submission was based on positive results from the National Cancer Institute Cancer Therapy Evaluation Program-sponsored SPRINT Phase 2 Stratum 1 trial. A PDUFA date is set for the second quarter of 2020.

V503 is under review in Japan for an initial indication in females for the prevention of certain HPV-related diseases and precursors.

In February 2020, the FDA accepted for Priority Review a supplemental BLA for *Gardasil* 9 for the prevention of certain head and neck cancers caused by vaccine-type HPV in females and males 9 through 45 years of age. The FDA set a PDUFA date of June 2020.

In addition to the candidates under regulatory review, the Company has several drug candidates in Phase 3 clinical development in addition to the *Keytruda* programs discussed above.

Lynparza, in addition to the indications under review discussed above, is in Phase 3 development in combination with *Keytruda* for the treatment of NSCLC.

Lenvima is an orally available tyrosine kinase inhibitor currently approved for certain types of thyroid cancer, HCC, and in combination for certain patients with RCC being co-developed as part of a strategic collaboration with Eisai (see Note 4 to the consolidated financial statements). Pursuant to the agreement, the companies will jointly

initiate clinical studies evaluating the *Keytruda*/Lenvima combination in six types of cancer (endometrial cancer, NSCLC, HCC, HNSCC, bladder cancer and melanoma), as well as a basket trial targeting multiple cancer types. The FDA granted Breakthrough Therapy designation for *Keytruda* in combination with Lenvima both for the potential treatment of patients with advanced and/or metastatic RCC and for the potential treatment of patients with unresectable HCC not amenable to locoregional treatment.

MK-7264, gefapixant, is a selective, non-narcotic, orally-administered P2X3-receptor antagonist being investigated in Phase 3 trials for the treatment of refractory, chronic cough and in a Phase 2 trial for the treatment of women with endometriosis-related pain.

MK-1242, vericiguat, is a sGC stimulator for the potential treatment of patients with worsening chronic heart failure being developed as part of a worldwide strategic collaboration between Merck and Bayer (see Note 4 to the consolidated financial statements). Vericiguat is being studied in patients suffering from chronic heart failure with reduced ejection fraction (Phase 3 clinical trial) and from chronic heart failure with preserved ejection fraction (Phase 2 clinical trial). In November 2019, Merck announced that the Phase 3 VICTORIA study evaluating the efficacy and safety of vericiguat met the primary efficacy endpoint. Vericiguat reduced the risk of the composite endpoint of heart failure hospitalization or cardiovascular death in patients with worsening chronic heart failure with reduced ejection fraction compared to placebo when given in combination with available heart failure therapies. The results of the VICTORIA study will be presented at an upcoming medical meeting in 2020.

V114 is an investigational polyvalent conjugate vaccine for the prevention of pneumococcal disease. In June 2018, Merck initiated the first Phase 3 study in the adult population for the prevention of invasive pneumococcal disease. Currently six Phase 3 adult studies are ongoing, including studies in healthy adults 50 years of age or older, adults with risk factors for pneumococcal disease, those infected with HIV, and those who are recipients of allogeneic hematopoietic stem cell transplant. In October 2018, Merck began the first Phase 3 study in the pediatric population. Currently, eight studies are ongoing, including studies in healthy infants and in children afflicted with sickle cell disease. V114 has received Breakthrough Therapy designation from the FDA for the prevention of invasive pneumococcal disease caused by the vaccine serotypes in pediatric patients (6 weeks to 18 years of age) and in adults.

The Company maintains a number of long-term exploratory and fundamental research programs in biology and chemistry as well as research programs directed toward product development. The Company's research and development model is designed to increase productivity and improve the probability of success by prioritizing the Company's research and development resources on candidates the Company believes are capable of providing unambiguous, promotable advantages to patients and payers and delivering the maximum value of its approved medicines and vaccines through new indications and new formulations. Merck is pursuing emerging product opportunities independent of therapeutic area or modality (small molecule, biologics and vaccines) and is building its biologics capabilities. The Company is committed to ensuring that externally sourced programs remain an important component of its pipeline strategy, with a focus on supplementing its internal research with a licensing and external alliance strategy focused on the entire spectrum of collaborations from early research to late-stage compounds, as well as access to new technologies.

The Company's clinical pipeline includes candidates in multiple disease areas, including cancer, cardiovascular diseases, diabetes and other metabolic diseases, infectious diseases, neurosciences, pain, respiratory diseases, and vaccines.

Acquired In-Process Research and Development

In connection with business acquisitions, the Company has recorded the fair value of in-process research projects which, at the time of acquisition, had not yet reached technological feasibility. At December 31, 2019, the balance of IPR&D was $1.0 billion.

The IPR&D projects that remain in development are subject to the inherent risks and uncertainties in drug development and it is possible that the Company will not be able to successfully develop and complete the IPR&D programs and profitably commercialize the underlying product candidates. The time periods to receive approvals from the FDA and other regulatory agencies are subject to uncertainty. Significant delays in the approval process, or the Company's failure to obtain approval at all, would delay or prevent the Company from realizing revenues from these products. Additionally, if certain of the IPR&D programs fail or are abandoned during development, then the Company will not realize the future cash flows it has estimated and recorded as IPR&D as of the acquisition date. If such

circumstances were to occur, the Company's future operating results could be adversely affected and the Company may recognize impairment charges and such charges could be material.

In 2019, 2018, and 2017 the Company recorded IPR&D impairment charges within *Research and development* expenses of $172 million, $152 million and $483 million, respectively (see Note 8 to the consolidated financial statements).

Additional research and development will be required before any of the remaining programs reach technological feasibility. The costs to complete the research projects will depend on whether the projects are brought to their final stages of development and are ultimately submitted to the FDA or other regulatory agencies for approval.

Acquisitions, Research Collaborations and License Agreements

Merck continues to remain focused on pursuing opportunities that have the potential to drive both near- and long-term growth. Certain recent transactions are described below. Merck is actively monitoring the landscape for growth opportunities that meet the Company's strategic criteria.

In April 2019, Merck acquired Immune Design, a late-stage immunotherapy company employing next-generation *in vivo* approaches to enable the body's immune system to fight disease, for $301 million in cash. The transaction was accounted for as an acquisition of a business. Merck recognized intangible assets for IPR&D of $156 million, cash of $83 million and other net assets of $42 million. The excess of the consideration transferred over the fair value of net assets acquired of $20 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair values of the identifiable intangible assets related to IPR&D were determined using an income approach. Actual cash flows are likely to be different than those assumed.

In July 2019, Merck acquired Peloton, a clinical-stage biopharmaceutical company focused on the development of novel small molecule therapeutic candidates targeting hypoxia-inducible factor-2α (HIF-2α) for the treatment of patients with cancer and other non-oncology diseases. Peloton's lead candidate, MK-6482 (formerly PT2977), is a novel oral HIF-2α inhibitor in late-stage development for renal cell carcinoma. Merck made an upfront payment of $1.2 billion in cash; additionally, former Peloton shareholders will be eligible to receive $50 million upon U.S. regulatory approval, $50 million upon first commercial sale in the United States, and up to $1.05 billion of sales-based milestones. The transaction was accounted for as an acquisition of an asset. Merck recorded cash of $157 million, deferred tax liabilities of $52 million, and other net liabilities of $4 million at the acquisition date and *Research and development* expenses of $993 million in 2019 related to the transaction.

In January 2020, Merck acquired ArQule, Inc. (ArQule), a publicly traded biopharmaceutical company focused on kinase inhibitor discovery and development for the treatment of patients with cancer and other diseases for $2.7 billion. ArQule's lead investigational candidate, MK-1026 (formerly ARQ 531), is a novel, oral Bruton's tyrosine kinase (BTK) inhibitor currently in a Phase 2 dose expansion study for the treatment of B-cell malignancies. The Company is in the process of determining the preliminary fair value of assets acquired, liabilities assumed and total consideration transferred in this transaction, which will be accounted for as an acquisition of a business.

Capital Expenditures

Capital expenditures were $3.5 billion in 2019, $2.6 billion in 2018 and $1.9 billion in 2017. Expenditures in the United States were $1.9 billion in 2019, $1.5 billion in 2018 and $1.2 billion in 2017. The increased capital expenditures in 2019 reflect investment in new capital projects focused primarily on increasing manufacturing capacity for Merck's key products. As previously announced, the Company plans to invest more than $19 billion in new capital projects from 2019-2023.

Depreciation expense was $1.7 billion in 2019, $1.4 billion in 2018 and $1.5 billion in 2017, of which $1.2 billion in 2019, $1.0 billion in 2018 and $1.0 billion in 2017, related to locations in the United States. Total depreciation expense in 2019 and 2017 included accelerated depreciation of $233 million and $60 million, respectively, associated with restructuring activities (see Note 5 to the consolidated financial statements).

Analysis of Liquidity and Capital Resources

Merck's strong financial profile enables it to fund research and development, focus on external alliances, support in-line products and maximize upcoming launches while providing significant cash returns to shareholders.

Selected Data

($ in millions)	**2019**	2018	2017
Working capital	**$ 5,263**	$ 3,669	$ 6,152
Total debt to total liabilities and equity	**31.2 %**	30.4 %	27.8 %
Cash provided by operations to total debt	**0.5:1**	0.4:1	0.3:1

Cash provided by operating activities was $13.4 billion in 2019 compared with $10.9 billion in 2018, reflecting stronger operating performance and increased accounts receivable factoring as discussed below. Cash provided by operating activities continues to be the Company's primary source of funds to finance operating needs, capital expenditures, treasury stock purchases and dividends paid to shareholders.

Cash used in investing activities was $2.6 billion in 2019 compared with cash provided by investing activities of $4.3 billion in 2018. The change was driven primarily by lower proceeds from the sales of securities and other investments, the acquisitions of Antelliq and Peloton in 2019, and higher capital expenditures, partially offset by lower purchases of securities and other investments.

Cash used in financing activities was $8.9 billion in 2019 compared with $13.2 billion in 2018. The lower use of cash in financing activities was driven primarily by proceeds from the issuance of debt and lower purchases of treasury stock reflecting the accelerated share repurchase (ASR) program in 2018 as discussed below, as well as lower payments on debt, partially offset by the repayment of short-term borrowings, higher dividends paid to shareholders and lower proceeds from the exercise of stock options.

The Company has accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable (see Note 6 to the consolidated financial statements). The Company factored $2.7 billion and $1.1 billion of accounts receivable in the fourth quarter of 2019 and 2018, respectively, under these factoring arrangements, which reduced outstanding accounts receivable. The cash received from the financial institutions is reported within operating activities in the Consolidated Statement of Cash Flows. In certain of these factoring arrangements, for ease of administration, the Company will collect customer payments related to the factored receivables, which it then remits to the financial institutions. At December 31, 2019, the Company had collected $256 million on behalf of the financial institutions, which was remitted to them in January 2020. The net cash flows from these collections are reported as financing activities in the Consolidated Statement of Cash Flows.

The Company's contractual obligations as of December 31, 2019 are as follows:

Payments Due by Period

($ in millions)	Total	2020	2021—2022	2023—2024	Thereafter
Purchase obligations *(1)*	$ 3,167	$ 1,097	$ 1,108	$ 421	$ 541
Loans payable and current portion of long-term debt	3,612	3,612	—	—	—
Long-term debt	22,779	—	4,515	3,058	15,206
Interest related to debt obligations	10,021	760	1,372	1,189	6,700
Unrecognized tax benefits *(2)*	49	49	—	—	—
Transition tax related to the enactment of the TCJA *(3)*	3,397	390	781	1,181	1,045
Milestone payments related to collaborations *(4)*	400	400	—	—	—
Leases *(5)*	1,012	254	354	202	202
	$ 44,437	$ 6,562	$ 8,130	$ 6,051	$ 23,694

(1) Includes future inventory purchases the Company has committed to in connection with certain divestitures.

(2) As of December 31, 2019, the Company's Consolidated Balance Sheet reflects liabilities for unrecognized tax benefits, interest and penalties of $1.5 billion, including $49 million reflected as a current liability. Due to the high degree of uncertainty regarding the timing of future cash outflows of liabilities for unrecognized tax benefits beyond one year, a reasonable estimate of the period of cash settlement for years beyond 2020 cannot be made.

(3) In connection with the enactment of the TCJA, the Company is required to pay a one-time transition tax, which the Company has elected to pay over a period of eight years through 2025 as permitted under the TCJA (see Note 15 to the consolidated financial statements).

(4)

Reflects payments under collaborative agreements for sales-based milestones that were achieved in 2019 (and therefore deemed to be contractual obligations) but not paid until January 2020 (see Note 4 to the consolidated financial statements).

(5) Amounts exclude reasonably certain lease renewals that have not yet been executed (see Note 9 to the consolidated financial statements).

Purchase obligations are enforceable and legally binding obligations for purchases of goods and services including minimum inventory contracts, research and development and advertising. Amounts do not include contingent milestone payments related to collaborative arrangements or acquisitions as they are not considered contractual obligations until the successful achievement of developmental, regulatory approval or commercial milestones. At December 31, 2019, the Company has recognized liabilities for contingent sales-based milestone payments related to collaborations with AstraZeneca, Eisai and Bayer where payment remains subject to the achievement of the related sales milestone aggregating $1.4 billion (see Note 4 to the consolidated financial statements). Excluded from research and development obligations are potential future funding commitments of up to approximately $60 million for investments in research venture capital funds. Loans payable and current portion of long-term debt reflects $226 million of long-dated notes that are subject to repayment at the option of the holders. Required funding obligations for 2020 relating to the Company's pension and other postretirement benefit plans are not expected to be material. However, the Company currently anticipates contributing approximately $100 million to its U.S. pension plans, $150 million to its international pension plans and $15 million to its other postretirement benefit plans during 2020.

In March 2019, the Company issued $5.0 billion principal amount of senior unsecured notes consisting of $750 million of 2.90% notes due 2024, $1.75 billion of 3.40% notes due 2029, $1.0 billion of 3.90% notes due 2039, and $1.5 billion of 4.00% notes due 2049. The Company used the net proceeds from the offering of $5.0 billion for general corporate purposes, including the repayment of outstanding commercial paper borrowings.

In December 2018, the Company exercised a make-whole provision on its $1.25 billion, 5.00% notes due 2019 and repaid this debt.

In November 2017, the Company launched tender offers for certain outstanding notes and debentures. The Company paid $810 million in aggregate consideration (applicable purchase price together with accrued interest) to redeem $585 million principal amount of debt that was validly tendered in connection with the tender offers.

The Company has a $6.0 billion credit facility that matures in June 2024. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

In March 2018, the Company filed a securities registration statement with the U.S. Securities and Exchange Commission (SEC) under the automatic shelf registration process available to "well-known seasoned issuers" which is effective for three years.

Effective as of November 3, 2009, the Company executed a full and unconditional guarantee of the then existing debt of its subsidiary Merck Sharp & Dohme Corp. (MSD) and MSD executed a full and unconditional guarantee of the then existing debt of the Company (excluding commercial paper), including for payments of principal and interest. These guarantees do not extend to debt issued subsequent to that date.

The Company continues to maintain a conservative financial profile. The Company places its cash and investments in instruments that meet high credit quality standards, as specified in its investment policy guidelines. These guidelines also limit the amount of credit exposure to any one issuer. The Company does not participate in any off-balance sheet arrangements involving unconsolidated subsidiaries that provide financing or potentially expose the Company to unrecorded financial obligations.

In November 2019, Merck's Board of Directors declared a quarterly dividend of $0.61 per share on the Company's outstanding common stock that was paid in January 2020. In January 2020, the Board of Directors declared a quarterly dividend of $0.61 per share on the Company's common stock for the second quarter of 2020 payable in April 2020.

In October 2018, Merck's Board of Directors authorized purchases of up to $10 billion of Merck's common stock for its treasury. The treasury stock purchase authorization has no time limit and will be made over time in open-market transactions, block transactions, on or off an exchange, or in privately negotiated transactions. The Company spent $4.8 billion to purchase 59 million shares of its common stock for its treasury during 2019. In addition, the Company received 7.7 million shares in settlement of ASR agreements as discussed below. As of December 31, 2019, the Company's remaining share repurchase authorization was $7.2 billion. The Company purchased $9.1 billion and $4.0 billion of its common stock during 2018 and 2017, respectively, under authorized share repurchase programs.

On October 25, 2018, the Company entered into ASR agreements with two third-party financial institutions (Dealers). Under the ASR agreements, Merck agreed to purchase $5 billion of Merck's common stock, in total, with an initial delivery of 56.7 million shares of Merck's common stock, based on the then-current market price, made by the Dealers to Merck, and payments of $5 billion made by Merck to the Dealers on October 29, 2018, which were funded with existing cash and investments, as well as short-term borrowings. Upon settlement of the ASR agreements in April 2019, Merck received an additional 7.7 million shares as determined by the average daily volume weighted-average price of Merck's common stock during the term of the ASR program, less a negotiated discount, bringing the total shares received by Merck under this program to 64.4 million.

Financial Instruments Market Risk Disclosures

The Company manages the impact of foreign exchange rate movements and interest rate movements on its earnings, cash flows and fair values of assets and liabilities through operational means and through the use of various financial instruments, including derivative instruments.

A significant portion of the Company's revenues and earnings in foreign affiliates is exposed to changes in foreign exchange rates. The objectives of the Company's foreign currency risk management program, as well as its interest rate risk management activities are discussed below.

Foreign Currency Risk Management

The Company has established revenue hedging, balance sheet risk management, and net investment hedging programs to protect against volatility of future foreign currency cash flows and changes in fair value caused by changes in foreign exchange rates.

The objective of the revenue hedging program is to reduce the variability caused by changes in foreign exchange rates that would affect the U.S. dollar value of future cash flows derived from foreign currency denominated sales, primarily the euro, Japanese yen and Chinese renminbi. To achieve this objective, the Company will hedge a portion of its forecasted foreign currency denominated third-party and intercompany distributor entity sales (forecasted sales) that are expected to occur over its planning cycle, typically no more than two years into the future. The Company will layer in hedges over time, increasing the portion of forecasted sales hedged as it gets closer to the expected date of the forecasted sales. The portion of forecasted sales hedged is based on assessments of cost-benefit profiles that consider natural offsetting exposures, revenue and exchange rate volatilities and correlations, and the cost of hedging instruments. The Company manages its anticipated transaction exposure principally with purchased local currency put options, forward contracts, and purchased collar options.

Because Merck principally sells foreign currency in its revenue hedging program, a uniform weakening of the U.S. dollar would yield the largest overall potential loss in the market value of these hedge instruments. The market value of Merck's hedges would have declined by an estimated $456 million and $441 million at December 31, 2019 and 2018, respectively, from a uniform 10% weakening of the U.S. dollar. The market value was determined using a foreign exchange option pricing model and holding all factors except exchange rates constant. Although not predictive in nature, the Company believes that a 10% threshold reflects reasonably possible near-term changes in Merck's major foreign currency exposures relative to the U.S. dollar. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

The Company manages operating activities and net asset positions at each local subsidiary in order to mitigate the effects of exchange on monetary assets and liabilities. The Company also uses a balance sheet risk management program to mitigate the exposure of net monetary assets that are denominated in a currency other than a subsidiary's functional currency from the effects of volatility in foreign exchange. In these instances, Merck principally utilizes forward exchange contracts to offset the effects of exchange on exposures denominated in developed country currencies, primarily the euro and Japanese yen. For exposures in developing country currencies, the Company will enter into forward contracts to partially offset the effects of exchange on exposures when it is deemed economical to do so based on a cost-benefit analysis that considers the magnitude of the exposure, the volatility of the exchange rate and the cost of the hedging instrument. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

A sensitivity analysis to changes in the value of the U.S. dollar on foreign currency denominated derivatives, investments and monetary assets and liabilities indicated that if the U.S. dollar uniformly weakened by 10% against

all currency exposures of the Company at December 31, 2019 and 2018, *Income before taxes* would have declined by approximately $110 million and $134 million in 2019 and 2018, respectively. Because the Company was in a net short (payable) position relative to its major foreign currencies after consideration of forward contracts, a uniform weakening of the U.S. dollar will yield the largest overall potential net loss in earnings due to exchange. This measurement assumes that a change in one foreign currency relative to the U.S. dollar would not affect other foreign currencies relative to the U.S. dollar. Although not predictive in nature, the Company believes that a 10% threshold reflects reasonably possible near-term changes in Merck's major foreign currency exposures relative to the U.S. dollar. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

The economy of Argentina was determined to be hyperinflationary in 2018; consequently, in accordance with U.S. GAAP, the Company began remeasuring its monetary assets and liabilities for those operations in earnings. The impact to the Company's results was immaterial.

The Company also uses forward exchange contracts to hedge a portion of its net investment in foreign operations against movements in exchange rates. The forward contracts are designated as hedges of the net investment in a foreign operation. The unrealized gains or losses on these contracts are recorded in foreign currency translation adjustment within *Other Comprehensive Income (Loss)* (*OCI*), and remain in *Accumulated Other Comprehensive Income (Loss)* (*AOCI)* until either the sale or complete or substantially complete liquidation of the subsidiary. The Company excludes certain portions of the change in fair value of its derivative instruments from the assessment of hedge effectiveness (excluded component). Changes in fair value of the excluded components are recognized in *OCI*. The Company recognizes in earnings the initial value of the excluded component on a straight-line basis over the life of the derivative instrument, rather than using the mark-to-market approach. The cash flows from these contracts are reported as investing activities in the Consolidated Statement of Cash Flows.

Foreign exchange risk is also managed through the use of foreign currency debt. The Company's senior unsecured euro-denominated notes have been designated as, and are effective as, economic hedges of the net investment in a foreign operation. Accordingly, foreign currency transaction gains or losses due to spot rate fluctuations on the euro-denominated debt instruments are included in foreign currency translation adjustment within *OCI*.

Interest Rate Risk Management

The Company may use interest rate swap contracts on certain investing and borrowing transactions to manage its net exposure to interest rate changes and to reduce its overall cost of borrowing. The Company does not use leveraged swaps and, in general, does not leverage any of its investment activities that would put principal capital at risk.

At December 31, 2019, the Company was a party to 19 pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes as detailed in the table below.

($ in millions)	**2019**		
Debt Instrument	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
1.85% notes due 2020	$ 1,250	5	$ 1,250
3.875% notes due 2021	1,150	5	1,150
2.40% notes due 2022	1,000	4	1,000
2.35% notes due 2022	1,250	5	1,250

The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in the benchmark London Interbank Offered Rate (LIBOR) swap rate. The fair value changes in the notes attributable to changes in the LIBOR swap rate are recorded in interest expense along with the offsetting fair value changes in the swap contracts. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

The Company's investment portfolio includes cash equivalents and short-term investments, the market values of which are not significantly affected by changes in interest rates. The market value of the Company's medium- to long-term fixed-rate investments is modestly affected by changes in U.S. interest rates. Changes in medium- to long-term U.S. interest rates have a more significant impact on the market value of the Company's fixed-

rate borrowings, which generally have longer maturities. A sensitivity analysis to measure potential changes in the market value of

Merck's investments and debt from a change in interest rates indicated that a one percentage point increase in interest rates at December 31, 2019 and 2018 would have positively affected the net aggregate market value of these instruments by $2.0 billion and $1.2 billion, respectively. A one percentage point decrease at December 31, 2019 and 2018 would have negatively affected the net aggregate market value by $2.2 billion and $1.4 billion, respectively. The fair value of Merck's debt was determined using pricing models reflecting one percentage point shifts in the appropriate yield curves. The fair values of Merck's investments were determined using a combination of pricing and duration models.

Critical Accounting Policies

The Company's consolidated financial statements are prepared in conformity with GAAP and, accordingly, include certain amounts that are based on management's best estimates and judgments. Estimates are used when accounting for amounts recorded in connection with acquisitions, including initial fair value determinations of assets and liabilities, primarily IPR&D, other intangible assets and contingent consideration, as well as subsequent fair value measurements. Additionally, estimates are used in determining such items as provisions for sales discounts and returns, depreciable and amortizable lives, recoverability of inventories, including those produced in preparation for product launches, amounts recorded for contingencies, environmental liabilities, accruals for contingent sales-based milestone payments and other reserves, pension and other postretirement benefit plan assumptions, share-based compensation assumptions, restructuring costs, impairments of long-lived assets (including intangible assets and goodwill) and investments, and taxes on income. Because of the uncertainty inherent in such estimates, actual results may differ from these estimates. Application of the following accounting policies result in accounting estimates having the potential for the most significant impact on the financial statements.

Acquisitions and Dispositions

To determine whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses, the Company makes certain judgments, which include assessment of the inputs, processes, and outputs associated with the acquired set of activities. If the Company determines that substantially all of the fair value of gross assets included in a transaction is concentrated in a single asset (or a group of similar assets), the assets would not represent a business. To be considered a business, the assets in a transaction need to include an input and a substantive process that together significantly contribute to the ability to create outputs.

In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the acquisition at their respective fair values with limited exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are generally recognized at fair value. If fair value cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Accordingly, the Company may be required to value assets at fair value measures that do not reflect the Company's intended use of those assets. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in the Company's consolidated financial statements after the date of the acquisition. The fair values of intangible assets, including acquired IPR&D, are determined utilizing information available near the acquisition date based on expectations and assumptions that are deemed reasonable by management. Given the considerable judgment involved in determining fair values, the Company typically obtains assistance from third-party valuation specialists for significant items. Amounts allocated to acquired IPR&D are capitalized and accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, Merck will make a determination as to the then-useful life of the intangible asset, generally determined by the period in which the substantial majority of the cash flows are expected to be generated, and begin amortization. Certain of the Company's business acquisitions involve the potential for future payment of consideration that is contingent upon the achievement of performance milestones, including product development milestones and royalty payments on future product sales. The fair value of contingent consideration liabilities is determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date, at each reporting period until the contingency is resolved, the contingent consideration liability is

remeasured at current fair value with changes (either expense or income) recorded in earnings. Changes in any of the inputs may result in a significantly different fair value adjustment.

The judgments made in determining estimated fair values assigned to assets acquired and liabilities assumed in a business combination, as well as asset lives, can materially affect the Company's results of operations.

The fair values of identifiable intangible assets related to currently marketed products and product rights are primarily determined by using an income approach through which fair value is estimated based on each asset's discounted projected net cash flows. The Company's estimates of market participant net cash flows consider historical and projected pricing, margins and expense levels; the performance of competing products where applicable; relevant industry and therapeutic area growth drivers and factors; current and expected trends in technology and product life cycles; the time and investment that will be required to develop products and technologies; the ability to obtain marketing and regulatory approvals; the ability to manufacture and commercialize the products; the extent and timing of potential new product introductions by the Company's competitors; and the life of each asset's underlying patent, if any. The net cash flows are then probability-adjusted where appropriate to consider the uncertainties associated with the underlying assumptions, as well as the risk profile of the net cash flows utilized in the valuation. The probability-adjusted future net cash flows of each product are then discounted to present value utilizing an appropriate discount rate.

The fair values of identifiable intangible assets related to IPR&D are also determined using an income approach, through which fair value is estimated based on each asset's probability-adjusted future net cash flows, which reflect the different stages of development of each product and the associated probability of successful completion. The net cash flows are then discounted to present value using an appropriate discount rate.

If the Company determines the transaction will not be accounted for as an acquisition of a business, the transaction will be accounted for as an asset acquisition rather than a business combination and, therefore, no goodwill will be recorded. In an asset acquisition, acquired IPR&D with no alternative future use is charged to expense and contingent consideration is not recognized at the acquisition date. In these instances, product development milestones are recognized upon achievement and sales-based milestones are recognized when the milestone is deemed probable by the Company of being achieved.

Revenue Recognition

Recognition of revenue requires evidence of a contract, probable collection of sales proceeds and completion of substantially all performance obligations. Merck acts as the principal in substantially all of its customer arrangements and therefore records revenue on a gross basis. The majority of the Company's contracts related to the Pharmaceutical and Animal Health segments have a single performance obligation - the promise to transfer goods. Shipping is considered immaterial in the context of the overall customer arrangement and damages or loss of goods in transit are rare. Therefore, shipping is not deemed a separately recognized performance obligation.

The vast majority of revenues from sales of products are recognized at a point in time when control of the goods is transferred to the customer, which the Company has determined is when title and risks and rewards of ownership transfer to the customer and the Company is entitled to payment. For businesses within the Company's Healthcare Services segment and certain services in the Animal Health segment, revenue is recognized over time, generally ratably over the contract term as services are provided. These service revenues are not material.

The nature of the Company's business gives rise to several types of variable consideration including discounts and returns, which are estimated at the time of sale generally using the expected value method, although the most likely amount method is used for prompt pay discounts.

In the United States, sales discounts are issued to customers at the point-of-sale, through an intermediary wholesaler (known as chargebacks), or in the form of rebates. Additionally, sales are generally made with a limited right of return under certain conditions. Revenues are recorded net of provisions for sales discounts and returns, which are established at the time of sale. In addition, revenues are recorded net of time value of money discounts if collection of accounts receivable is expected to be in excess of one year.

The U.S. provision for aggregate customer discounts covers chargebacks and rebates. Chargebacks are discounts that occur when a contracted customer purchases through an intermediary wholesaler. The contracted customer generally purchases product from the wholesaler at its contracted price plus a mark-up. The wholesaler, in turn, charges

the Company back for the difference between the price initially paid by the wholesaler and the contract price paid to the wholesaler by the customer. The provision for chargebacks is based on expected sell-through levels by the Company's wholesale customers to contracted customers, as well as estimated wholesaler inventory levels. Rebates are amounts owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. The Company uses historical customer segment utilization mix, sales forecasts, changes to product mix and price, inventory levels in the distribution channel, government pricing calculations and prior payment history in order to estimate the expected provision. Amounts accrued for aggregate customer discounts are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal and state agencies, and other customers to the amounts accrued.

The Company continually monitors its provision for aggregate customer discounts. There were no material adjustments to estimates associated with the aggregate customer discount provision in 2019, 2018 or 2017.

Summarized information about changes in the aggregate customer discount accrual related to U.S. sales is as follows:

($ in millions)	**2019**	2018
Balance January 1	**$ 2,630**	$ 2,551
Current provision	**11,999**	10,837
Adjustments to prior years	**(230)**	(117)
Payments	**(11,963)**	(10,641)
Balance December 31	**$ 2,436**	$ 2,630

Accruals for chargebacks are reflected as a direct reduction to accounts receivable and accruals for rebates as current liabilities. The accrued balances relative to these provisions included in *Accounts receivable* and *Accrued and other current liabilities* were $233 million and $2.2 billion, respectively, at December 31, 2019 and were $245 million and $2.4 billion, respectively, at December 31, 2018.

Outside of the United States, variable consideration in the form of discounts and rebates are a combination of commercially-driven discounts in highly competitive product classes, discounts required to gain or maintain reimbursement, or legislatively mandated rebates. In certain European countries, legislatively mandated rebates are calculated based on an estimate of the government's total unbudgeted spending and the Company's specific payback obligation. Rebates may also be required based on specific product sales thresholds. The Company applies an estimated factor against its actual invoiced sales to represent the expected level of future discount or rebate obligations associated with the sale.

The Company maintains a returns policy that allows its U.S. pharmaceutical customers to return product within a specified period prior to and subsequent to the expiration date (generally, three to six months before and 12 months after product expiration). The estimate of the provision for returns is based upon historical experience with actual returns. Additionally, the Company considers factors such as levels of inventory in the distribution channel, product dating and expiration period, whether products have been discontinued, entrance in the market of generic competition, changes in formularies or launch of over-the-counter products, among others. The product returns provision for U.S. pharmaceutical sales as a percentage of U.S. net pharmaceutical sales was 1.1% in 2019, 1.6% in 2018 and 2.1% in 2017. Outside of the United States, returns are only allowed in certain countries on a limited basis.

Merck's payment terms for U.S. pharmaceutical customers are typically 36 days from receipt of invoice and for U.S. animal health customers are typically 30 days from receipt of invoice; however, certain products, including *Keytruda*, have longer payment terms up to 90 days. Outside of the United States, payment terms are typically 30 days to 90 days, although certain markets have longer payment terms.

Through its distribution programs with U.S. wholesalers, the Company encourages wholesalers to align purchases with underlying demand and maintain inventories below specified levels. The terms of the programs allow the wholesalers to earn fees upon providing visibility into their inventory levels, as well as by achieving certain performance parameters such as inventory management, customer service levels, reducing shortage claims and reducing

product returns. Information provided through the wholesaler distribution programs includes items such as sales trends, inventory on-hand, on-order quantity and product returns.

Wholesalers generally provide only the above-mentioned data to the Company, as there is no regulatory requirement to report lot level information to manufacturers, which is the level of information needed to determine the remaining shelf life and original sale date of inventory. Given current wholesaler inventory levels, which are generally less than a month, the Company believes that collection of order lot information across all wholesale customers would have limited use in estimating sales discounts and returns.

Inventories Produced in Preparation for Product Launches

The Company capitalizes inventories produced in preparation for product launches sufficient to support estimated initial market demand. Typically, capitalization of such inventory does not begin until the related product candidates are in Phase 3 clinical trials and are considered to have a high probability of regulatory approval. The Company monitors the status of each respective product within the regulatory approval process; however, the Company generally does not disclose specific timing for regulatory approval. If the Company is aware of any specific risks or contingencies other than the normal regulatory approval process or if there are any specific issues identified during the research process relating to safety, efficacy, manufacturing, marketing or labeling, the related inventory would generally not be capitalized. Expiry dates of the inventory are affected by the stage of completion. The Company manages the levels of inventory at each stage to optimize the shelf life of the inventory in relation to anticipated market demand in order to avoid product expiry issues. For inventories that are capitalized, anticipated future sales and shelf lives support the realization of the inventory value as the inventory shelf life is sufficient to meet initial product launch requirements. Inventories produced in preparation for product launches capitalized at December 31, 2019 and 2018 were $168 million and $7 million, respectively.

Contingencies and Environmental Liabilities

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property and commercial litigation, as well as certain additional matters including governmental and environmental matters (see Note 10 to the consolidated financial statements). The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. For product liability claims, a portion of the overall accrual is actuarially determined and considers such factors as past experience, number of claims reported and estimates of claims incurred but not yet reported. Individually significant contingent losses are accrued when probable and reasonably estimable.

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of December 31, 2019 and 2018 of approximately $240 million and $245 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

The Company and its subsidiaries are parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund, and other federal and state equivalents. When a legitimate claim for contribution is asserted, a liability is initially accrued based upon the estimated transaction costs to manage the site. Accruals are adjusted as site investigations, feasibility studies and related cost assessments of remedial techniques are completed, and as the extent to which other potentially responsible parties who may be jointly and severally liable can be expected to contribute is determined.

The Company is also remediating environmental contamination resulting from past industrial activity at certain of its sites and takes an active role in identifying and accruing for these costs. In the past, Merck performed a worldwide survey to assess all sites for potential contamination resulting from past industrial activities. Where

assessment indicated that physical investigation was warranted, such investigation was performed, providing a better evaluation of the need for remedial action. Where such need was identified, remedial action was then initiated. As definitive information became available during the course of investigations and/or remedial efforts at each site, estimates were refined and accruals were established or adjusted accordingly. These estimates and related accruals continue to be refined annually.

The Company believes that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on the Company. Expenditures for remediation and environmental liabilities were $19 million in 2019 and are estimated at $47 million in the aggregate for the years 2020 through 2024. In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $67 million and $71 million at December 31, 2019 and 2018, respectively. These liabilities are undiscounted, do not consider potential recoveries from other parties and will be paid out over the periods of remediation for the applicable sites, which are expected to occur primarily over the next 15 years. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed $58 million in the aggregate. Management also does not believe that these expenditures should result in a material adverse effect on the Company's financial condition, results of operations or liquidity for any year.

Share-Based Compensation

The Company expenses all share-based payment awards to employees, including grants of stock options, over the requisite service period based on the grant date fair value of the awards. The Company determines the fair value of certain share-based awards using the Black-Scholes option-pricing model which uses both historical and current market data to estimate the fair value. This method incorporates various assumptions such as the risk-free interest rate, expected volatility, expected dividend yield and expected life of the options. Total pretax share-based compensation expense was $417 million in 2019, $348 million in 2018 and $312 million in 2017. At December 31, 2019, there was $603 million of total pretax unrecognized compensation expense related to nonvested stock option, restricted stock unit and performance share unit awards which will be recognized over a weighted average period of 1.9 years. For segment reporting, share-based compensation costs are unallocated expenses.

Pensions and Other Postretirement Benefit Plans

Net periodic benefit cost for pension plans totaled $137 million in 2019, $195 million in 2018 and $201 million in 2017. Net periodic benefit (credit) for other postretirement benefit plans was $(49) million in 2019, $(45) million in 2018 and $(60) million in 2017. Pension and other postretirement benefit plan information for financial reporting purposes is calculated using actuarial assumptions including a discount rate for plan benefit obligations and an expected rate of return on plan assets. The changes in net periodic benefit cost year over year for pension plans are largely attributable to changes in the discount rate affecting net loss amortization.

The Company reassesses its benefit plan assumptions on a regular basis. For both the pension and other postretirement benefit plans, the discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due. The discount rates for the Company's U.S. pension and other postretirement benefit plans ranged from 3.20% to 3.50% at December 31, 2019, compared with a range of 4.00% to 4.40% at December 31, 2018.

The expected rate of return for both the pension and other postretirement benefit plans represents the average rate of return to be earned on plan assets over the period the benefits included in the benefit obligation are to be paid. In developing the expected rate of return, the Company considers long-term compound annualized returns of historical market data, current market conditions and actual returns on the Company's plan assets. Using this reference information, the Company develops forward-looking return expectations for each asset category and a weighted-average expected long-term rate of return for a target portfolio allocated across these investment categories. The expected portfolio performance reflects the contribution of active management as appropriate. For 2020, the expected rate of return for the Company's U.S. pension and other postretirement benefit plans will range from 7.00% to 7.30%, compared to a range of 7.70% to 8.10% in 2019. The decrease reflects lower expected asset returns and a modest shift in asset allocation.

The Company has established investment guidelines for its U.S. pension and other postretirement plans to create an asset allocation that is expected to deliver a rate of return sufficient to meet the long-term obligation of each plan, given an acceptable level of risk. The target investment portfolio of the Company's U.S. pension and other

postretirement benefit plans is allocated 30% to 45% in U.S. equities, 15% to 30% in international equities, 35% to 45% in fixed-income investments, and up to 5% in cash and other investments. The portfolio's equity weighting is consistent with the long-term nature of the plans' benefit obligations. The expected annual standard deviation of returns of the target portfolio, which approximates 10%, reflects both the equity allocation and the diversification benefits among the asset classes in which the portfolio invests. For non-U.S. pension plans, the targeted investment portfolio varies based on the duration of pension liabilities and local government rules and regulations. Although a significant percentage of plan assets are invested in U.S. equities, concentration risk is mitigated through the use of strategies that are diversified within management guidelines.

Actuarial assumptions are based upon management's best estimates and judgment. A reasonably possible change of plus (minus) 25 basis points in the discount rate assumption, with other assumptions held constant, would have had an estimated $70 million favorable (unfavorable) impact on the Company's net periodic benefit cost in 2019. A reasonably possible change of plus (minus) 25 basis points in the expected rate of return assumption, with other assumptions held constant, would have had an estimated $50 million favorable (unfavorable) impact on Merck's net periodic benefit cost in 2019. Required funding obligations for 2020 relating to the Company's pension and other postretirement benefit plans are not expected to be material. The preceding hypothetical changes in the discount rate and expected rate of return assumptions would not impact the Company's funding requirements.

Net loss amounts, which reflect experience differentials primarily relating to differences between expected and actual returns on plan assets as well as the effects of changes in actuarial assumptions, are recorded as a component of *AOCI*. Expected returns for pension plans are based on a calculated market-related value of assets. Under this methodology, asset gains/losses resulting from actual returns that differ from the Company's expected returns are recognized in the market-related value of assets ratably over a five-year period. Also, net loss amounts in *AOCI* in excess of certain thresholds are amortized into net periodic benefit cost over the average remaining service life of employees.

Restructuring Costs

Restructuring costs have been recorded in connection with restructuring programs designed to streamline the Company's cost structure. As a result, the Company has made estimates and judgments regarding its future plans, including future termination benefits and other exit costs to be incurred when the restructuring actions take place. When accruing termination costs, the Company will recognize the amount within a range of costs that is the best estimate within the range. When no amount within the range is a better estimate than any other amount, the Company recognizes the minimum amount within the range. In connection with these actions, management also assesses the recoverability of long-lived assets employed in the business. In certain instances, asset lives have been shortened based on changes in the expected useful lives of the affected assets. Severance and other related costs are reflected within *Restructuring costs*. Asset-related charges are reflected within *Cost of sales*, *Selling, general and administrative* expenses and *Research and development* expenses depending upon the nature of the asset.

Impairments of Long-Lived Assets

The Company assesses changes in economic, regulatory and legal conditions and makes assumptions regarding estimated future cash flows in evaluating the value of the Company's property, plant and equipment, goodwill and other intangible assets.

The Company periodically evaluates whether current facts or circumstances indicate that the carrying values of its long-lived assets to be held and used may not be recoverable. If such circumstances are determined to exist, an estimate of the undiscounted future cash flows of these assets, or appropriate asset groupings, is compared to the carrying value to determine whether an impairment exists. If the asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows approach.

Goodwill represents the excess of the consideration transferred over the fair value of net assets of businesses acquired. Goodwill is assigned to reporting units and evaluated for impairment on at least an annual basis, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. Some of the factors considered in the assessment include general macroeconomic conditions, conditions specific to the industry and market, cost factors which could have a significant effect on earnings or cash flows, the overall financial performance of the reporting unit, and whether there have been sustained declines in the Company's share price. If the Company concludes it is more

likely than not that the fair value of a reporting unit is less than its carrying amount, a quantitative fair value test is performed. If the carrying value of a reporting unit is greater than its fair value, a goodwill impairment charge will be recorded for the difference (up to the carrying value of goodwill).

Other acquired intangible assets (excluding IPR&D) are initially recorded at fair value, assigned an estimated useful life, and amortized primarily on a straight-line basis over their estimated useful lives. When events or circumstances warrant a review, the Company will assess recoverability from future operations using pretax undiscounted cash flows derived from the lowest appropriate asset groupings. Impairments are recognized in operating results to the extent that the carrying value of the intangible asset exceeds its fair value, which is determined based on the net present value of estimated future cash flows.

IPR&D that the Company acquires in conjunction with the acquisition of a business represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. The amounts are capitalized and accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. The Company evaluates IPR&D for impairment at least annually, or more frequently if impairment indicators exist, by performing a quantitative test that compares the fair value of the IPR&D intangible asset with its carrying value. For impairment testing purposes, the Company may combine separately recorded IPR&D intangible assets into one unit of account based on the relevant facts and circumstances. Generally, the Company will combine IPR&D intangible assets for testing purposes if they operate as a single asset and are essentially inseparable. If the fair value is less than the carrying amount, an impairment loss is recognized in operating results.

The judgments made in evaluating impairment of long-lived intangibles can materially affect the Company's results of operations.

Impairments of Investments

The Company reviews its investments in marketable debt securities for impairments based on the determination of whether the decline in market value of the investment below the carrying value is other-than-temporary. The Company considers available evidence in evaluating potential impairments of its investments in marketable debt securities, including the duration and extent to which fair value is less than cost. Changes in fair value that are considered temporary are reported net of tax in *OCI*. An other-than-temporary impairment has occurred if the Company does not expect to recover the entire amortized cost basis of the marketable debt security. If the Company does not intend to sell the impaired debt security, and it is not more likely than not it will be required to sell the debt security before the recovery of its amortized cost basis, the amount of the other-than-temporary impairment recognized in earnings, recorded in *Other (income) expense, net*, is limited to the portion attributed to credit loss. The remaining portion of the other-than-temporary impairment related to other factors is recognized in *OCI*.

Investments in publicly traded equity securities are reported at fair value determined using quoted market prices in active markets for identical assets or quoted prices for similar assets or other inputs that are observable or can be corroborated by observable market data. Changes in fair value are included in *Other (income) expense, net*. Investments in equity securities without readily determinable fair values are recorded at cost, plus or minus subsequent observable price changes in orderly transactions for identical or similar investments, minus impairments. Such adjustments are recognized in *Other (income) expense, net*. Realized gains and losses for equity securities are included in *Other (income) expense, net*.

Taxes on Income

The Company's effective tax rate is based on pretax income, statutory tax rates and tax planning opportunities available in the various jurisdictions in which the Company operates. An estimated effective tax rate for a year is applied to the Company's quarterly operating results. In the event that there is a significant unusual or one-time item recognized, or expected to be recognized, in the Company's quarterly operating results, the tax attributable to that item would be separately calculated and recorded at the same time as the unusual or one-time item. The Company considers the resolution of prior year tax matters to be such items. Significant judgment is required in determining the Company's tax provision and in evaluating its tax positions. The recognition and measurement of a tax position is based on management's best judgment given the facts, circumstances and information available at the reporting date. The Company evaluates tax positions to determine whether the benefits of tax positions are more likely than not of being sustained upon audit based on the technical merits of the tax position. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely

of being realized upon ultimate settlement in the financial statements. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit in the financial statements. If the more likely than not threshold is not met in the period for which a tax position is taken, the Company may subsequently recognize the benefit of that tax position if the tax matter is effectively settled, the statute of limitations expires, or if the more likely than not threshold is met in a subsequent period (see Note 15 to the consolidated financial statements).

Tax regulations require items to be included in the tax return at different times than the items are reflected in the financial statements. Timing differences create deferred tax assets and liabilities. Deferred tax assets generally represent items that can be used as a tax deduction or credit in the tax return in future years for which the Company has already recorded the tax benefit in the financial statements. The Company establishes valuation allowances for its deferred tax assets when the amount of expected future taxable income is not likely to support the use of the deduction or credit. Deferred tax liabilities generally represent tax expense recognized in the financial statements for which payment has been deferred or expense for which the Company has already taken a deduction on the tax return, but has not yet recognized as expense in the financial statements.

Recently Issued Accounting Standards

For a discussion of recently issued accounting standards, see Note 2 to the consolidated financial statements.

Cautionary Factors That May Affect Future Results

This report and other written reports and oral statements made from time to time by the Company may contain so-called “forward-looking statements,” all of which are based on management’s current expectations and are subject to risks and uncertainties which may cause results to differ materially from those set forth in the statements. One can identify these forward-looking statements by their use of words such as “anticipates,” “expects,” “plans,” “will,” “estimates,” “forecasts,” “projects” and other words of similar meaning, or negative variations of any of the foregoing. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address the Company’s growth strategy, financial results, product development, product approvals, product potential and development programs. One must carefully consider any such statement and should understand that many factors could cause actual results to differ materially from the Company’s forward-looking statements. These factors include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. No forward-looking statement can be guaranteed and actual future results may vary materially.

The Company does not assume the obligation to update any forward-looking statement. One should carefully evaluate such statements in light of factors, including risk factors, described in the Company’s filings with the Securities and Exchange Commission, especially on this Form 10-K and Forms 10-Q and 8-K. In Item 1A. “Risk Factors” of this annual report on Form 10-K the Company discusses in more detail various important risk factors that could cause actual results to differ from expected or historic results. The Company notes these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. One should understand that it is not possible to predict or identify all such factors. Consequently, the reader should not consider any such list to be a complete statement of all potential risks or uncertainties.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

The information required by this Item is incorporated by reference to the discussion under “Financial Instruments Market Risk Disclosures” in Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

Item 8. Financial Statements and Supplementary Data.

(a) Financial Statements

The consolidated balance sheet of Merck & Co., Inc. and subsidiaries as of December 31, 2019 and 2018, and the related consolidated statements of income, of comprehensive income, of equity and of cash flows for each of the three years in the period ended December 31, 2019, the notes to consolidated financial statements, and the report dated February 26, 2020 of PricewaterhouseCoopers LLP, independent registered public accounting firm, are as follows:

Consolidated Statement of Income
Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions except per share amounts)

	2019	2018	2017
Sales	**$ 46,840**	$ 42,294	$ 40,122
Costs, Expenses and Other			
Cost of sales	**14,112**	13,509	12,912
Selling, general and administrative	**10,615**	10,102	10,074
Research and development	**9,872**	9,752	10,339
Restructuring costs	**638**	632	776
Other (income) expense, net	**139**	(402)	(500)
	35,376	33,593	33,601
Income Before Taxes	**11,464**	8,701	6,521
Taxes on Income	**1,687**	2,508	4,103
Net Income	**9,777**	6,193	2,418
Less: Net (Loss) Income Attributable to Noncontrolling Interests	**(66)**	(27)	24
Net Income Attributable to Merck & Co., Inc.	**$ 9,843**	$ 6,220	$ 2,394
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	**$ 3.84**	$ 2.34	$ 0.88
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	**$ 3.81**	$ 2.32	$ 0.87

Consolidated Statement of Comprehensive Income
Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions)

	2019	2018	2017
Net Income Attributable to Merck & Co., Inc.	**$ 9,843**	$ 6,220	$ 2,394
Other Comprehensive (Loss) Income Net of Taxes:			
Net unrealized (loss) gain on derivatives, net of reclassifications	**(135)**	297	(446)
Net unrealized gain (loss) on investments, net of reclassifications	**96**	(10)	(58)
Benefit plan net (loss) gain and prior service (cost) credit, net of amortization	**(705)**	(425)	419
Cumulative translation adjustment	**96**	(223)	401
	(648)	(361)	316
Comprehensive Income Attributable to Merck & Co., Inc.	**$ 9,195**	$ 5,859	$ 2,710

The accompanying notes are an integral part of these consolidated financial statements.

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Consolidated Balance Sheet
Merck & Co., Inc. and Subsidiaries
December 31
($ in millions except per share amounts)

	2019	2018
Assets		
Current Assets		
Cash and cash equivalents	**$ 9,676**	$ 7,965
Short-term investments	**774**	899
Accounts receivable (net of allowance for doubtful accounts of $86 in 2019 and $119 in 2018)	**6,778**	7,071
Inventories (excludes inventories of $1,480 in 2019 and $1,417 in 2018 classified in Other assets - see Note 7)	**5,978**	5,440
Other current assets	**4,277**	4,500
Total current assets	**27,483**	25,875
Investments	**1,469**	6,233
Property, Plant and Equipment (at cost)		
Land	**343**	333
Buildings	**11,989**	11,486
Machinery, equipment and office furnishings	**15,394**	14,441
Construction in progress	**5,013**	3,355
	32,739	29,615
Less: accumulated depreciation	**17,686**	16,324
	15,053	13,291
Goodwill	**19,425**	18,253
Other Intangibles, Net	**14,196**	13,104
Other Assets	**6,771**	5,881
	$ 84,397	$ 82,637
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	**$ 3,610**	$ 5,308
Trade accounts payable	**3,738**	3,318
Accrued and other current liabilities	**12,549**	10,151
Income taxes payable	**736**	1,971
Dividends payable	**1,587**	1,458
Total current liabilities	**22,220**	22,206
Long-Term Debt	**22,736**	19,806
Deferred Income Taxes	**1,470**	1,702
Other Noncurrent Liabilities	**11,970**	12,041
Merck & Co., Inc. Stockholders' Equity		
Common stock, $0.50 par value Authorized - 6,500,000,000 shares Issued - 3,577,103,522 shares in 2019 and 2018	**1,788**	1,788
Other paid-in capital	**39,660**	38,808
Retained earnings	**46,602**	42,579
Accumulated other comprehensive loss	**(6,193)**	(5,545)
	81,857	77,630
Less treasury stock, at cost: 1,038,087,496 shares in 2019 and 984,543,979 shares in 2018	**55,950**	50,929
Total Merck & Co., Inc. stockholders' equity	**25,907**	26,701

Noncontrolling Interests	**94**	181
Total equity	**26,001**	26,882
	$ 84,397	$ 82,637

The accompanying notes are an integral part of this consolidated financial statement.

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Consolidated Statement of Equity
Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions except per share amounts)

	Common Stock	Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock	Non-controlling Interests	Total
Balance January 1, 2017	$1,788	$ 39,939	$ 44,133	$ (5,226)	$ (40,546)	$ 220	$ 40,308
Net income attributable to Merck & Co., Inc.	—	—	2,394	—	—	—	2,394
Other comprehensive income, net of taxes	—	—	—	316	—	—	316
Cash dividends declared on common stock ($1.89 per share)	—	—	(5,177)	—	—	—	(5,177)
Treasury stock shares purchased	—	—	—	—	(4,014)	—	(4,014)
Acquisition of Vallée S.A.	—	—	—	—	—	7	7
Net income attributable to noncontrolling interests	—	—	—	—	—	24	24
Distributions attributable to noncontrolling interests	—	—	—	—	—	(18)	(18)
Share-based compensation plans and other	—	(37)	—	—	766	—	729
Balance December 31, 2017	1,788	39,902	41,350	(4,910)	(43,794)	233	34,569
Net income attributable to Merck & Co., Inc.	—	—	6,220	—	—	—	6,220
Adoption of new accounting standards	—	—	322	(274)	—	—	48
Other comprehensive loss, net of taxes	—	—	—	(361)	—	—	(361)
Cash dividends declared on common stock ($1.99 per share)	—	—	(5,313)	—	—	—	(5,313)
Treasury stock shares purchased	—	(1,000)	—	—	(8,091)	—	(9,091)
Net loss attributable to noncontrolling interests	—	—	—	—	—	(27)	(27)
Distributions attributable to noncontrolling interests	—	—	—	—	—	(25)	(25)
Share-based compensation plans and other	—	(94)	—	—	956	—	862
Balance December 31, 2018	1,788	38,808	42,579	(5,545)	(50,929)	181	26,882
Net income attributable to Merck & Co., Inc.	—	—	**9,843**	—	—	—	**9,843**
Other comprehensive loss, net of taxes	—	—	—	**(648)**	—	—	**(648)**
Cash dividends declared on common stock ($2.26 per share)	—	—	**(5,820)**	—	—	—	**(5,820)**
Treasury stock shares purchased	—	**1,000**	—	—	**(5,780)**	—	**(4,780)**
Net loss attributable to noncontrolling interests	—	—	—	—	—	**(66)**	**(66)**
Distributions attributable to noncontrolling interests	—	—	—	—	—	**(21)**	**(21)**
Share-based compensation plans and other	—	**(148)**	—	—	**759**	—	**611**
Balance December 31, 2019	**$ 1,788**	**$ 39,660**	**$ 46,602**	**$ (6,193)**	**$ (55,950)**	**$ 94**	**$ 26,001**

The accompanying notes are an integral part of this consolidated financial statement.

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Consolidated Statement of Cash Flows
Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions)

	2019	2018	2017
Cash Flows from Operating Activities			
Net income	**$ 9,777**	$ 6,193	$ 2,418
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	**3,652**	4,519	4,676
Intangible asset impairment charges	**1,040**	296	646
Charge for the acquisition of Peloton Therapeutics, Inc.	**993**	—	—
Charge for future payments related to collaboration license options	**—**	650	500
Provisional charge for one-time transition tax related to the enactment of U.S. tax legislation	**—**	—	5,347
Deferred income taxes	**(556)**	(509)	(2,621)
Share-based compensation	**417**	348	312
Other	**184**	978	190
Net changes in assets and liabilities:			
Accounts receivable	**294**	(418)	297
Inventories	**(508)**	(911)	(145)
Trade accounts payable	**399**	230	254
Accrued and other current liabilities	**376**	(341)	(922)
Income taxes payable	**(2,359)**	827	(3,291)
Noncurrent liabilities	**(237)**	(266)	(123)
Other	**(32)**	(674)	(1,087)
Net Cash Provided by Operating Activities	**13,440**	10,922	6,451
Cash Flows from Investing Activities			
Capital expenditures	**(3,473)**	(2,615)	(1,888)
Purchases of securities and other investments	**(3,202)**	(7,994)	(10,739)
Proceeds from sales of securities and other investments	**8,622**	15,252	15,664
Acquisition of Antelliq Corporation, net of cash acquired	**(3,620)**	—	—
Acquisition of Peloton Therapeutics, Inc., net of cash acquired	**(1,040)**	—	—
Other acquisitions, net of cash acquired	**(294)**	(431)	(396)
Other	**378**	102	38
Net Cash (Used in) Provided by Investing Activities	**(2,629)**	4,314	2,679
Cash Flows from Financing Activities			
Net change in short-term borrowings	**(3,710)**	5,124	(26)
Payments on debt	**—**	(4,287)	(1,103)
Proceeds from issuance of debt	**4,958**	—	—
Purchases of treasury stock	**(4,780)**	(9,091)	(4,014)
Dividends paid to stockholders	**(5,695)**	(5,172)	(5,167)
Proceeds from exercise of stock options	**361**	591	499
Other	**5**	(325)	(195)
Net Cash Used in Financing Activities	**(8,861)**	(13,160)	(10,006)
Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash	**17**	(205)	457
Net Increase (Decrease) in Cash, Cash Equivalents and Restricted Cash	**1,967**	1,871	(419)
Cash, Cash Equivalents and Restricted Cash at Beginning of Year (includes $2 million of restricted cash at January 1, 2019 included in Other Assets)	**7,967**	6,096	6,515
Cash, Cash Equivalents and Restricted Cash at End of Year (includes $258 million of restricted cash at December 31, 2019 included in Other Assets - see Note 6)	**$ 9,934**	$ 7,967	$ 6,096

Notes to Consolidated Financial Statements
Merck & Co., Inc. and Subsidiaries
($ in millions except per share amounts)

1. Nature of Operations

Merck & Co., Inc. (Merck or the Company) is a global health care company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies and animal health products. The Company's operations are principally managed on a products basis and include four operating segments, which are the Pharmaceutical, Animal Health, Healthcare Services and Alliances segments. The Pharmaceutical and Animal Health segments are the only reportable segments.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities.

The Animal Health segment discovers, develops, manufactures and markets a wide range of veterinary pharmaceutical and vaccine products, as well as health management solutions and services, for the prevention, treatment and control of disease in all major livestock and companion animal species. The Company also offers an extensive suite of digitally connected identification, traceability and monitoring products. The Company sells its products to veterinarians, distributors and animal producers.

The Healthcare Services segment provides services and solutions that focus on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company has recently sold certain businesses in the Healthcare Services segment and is in the process of divesting the remaining businesses.

The Alliances segment primarily includes activity from the Company's relationship with AstraZeneca LP related to sales of Nexium and Prilosec, which concluded in 2018.

Planned Spin-Off of Women's Health, Legacy Brands and Biosimilars into New Company

In February 2020, Merck announced its intention to spin-off products from its women's health, trusted legacy brands and biosimilars businesses into a new, yet-to-be-named, independent, publicly traded company (NewCo) through a distribution of NewCo's publicly traded stock to Company shareholders. The distribution is expected to qualify as tax-free to the Company and its shareholders for U.S. federal income tax purposes. The legacy brands included in the transaction consist of dermatology, pain, respiratory, and select cardiovascular products including *Zetia* and *Vytorin*, as well as the rest of Merck's diversified brands franchise. Merck's existing research pipeline programs will continue to be owned and developed within Merck as planned. NewCo will have development capabilities initially focused on late-stage development and life-cycle management, and is expected over time to develop research capabilities in selected therapeutic areas. The spin-off is expected to be completed in the first half of 2021, subject to market and certain other conditions. Subsequent to the spin-off, the historical results of the woman's health, legacy brands and biosimilars businesses will be reflected as discontinued operations in the Company's consolidated financial statements.

2. Summary of Accounting Policies

Principles of Consolidation — The consolidated financial statements include the accounts of the Company and all of its subsidiaries in which a controlling interest is maintained. Intercompany balances and transactions are eliminated. Controlling interest is determined by majority ownership interest and the absence of substantive third-party participating rights or, in the case of variable interest entities, by majority exposure to expected losses, residual returns or both. For those consolidated subsidiaries where Merck ownership is less than 100%, the outside shareholders' interests are shown as *Noncontrolling interests* in equity. Investments in affiliates over which the Company has significant influence but not a controlling interest, such as interests in entities owned equally by the Company and a third party that are under shared control, are carried on the equity basis.

Acquisitions — In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the acquisition at their respective fair values with limited exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are generally recognized at fair value. If fair value cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Accordingly, the Company may be required to value assets at fair value measures that do not reflect the Company's intended use of those assets. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in the Company's consolidated financial statements after the date of the acquisition. If the Company determines the assets acquired do not meet the definition of a business under the acquisition method of accounting, the transaction will be accounted for as an acquisition of assets rather than a business combination and, therefore, no goodwill will be recorded. In an asset acquisition, acquired in-process research and development (IPR&D) with no alternative future use is charged to expense and contingent consideration is not recognized at the acquisition date.

Foreign Currency Translation — The net assets of international subsidiaries where the local currencies have been determined to be the functional currencies are translated into U.S. dollars using current exchange rates. The U.S. dollar effects that arise from translating the net assets of these subsidiaries at changing rates are recorded in the foreign currency translation account, which is included in *Accumulated other comprehensive income (loss)* (*AOCI*) and reflected as a separate component of equity. For those subsidiaries that operate in highly inflationary economies and for those subsidiaries where the U.S. dollar has been determined to be the functional currency, non-monetary foreign currency assets and liabilities are translated using historical rates, while monetary assets and liabilities are translated at current rates, with the U.S. dollar effects of rate changes included in *Other (income) expense, net*.

Cash Equivalents — Cash equivalents are comprised of certain highly liquid investments with original maturities of less than three months.

Inventories — Inventories are valued at the lower of cost or net realizable value. The cost of a substantial majority of U.S. pharmaceutical and vaccine inventories is determined using the last-in, first-out (LIFO) method for both financial reporting and tax purposes. The cost of all other inventories is determined using the first-in, first-out (FIFO) method. Inventories consist of currently marketed products, as well as certain inventories produced in preparation for product launches that are considered to have a high probability of regulatory approval. In evaluating the recoverability of inventories produced in preparation for product launches, the Company considers the likelihood that revenue will be obtained from the future sale of the related inventory together with the status of the product within the regulatory approval process.

Investments — Investments in marketable debt securities classified as available-for-sale are reported at fair value. Fair values of the Company's investments in marketable debt securities are determined using quoted market prices in active markets for identical assets or liabilities or quoted prices for similar assets or liabilities or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Changes in fair value that are considered temporary are reported net of tax in *Other Comprehensive Income* (*OCI*). The Company considers available evidence in evaluating potential impairments of its investments in marketable debt securities, including the duration and extent to which fair value is less than cost. An other-than-temporary impairment has occurred if the Company does not expect to recover the entire amortized cost basis of the marketable debt security. If the Company does not intend to sell the impaired debt security, and it is not more likely than not it will be required to sell the debt security before the recovery of its amortized cost basis, the amount of the other-than-temporary impairment recognized in earnings, recorded in *Other (income) expense, net*, is limited to the portion attributed to credit loss. The remaining portion of the other-than-temporary impairment related to other factors is recognized in *OCI*. Realized gains and losses for debt securities are included in *Other (income) expense, net*.

Investments in publicly traded equity securities are reported at fair value determined using quoted market prices in active markets for identical assets or quoted prices for similar assets or other inputs that are observable or can be corroborated by observable market data. Changes in fair value are included in *Other (income) expense, net*.

Investments in equity securities without readily determinable fair values are recorded at cost, plus or minus subsequent observable price changes in orderly transactions for identical or similar investments, minus impairments. Such adjustments are recognized in *Other (income) expense, net*. Realized gains and losses for equity securities are included in *Other (income) expense, net*.

Revenue Recognition — On January 1, 2018, the Company adopted ASU 2014-09, *Revenue from Contracts with Customers*, and subsequent amendments (ASC 606 or new guidance), using the modified retrospective method. Comparative information for prior periods has not been restated and continues to be reported under the accounting standards in effect for those periods.

Recognition of revenue requires evidence of a contract, probable collection of sales proceeds and completion of substantially all performance obligations. Merck acts as the principal in substantially all of its customer arrangements and therefore records revenue on a gross basis. The majority of the Company's contracts related to the Pharmaceutical and Animal Health segments have a single performance obligation - the promise to transfer goods. Shipping is considered immaterial in the context of the overall customer arrangement and damages or loss of goods in transit are rare. Therefore, shipping is not deemed a separately recognized performance obligation.

The vast majority of revenues from sales of products are recognized at a point in time when control of the goods is transferred to the customer, which the Company has determined is when title and risks and rewards of ownership transfer to the customer and the Company is entitled to payment. The Company recognizes revenue from the sales of vaccines to the Federal government for placement into vaccine stockpiles in accordance with Securities and Exchange Commission (SEC) Interpretation, *Commission Guidance Regarding Accounting for Sales of Vaccines and BioTerror Countermeasures to the Federal Government for Placement into the Pediatric Vaccine Stockpile or the Strategic National Stockpile*. This interpretation allows companies to recognize revenue for sales of vaccines into U.S. government stockpiles even though these sales might not meet the criteria for revenue recognition under other accounting guidance. For businesses within the Company's Healthcare Services segment and certain services in the Animal Health segment, revenue is recognized over time, generally ratably over the contract term as services are provided. These service revenues are not material.

The nature of the Company's business gives rise to several types of variable consideration including discounts and returns, which are estimated at the time of sale generally using the expected value method, although the most likely amount method is used for prompt pay discounts.

In the United States, sales discounts are issued to customers at the point-of-sale, through an intermediary wholesaler (known as chargebacks), or in the form of rebates. Additionally, sales are generally made with a limited right of return under certain conditions. Revenues are recorded net of provisions for sales discounts and returns, which are established at the time of sale. In addition, revenues are recorded net of time value of money discounts if collection of accounts receivable is expected to be in excess of one year.

The U.S. provision for aggregate customer discounts covering chargebacks and rebates was $11.8 billion in 2019, $10.7 billion in 2018 and $10.7 billion in 2017. Chargebacks are discounts that occur when a contracted customer purchases through an intermediary wholesaler. The contracted customer generally purchases product from the wholesaler at its contracted price plus a mark-up. The wholesaler, in turn, charges the Company back for the difference between the price initially paid by the wholesaler and the contract price paid to the wholesaler by the customer. The provision for chargebacks is based on expected sell-through levels by the Company's wholesale customers to contracted customers, as well as estimated wholesaler inventory levels. Rebates are amounts owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. The Company uses historical customer segment utilization mix, sales forecasts, changes to product mix and price, inventory levels in the distribution channel, government pricing calculations and prior payment history in order to estimate the expected provision. Amounts accrued for aggregate customer discounts are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal and state agencies, and other customers to the amounts accrued. The accrued balances relative to the provisions for chargebacks and rebates included in *Accounts*

receivable and *Accrued and other current liabilities* were $233 million and $2.2 billion, respectively, at December 31, 2019 and were $245 million and $2.4 billion, respectively, at December 31, 2018.

Outside of the United States, variable consideration in the form of discounts and rebates are a combination of commercially-driven discounts in highly competitive product classes, discounts required to gain or maintain reimbursement, or legislatively mandated rebates. In certain European countries, legislatively mandated rebates are calculated based on an estimate of the government's total unbudgeted spending and the Company's specific payback obligation. Rebates may also be required based on specific product sales thresholds. The Company applies an estimated factor against its actual invoiced sales to represent the expected level of future discount or rebate obligations associated with the sale.

The Company maintains a returns policy that allows its U.S. pharmaceutical customers to return product within a specified period prior to and subsequent to the expiration date (generally, three to six months before and 12 months after product expiration). The estimate of the provision for returns is based upon historical experience with actual returns. Additionally, the Company considers factors such as levels of inventory in the distribution channel, product dating and expiration period, whether products have been discontinued, entrance in the market of generic competition, changes in formularies or launch of over-the-counter products, among others. Outside of the United States, returns are only allowed in certain countries on a limited basis.

Merck's payment terms for U.S. pharmaceutical customers are typically 36 days from receipt of invoice and for U.S. animal health customers are typically 30 days from receipt of invoice; however, certain products, including *Keytruda*, have longer payment terms up to 90 days. Outside of the United States, payment terms are typically 30 days to 90 days, although certain markets have longer payment terms.

Depreciation — Depreciation is provided over the estimated useful lives of the assets, principally using the straight-line method. For tax purposes, accelerated tax methods are used. The estimated useful lives primarily range from 25 to 45 years for *Buildings*, and from 3 to 15 years for *Machinery, equipment and office furnishings*. Depreciation expense was $1.7 billion in 2019, $1.4 billion in 2018 and $1.5 billion in 2017.

Advertising and Promotion Costs — Advertising and promotion costs are expensed as incurred. The Company recorded advertising and promotion expenses of $2.1 billion, $2.1 billion and $2.2 billion in 2019, 2018 and 2017, respectively.

Software Capitalization — The Company capitalizes certain costs incurred in connection with obtaining or developing internal-use software including external direct costs of material and services, and payroll costs for employees directly involved with the software development. These costs are included in *Property, plant and equipment*. In addition, the Company capitalizes certain costs incurred to implement a cloud computing arrangement that is considered a service agreement, which are included in *Other Assets*. Capitalized software costs are amortized beginning when the software project is substantially complete and the asset is ready for its intended use. Capitalized software costs associated with projects that are being amortized over 6 to 10 years (including the Company's on-going multi-year implementation of an enterprise-wide resource planning system) were $548 million and $439 million, net of accumulated amortization at December 31, 2019 and 2018, respectively. All other capitalized software costs are being amortized over periods ranging from 3 to 5 years. Costs incurred during the preliminary project stage and post-implementation stage, as well as maintenance and training costs, are expensed as incurred.

Goodwill — Goodwill represents the excess of the consideration transferred over the fair value of net assets of businesses acquired. Goodwill is assigned to reporting units and evaluated for impairment on at least an annual basis, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If the Company concludes it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a quantitative fair value test is performed. If the carrying value of a reporting unit is greater than its fair value, a goodwill impairment charge will be recorded for the difference (up to the carrying value of goodwill).

Acquired Intangibles — Acquired intangibles include products and product rights, licenses, trade names and patents, which are initially recorded at fair value, assigned an estimated useful life, and amortized primarily on a straight-line basis over their estimated useful lives ranging from 2 to 24 years (see Note 8). The Company periodically evaluates whether current facts or circumstances indicate that the carrying values of its acquired intangibles may not

be recoverable. If such circumstances are determined to exist, an estimate of the undiscounted future cash flows of these assets, or appropriate asset groupings, is compared to the carrying value to determine whether an impairment exists. If the asset is determined to be impaired, the loss is measured based on the difference between the carrying value of the intangible asset and its fair value, which is determined based on the net present value of estimated future cash flows.

Acquired In-Process Research and Development — IPR&D that the Company acquires in conjunction with the acquisition of a business represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. The amounts are capitalized and are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, Merck will make a determination as to the then-useful life of the intangible asset, generally determined by the period in which the substantial majority of the cash flows are expected to be generated, and begin amortization. The Company evaluates IPR&D for impairment at least annually, or more frequently if impairment indicators exist, by performing a quantitative test that compares the fair value of the IPR&D intangible asset with its carrying value. If the fair value is less than the carrying amount, an impairment loss is recognized in operating results.

Contingent Consideration — Certain of the Company's acquisitions involve the potential for future payment of consideration that is contingent upon the achievement of performance milestones, including product development milestones and royalty payments on future product sales. If the transaction is accounted for as an acquisition of a business, the fair value of contingent consideration liabilities is determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date, at each reporting period until the contingency is resolved, the contingent consideration liability is remeasured at current fair value with changes (either expense or income) recorded in earnings. Significant events that increase or decrease the probability of achieving development and regulatory milestones or that increase or decrease projected cash flows will result in corresponding increases or decreases in the fair values of the related contingent consideration obligations. If the transaction is accounted for as an acquisition of an asset rather than a business, contingent consideration is not recognized at the acquisition date. In these instances, product development milestones are recognized upon achievement and sales-based milestones are recognized when the milestone is deemed probable by the Company of being achieved.

Research and Development — Research and development is expensed as incurred. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Research and development expenses include restructuring costs and IPR&D impairment charges. In addition, research and development expenses include expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration. Research and development expenses also include upfront and milestone payments related to asset acquisitions and licensing transactions involving clinical development programs that have not yet received regulatory approval.

Collaborative Arrangements — Merck has entered into collaborative arrangements that provide the Company with varying rights to develop, produce and market products together with its collaborative partners. When Merck is the principal on sales transactions with third parties, the Company recognizes sales, cost of sales and selling, general and administrative expenses on a gross basis. Profit sharing amounts it pays to its collaborative partners are recorded within *Cost of sales*. When the collaborative partner is the principal on sales transactions with third parties, the Company records profit sharing amounts received from its collaborative partners as alliance revenue (within *Sales*). Alliance revenue is recorded net of cost of sales and includes an adjustment to share commercialization costs between the partners in accordance with the collaboration agreement. The adjustment is determined by comparing the commercialization costs Merck has incurred directly and reported within *Selling, general and administrative* expenses with the costs the collaborative partner has incurred. Research and development costs Merck incurs related to collaborations are recorded within *Research and development* expenses. Cost reimbursements to the collaborative partner or payments received from the collaborative partner to share these costs pursuant to the terms of the collaboration agreements are recorded as increases or decreases to *Research and development* expenses.

In addition, the terms of the collaboration agreements may require the Company to make payments based upon the achievement of certain developmental, regulatory approval or commercial milestones. Upfront and milestone payments payable by Merck to collaborative partners prior to regulatory approval are expensed as incurred and included in *Research and development* expenses. Payments due to collaborative partners upon or subsequent to regulatory approval are capitalized and amortized over the estimated useful life of the corresponding intangible asset to *Cost of sales* provided that future cash flows support the amounts capitalized. Sales-based milestones payable by Merck to collaborative partners are accrued and capitalized, subject to cumulative amortization catch-up, when probable of being achieved. The amortization catch-up is calculated either from the time of the first regulatory approval for indications that were unapproved at the time the collaboration was formed, or from time of the formation of the collaboration for approved products. The related intangible asset that is recognized is amortized to *Cost of sales* over its remaining useful life, subject to impairment testing.

Share-Based Compensation — The Company expenses all share-based payments to employees over the requisite service period based on the grant-date fair value of the awards.

Restructuring Costs — The Company records liabilities for costs associated with exit or disposal activities in the period in which the liability is incurred. In accordance with existing benefit arrangements, employee termination costs are accrued when the restructuring actions are probable and estimable. When accruing these costs, the Company will recognize the amount within a range of costs that is the best estimate within the range. When no amount within the range is a better estimate than any other amount, the Company recognizes the minimum amount within the range. Costs for one-time termination benefits in which the employee is required to render service until termination in order to receive the benefits are recognized ratably over the future service period.

Contingencies and Legal Defense Costs — The Company records accruals for contingencies and legal defense costs expected to be incurred in connection with a loss contingency when it is probable that a liability has been incurred and the amount can be reasonably estimated.

Taxes on Income — Deferred taxes are recognized for the future tax effects of temporary differences between financial and income tax reporting based on enacted tax laws and rates. The Company evaluates tax positions to determine whether the benefits of tax positions are more likely than not of being sustained upon audit based on the technical merits of the tax position. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely of being realized upon ultimate settlement in the financial statements. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit in the financial statements. The Company recognizes interest and penalties associated with uncertain tax positions as a component of *Taxes on income* in the Consolidated Statement of Income. The Company accounts for the tax effects of the tax on global intangible low-taxed income (GILTI) of certain foreign subsidiaries in the income tax provision in the period the tax arises.

Use of Estimates — The consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States (GAAP) and, accordingly, include certain amounts that are based on management's best estimates and judgments. Estimates are used when accounting for amounts recorded in connection with acquisitions, including initial fair value determinations of assets and liabilities, primarily IPR&D, other intangible assets and contingent consideration, as well as subsequent fair value measurements. Additionally, estimates are used in determining such items as provisions for sales discounts and returns, depreciable and amortizable lives, recoverability of inventories, including those produced in preparation for product launches, amounts recorded for contingencies, environmental liabilities, accruals for contingent sales-based milestone payments and other reserves, pension and other postretirement benefit plan assumptions, share-based compensation assumptions, restructuring costs, impairments of long-lived assets (including intangible assets and goodwill) and investments, and taxes on income. Because of the uncertainty inherent in such estimates, actual results may differ from these estimates.

Reclassifications — Certain reclassifications have been made to prior year amounts to conform to the current year presentation.

Recently Adopted Accounting Standards — In February 2016, the Financial Accounting Standards Board (FASB) issued new accounting guidance for the accounting and reporting of leases (ASU 2016-02) and subsequently issued several updates to the new guidance (ASC 842 or new leasing guidance). The new leasing guidance requires

that lessees recognize a right-of-use asset and a lease liability for each of its leases (other than leases that meet the definition of a short-term lease). Leases are classified as either operating or finance. Operating leases result in straight-line expense in the income statement (similar to previous operating leases), while finance leases result in more expense being recognized in the earlier years of the lease term (similar to previous capital leases). The Company adopted the new standard on January 1, 2019 using a modified retrospective approach. Merck elected the transition method that allows for application of the standard at the adoption date rather than at the beginning of the earliest comparative period presented in the financial statements. The Company also elected available practical expedients. Upon adoption, the Company recognized $1.1 billion of additional assets and related liabilities on its consolidated balance sheet (see Note 9). The adoption of the new leasing guidance did not impact the Company's consolidated statements of income or of cash flows.

In April 2018, the FASB issued new guidance on the accounting for costs incurred to implement a cloud computing arrangement that is considered a service arrangement. The new guidance requires the capitalization of such costs, aligning it with the accounting for costs associated with developing or obtaining internal-use software. The Company adopted the new standard in the third quarter of 2019 using prospective application for eligible costs, which were immaterial.

In August 2018, the FASB issued new guidance modifying the disclosure requirements for employers that sponsor defined benefit pension or other postretirement plans. The new guidance removes disclosures that no longer are considered cost beneficial, clarifies the specific requirements of certain disclosures, and adds disclosure requirements identified as relevant. The Company elected to early adopt the new guidance in 2019 on a retrospective basis resulting in minor changes to its employee benefit plan disclosures (see Note 13).

Also, in August 2018, the FASB issued new guidance on fair value measurements that adds, removes, and modifies certain disclosure requirements. The Company elected to early adopt the new guidance in 2019 resulting in minor changes to its fair value disclosures (see Note 6).

Recently Issued Accounting Standards Not Yet Adopted — In June 2016, the FASB issued new guidance on the accounting for credit losses on financial instruments. The new guidance introduces an expected loss model for estimating credit losses, replacing the incurred loss model. The new guidance also changes the impairment model for available-for-sale debt securities, requiring the use of an allowance to record estimated credit losses (and subsequent recoveries). The Company adopted the new guidance effective January 1, 2020. There was no impact to the Company's consolidated financial statements upon adoption.

In November 2018, the FASB issued new guidance for collaborative arrangements intended to reduce diversity in practice by clarifying whether certain transactions between collaborative arrangement participants should be accounted for under revenue recognition guidance (ASC 606). The Company adopted the new guidance effective January 1, 2020, which will result in minor changes to the footnote presentation of information related to the Company's collaborative arrangements.

In December 2019, the FASB issued amended guidance on the accounting and reporting of income taxes. The guidance is intended to simplify the accounting for income taxes by removing exceptions related to certain intraperiod tax allocations and deferred tax liabilities; clarifying guidance primarily related to evaluating the step-up tax basis for goodwill in a business combination; and reflecting enacted changes in tax laws or rates in the annual effective tax rate. The amended guidance is effective for interim and annual periods in 2021. Early adoption is permitted. The application of the amendments in the new guidance are to be applied on a retrospective basis, on a modified retrospective basis through a cumulative-effect adjustment to retained earnings or prospectively, depending on the amendment. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In January 2020, the FASB issued new guidance intended to clarify certain interactions between accounting standards related to equity securities, equity method investments and certain derivatives. The guidance addresses accounting for the transition into and out of the equity method of accounting and measuring certain purchased options and forward contracts to acquire investments. The new guidance is effective for interim and annual periods in 2021 and is to be applied prospectively. Early adoption is permitted. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

3. Acquisitions, Divestitures, Research Collaborations and License Agreements

The Company continues to pursue the acquisition of businesses and establishment of external alliances such as research collaborations and licensing agreements to complement its internal research capabilities. These arrangements often include upfront payments, as well as expense reimbursements or payments to the third party, and milestone, royalty or profit share arrangements, contingent upon the occurrence of certain future events linked to the success of the asset in development. The Company also reviews its marketed products and pipeline to examine candidates which may provide more value through out-licensing and, as part of its portfolio assessment process, may also divest certain assets. Pro forma financial information for acquired businesses is not presented if the historical financial results of the acquired entity are not significant when compared with the Company's financial results.

Recently Completed Transaction

In January 2020, Merck acquired ArQule, Inc. (ArQule), a publicly traded biopharmaceutical company focused on kinase inhibitor discovery and development for the treatment of patients with cancer and other diseases for $2.7 billion. ArQule's lead investigational candidate, MK-1026 (formerly ARQ 531), is a novel, oral Bruton's tyrosine kinase (BTK) inhibitor currently in a Phase 2 dose expansion study for the treatment of B-cell malignancies. The Company is in the process of determining the preliminary fair value of assets acquired, liabilities assumed and total consideration transferred in this transaction, which will be accounted for as an acquisition of a business.

2019 Transactions

In July 2019, Merck acquired Peloton Therapeutics, Inc. (Peloton), a clinical-stage biopharmaceutical company focused on the development of novel small molecule therapeutic candidates targeting hypoxia-inducible factor-2α (HIF-2α) for the treatment of patients with cancer and other non-oncology diseases. Peloton's lead candidate, MK-6482 (formerly PT2977), is a novel oral HIF-2α inhibitor in late-stage development for renal cell carcinoma. Merck made an upfront payment of $1.2 billion in cash; additionally, former Peloton shareholders will be eligible to receive $50 million upon U.S. regulatory approval, $50 million upon first commercial sale in the United States, and up to $1.05 billion of sales-based milestones. The transaction was accounted for as an acquisition of an asset. Merck recorded cash of $157 million, deferred tax liabilities of $52 million, and other net liabilities of $4 million at the acquisition date and *Research and development* expenses of $993 million in 2019 related to the transaction.

On April 1, 2019, Merck acquired Antelliq Corporation (Antelliq), a leader in digital animal identification, traceability and monitoring solutions. These solutions help veterinarians, farmers and pet owners gather critical data to improve management, health and well-being of livestock and pets. Merck paid $2.3 billion to acquire all outstanding shares of Antelliq and spent $1.3 billion to repay Antelliq's debt. The transaction was accounted for as an acquisition of a business.

The estimated fair value of assets acquired and liabilities assumed from Antelliq is as follows:

($ in millions)	April 1, 2019
Cash and cash equivalents	$ 31
Accounts receivable	73
Inventories	95
Property, plant and equipment	62
Identifiable intangible assets (useful lives ranging from 18-24 years) [(1)]	2,689
Deferred income tax liabilities	(520)
Other assets and liabilities, net	(81)
Total identifiable net assets	2,349
Goodwill [(2)]	1,302
Consideration transferred	$ 3,651

[(1)] *The estimated fair values of identifiable intangible assets relate primarily to trade names and were determined using an income approach. The future net cash flows were discounted to present value utilizing a discount rate of 11.5%. Actual cash flows are likely to be different than those assumed.*

[(2)] *The goodwill recognized is largely attributable to anticipated synergies expected to arise after the acquisition and was allocated to the Animal Health segment. The goodwill is not deductible for tax purposes.*

The Company's results for 2019 include eight months of activity for Antelliq. The Company incurred $47 million of transaction costs directly related to the acquisition of Antelliq, consisting largely of advisory fees, which are reflected in *Selling, general and administrative* expenses in 2019.

Also in April 2019, Merck acquired Immune Design, a late-stage immunotherapy company employing next-generation *in vivo* approaches to enable the body's immune system to fight disease, for $301 million in cash. The transaction was accounted for as an acquisition of a business. Merck recognized intangible assets for IPR&D of $156 million, cash of $83 million and other net assets of $42 million. The excess of the consideration transferred over the fair value of net assets acquired of $20 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair values of the identifiable intangible assets related to IPR&D were determined using an income approach. Actual cash flows are likely to be different than those assumed.

2018 Transactions

In 2018, the Company recorded an aggregate charge of $423 million within *Cost of sales* in conjunction with the termination of a collaboration agreement entered into in 2014 with Samsung Bioepis Co., Ltd. (Samsung) for insulin glargine. The charge reflects a termination payment of $155 million, which represents the reimbursement of all fees previously paid by Samsung to Merck under the agreement, plus interest, as well as the release of Merck's ongoing obligations under the agreement. The charge also included fixed asset abandonment charges of $137 million, inventory write-offs of $122 million, as well as other related costs of $9 million. The termination of this agreement has no impact on the Company's other collaboration with Samsung.

In June 2018, Merck acquired Viralytics Limited (Viralytics), an Australian publicly traded company focused on oncolytic immunotherapy treatments for a range of cancers, for AUD 502 million ($378 million). The transaction provided Merck with full rights to V937 (formerly CVA21), Viralytics's investigational oncolytic immunotherapy. V937 is based on Viralytics's proprietary formulation of an oncolytic virus (Coxsackievirus Type A21) that has been shown to preferentially infect and kill cancer cells. V937 is currently being evaluated in multiple clinical trials, both as an intratumoral and intravenous agent, including in combination with *Keytruda*. Under a previous agreement between Merck and Viralytics, a study is investigating the use of the *Keytruda* and V937 combination in melanoma, prostate, lung and bladder cancers. The transaction was accounted for as an acquisition of an asset. Merck recorded net assets of $34 million (primarily cash) at the acquisition date and *Research and development* expenses of $344 million in 2018 related to the transaction. There are no future contingent payments associated with the acquisition.

In March 2018, Merck and Eisai Co., Ltd. (Eisai) entered into a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima, an orally available tyrosine kinase inhibitor discovered by Eisai (see Note 4).

2017 Transactions

In October 2017, Merck acquired Rigontec GmbH (Rigontec), a leader in accessing the retinoic acid-inducible gene I pathway, part of the innate immune system, as a novel and distinct approach in cancer immunotherapy to induce both immediate and long-term anti-tumor immunity. Rigontec's lead candidate, MK-4621 (formerly RGT100), is in development for the treatment in patients with various tumors. Under the terms of the agreement, Merck made an upfront cash payment of €119 million ($140 million) and may make additional contingent payments of up to €349 million (of which €184 million are related to the achievement of research milestones and regulatory approvals and €165 million are related to the achievement of commercial targets). The transaction was accounted for as an acquisition of an asset and the upfront payment is reflected within *Research and development* expenses in 2017.

In July 2017, Merck and AstraZeneca PLC (AstraZeneca) entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza for multiple cancer types (see Note 4).

In March 2017, Merck acquired a controlling interest in Vallée S.A. (Vallée), a leading privately held producer of animal health products in Brazil. Vallée has an extensive portfolio of products spanning parasiticides, anti-infectives and vaccines that include products for livestock, horses, and companion animals. Under the terms of the agreement, Merck acquired 93.5% of the shares of Vallée for $358 million. Of the total purchase price, $176 million was placed into escrow pending resolution of certain contingent items. The transaction was accounted for as an acquisition of a business. Merck recognized intangible assets of $297 million related to currently marketed products, net deferred tax liabilities of $102 million, other net assets of $32 million and noncontrolling interest of $25 million. In addition, the Company recorded liabilities of $37 million for contingencies identified at the acquisition date and corresponding

indemnification assets of $37 million, representing the amounts to be reimbursed to Merck if and when the contingent liabilities are paid. The excess of the consideration transferred over the fair value of net assets acquired of $156 million was recorded as goodwill. The goodwill was allocated to the Animal Health segment and is not deductible for tax purposes. The estimated fair values of identifiable intangible assets related to currently marketed products were determined using an income approach. Actual cash flows are likely to be different than those assumed. The intangible assets related to currently marketed products are being amortized over their estimated useful lives of 15 years. In the fourth quarter of 2017, Merck acquired an additional 4.5% interest in Vallée for $18 million, which reduced the noncontrolling interest related to Vallée.

Remicade/Simponi

In 1998, a subsidiary of Schering-Plough entered into a licensing agreement with Centocor Ortho Biotech Inc. (Centocor), a Johnson & Johnson (J&J) company, to market *Remicade,* which is prescribed for the treatment of inflammatory diseases. In 2005, Schering-Plough's subsidiary exercised an option under its contract with Centocor for license rights to develop and commercialize *Simponi*, a fully human monoclonal antibody. The Company has marketing rights to both products throughout Europe, Russia and Turkey. *Remicade* lost market exclusivity in major European markets in 2015 and the Company no longer has market exclusivity in any of its marketing territories. The Company continues to have market exclusivity for *Simponi* in all of its marketing territories. All profits derived from Merck's distribution of the two products in these countries are equally divided between Merck and J&J.

4. Collaborative Arrangements

Merck has entered into collaborative arrangements that provide the Company with varying rights to develop, produce and market products together with its collaborative partners. Both parties in these arrangements are active participants and exposed to significant risks and rewards dependent on the commercial success of the activities of the collaboration. Merck's more significant collaborative arrangements are discussed below.

AstraZeneca

In July 2017, Merck and AstraZeneca PLC (AstraZeneca) entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza for multiple cancer types. Lynparza is an oral poly (ADP-ribose) polymerase (PARP) inhibitor currently approved for certain types of ovarian and breast cancer. The companies are jointly developing and commercializing Lynparza, both as monotherapy and in combination trials with other potential medicines. Independently, Merck and AstraZeneca will develop and commercialize Lynparza in combinations with their respective PD-1 and PD-L1 medicines, *Keytruda* and Imfinzi. The companies will also jointly develop and commercialize AstraZeneca's selumetinib, an oral, potent, selective inhibitor of MEK, part of the mitogen-activated protein kinase (MAPK) pathway, currently being developed for multiple indications. Under the terms of the agreement, AstraZeneca and Merck will share the development and commercialization costs for Lynparza and selumetinib monotherapy and non-PD-L1/PD-1 combination therapy opportunities.

Gross profits from Lynparza and selumetinib product sales generated through monotherapies or combination therapies are shared equally. Merck will fund all development and commercialization costs of *Keytruda* in combination with Lynparza or selumetinib. AstraZeneca will fund all development and commercialization costs of Imfinzi in combination with Lynparza or selumetinib. AstraZeneca is the principal on Lynparza sales transactions. Merck records its share of Lynparza product sales, net of cost of sales and commercialization costs, as alliance revenue and its share of development costs associated with the collaboration as part of *Research and development* expenses. Reimbursements received from AstraZeneca for research and development expenses are recognized as reductions to *Research and development* costs.

As part of the agreement, Merck made an upfront payment to AstraZeneca of $1.6 billion in 2017 and made payments of $750 million over a multi-year period for certain license options (of which $250 million was paid in December 2017, $400 million was paid in December 2018 and $100 million was paid in December 2019). The Company recorded an aggregate charge of $2.35 billion in *Research and development* expenses in 2017 related to the upfront payment and license option payments. In addition, the agreement provides for additional contingent payments from Merck to AstraZeneca related to the successful achievement of sales-based and regulatory milestones.

In 2019, Merck determined it was probable that annual sales of Lynparza in the future would trigger a $300 million sales-based milestone payment from Merck to AstraZeneca. Accordingly, in 2019, Merck recorded a $300

million liability and a corresponding increase to the intangible asset related to Lynparza. Prior to 2019, Merck accrued sales-based milestone payments aggregating $700 million, of which $200 million and $250 million was paid to AstraZeneca in 2019 and 2018, respectively, and the remainder of $250 million was paid in January 2020. Potential future sales-based milestone payments of $3.1 billion have not yet been accrued as they are not deemed by the Company to be probable at this time.

In 2019, Lynparza received regulatory approval in the European Union (EU) both as a monotherapy for the treatment of certain adult patients with advanced breast cancer and as a monotherapy for the maintenance treatment of certain adult patients with *BRCA*-mutated advanced ovarian cancer. Each of these approvals triggered a $30 million capitalized milestone payment from Merck to AstraZeneca. In 2018, Lynparza received regulatory approvals triggering capitalized milestone payments of $140 million in the aggregate from Merck to AstraZeneca. Potential future regulatory milestone payments of $1.7 billion remain under the agreement.

The intangible asset balance related to Lynparza (which includes capitalized sales-based and regulatory milestone payments) was $955 million at December 31, 2019 and is included in *Other Intangibles, Net* on the Consolidated Balance Sheet. The amount is being amortized over its estimated useful life through 2028 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

Years Ended December 31	**2019**	2018	2017
Alliance revenue	**$ 444**	$ 187	$ 20
Cost of sales [1]	**148**	93	4
Selling, general and administrative	**138**	48	1
Research and development [2]	**168**	152	2,419

December 31	**2019**	2018
Receivables from AstraZeneca included in *Other current assets*	$ 128	$ 52
Payables to AstraZeneca included in *Accrued and other current liabilities* [3]	577	405
Payables to AstraZeneca included *Other Noncurrent Liabilities* [3]	—	250

[1] *Represents amortization of capitalized milestone payments.*

[2] *Amount for 2017 includes $2.35 billion related to the upfront payment and license option payments.*

[3] *Includes accrued milestone payments.*

Eisai

In March 2018, Merck and Eisai announced a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima, an orally available tyrosine kinase inhibitor discovered by Eisai. Under the agreement, Merck and Eisai will develop and commercialize Lenvima jointly, both as monotherapy and in combination with Merck's *Keytruda*. Eisai records Lenvima product sales globally (Eisai is the principal on Lenvima sales transactions), and Merck and Eisai share gross profits equally. Merck records its share of Lenvima product sales, net of cost of sales and commercialization costs, as alliance revenue. Expenses incurred during co-development, including for studies evaluating Lenvima as monotherapy, are shared equally by the two companies and reflected in *Research and development* expenses.

Under the agreement, Merck made an upfront payment to Eisai of $750 million and will make payments of up to $650 million for certain option rights through 2021 (of which $325 million was paid in March 2019, $200 million is expected to be paid in March 2020 and $125 million is expected to be paid in March 2021). The Company recorded an aggregate charge of $1.4 billion in *Research and development* expenses in 2018 related to the upfront payment and future option payments. In addition, the agreement provides for additional contingent payments from Merck to Eisai related to the successful achievement of sales-based and regulatory milestones.

In 2019, Merck determined it was probable that annual sales of Lenvima in the future would trigger sales-based milestone payments from Merck to Eisai aggregating $682 million. Accordingly, in 2019, Merck recorded $682 million of liabilities and corresponding increases to the intangible asset related to Lenvima. In 2018, Merck accrued sales-based milestone payments aggregating $268 million related to Lenvima. Of these amounts, $50 million was paid

to Eisai in 2019 and an additional $150 million was paid in January 2020. Potential future sales-based milestone payments of $3.0 billion have not yet been accrued as they are not deemed by the Company to be probable at this time.

In 2018, Lenvima received regulatory approvals triggering capitalized milestone payments of $250 million in the aggregate from Merck to Eisai. Potential future regulatory milestone payments of $135 million remain under the agreement.

The intangible asset balance related to Lenvima (which includes capitalized sales-based and regulatory milestone payments) was $956 million at December 31, 2019 and is included in *Other Intangibles, Net* on the Consolidated Balance Sheet. The amount is being amortized over its estimated useful life through 2026 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

Years Ended December 31	**2019**	2018
Alliance revenue	**$ 404**	$ 149
Cost of sales [1]	**206**	39
Selling, general and administrative	**80**	13
Research and development [2]	**189**	1,489

December 31	**2019**	2018
Receivables from Eisai included in *Other current assets*	**$ 150**	$ 71
Payables to Eisai included in *Accrued and other current liabilities* [3]	**700**	375
Payables to Eisai included in *Other Noncurrent Liabilities* [3]	**525**	543

[1] *Represents amortization of capitalized milestone payments.*

[2] *Amount for 2018 includes $1.4 billion related to the upfront payment and option payments.*

[3] *Includes accrued milestone and future option payments.*

Bayer AG

In 2014, the Company entered into a worldwide clinical development collaboration with Bayer AG (Bayer) to market and develop soluble guanylate cyclase (sGC) modulators including Bayer's Adempas, which is approved to treat pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension. The two companies have implemented a joint development and commercialization strategy. The collaboration also includes clinical development of Bayer's vericiguat, which is in Phase 3 trials for worsening heart failure, as well as opt-in rights for other early-stage sGC compounds in development by Bayer. Merck in turn made available its early-stage sGC compounds under similar terms. Under the agreement, Bayer leads commercialization of Adempas in the Americas, while Merck leads commercialization in the rest of the world. For vericiguat and other potential opt-in products, Bayer will lead commercialization in the rest of world and Merck will lead in the Americas. For all products and candidates included in the agreement, both companies will share in development costs and profits on sales and will have the right to co-promote in territories where they are not the lead. Revenue from Adempas includes sales in Merck's marketing territories, as well as Merck's share of profits from the sale of Adempas in Bayer's marketing territories. In addition, the agreement provides for additional contingent payments from Merck to Bayer related to the successful achievement of sales-based milestones.

In 2018, Merck determined it was probable that annual worldwide sales of Adempas in the future would trigger a $375 million sales-based milestone payment from Merck to Bayer. Accordingly, Merck recorded a $375 million liability and a corresponding increase to the intangible asset related to Adempas. In 2018, the Company made a $350 million milestone payment to Bayer, which was accrued for in 2016 when Merck deemed the payment to be probable. There is an additional $400 million potential future sales-based milestone payment that has not yet been accrued as it is not deemed by the Company to be probable at this time.

The intangible asset balance related to Adempas (which includes the acquired intangible asset balance, as well as capitalized sales-based milestone payments) was $883 million at December 31, 2019 and is included in *Other Intangibles, Net* on the Consolidated Balance Sheet. The amount is being amortized over its estimated useful life through 2027 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

Years Ended December 31	**2019**	2018	2017
Net product sales recorded by Merck	**$ 215**	$ 190	$ 149
Merck's profit share from sales in Bayer's marketing territories	**204**	139	151
Total sales	**419**	329	300
Cost of sales [1]	**113**	216	99
Selling, general and administrative	**41**	35	27
Research and development	**126**	127	101

December 31	**2019**	2018
Receivables from Bayer included in *Other current assets*	**$ 49**	$ 32
Payables to Bayer included in *Other Noncurrent Liabilities* [2]	**375**	375

[1] *Includes amortization of intangible assets.*

[2] *Represents accrued milestone payment.*

5. Restructuring

In early 2019, Merck approved a new global restructuring program (Restructuring Program) as part of a worldwide initiative focused on further optimizing the Company's manufacturing and supply network, as well as reducing its global real estate footprint. This program is a continuation of the Company's plant rationalization, builds on prior restructuring programs and does not include any actions associated with the planned spin-off of NewCo. As the Company continues to evaluate its global footprint and overall operating model, it has subsequently identified additional actions under the Restructuring Program, and could identify further actions over time. The actions currently contemplated under the Restructuring Program are expected to be substantially completed by the end of 2023, with the cumulative pretax costs to be incurred by the Company to implement the program now estimated to be approximately $2.5 billion. The Company estimates that approximately 60% of the cumulative pretax costs will result in cash outlays, primarily related to employee separation expense and facility shut-down costs. Approximately 40% of the cumulative pretax costs will be non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested. The Company expects to record charges of approximately $800 million in 2020 related to the Restructuring Program. Actions under previous global restructuring programs have been substantially completed.

The Company recorded total pretax costs of $927 million in 2019, $658 million in 2018 and $927 million in 2017 related to restructuring program activities. For segment reporting, restructuring charges are unallocated expenses.

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The following table summarizes the charges related to restructuring program activities by type of cost:

	Separation Costs	Accelerated Depreciation	Other	Total
Year Ended December 31, 2019				
Cost of sales	**$ —**	**$ 198**	**$ 53**	**$ 251**
Selling, general and administrative	**—**	**33**	**1**	**34**
Research and development	**—**	**2**	**2**	**4**
Restructuring costs	**572**	**—**	**66**	**638**
	$ 572	**$ 233**	**$ 122**	**$ 927**
Year Ended December 31, 2018				
Cost of sales	$ —	$ 10	$ 11	$ 21
Selling, general and administrative	—	2	1	3
Research and development	—	(13)	15	2
Restructuring costs	473	—	159	632
	$ 473	$ (1)	$ 186	$ 658
Year Ended December 31, 2017				
Cost of sales	$ —	$ 52	$ 86	$ 138
Selling, general and administrative	—	2	—	2
Research and development	—	6	5	11
Restructuring costs	552	—	224	776
	$ 552	$ 60	$ 315	$ 927

Separation costs are associated with actual headcount reductions, as well as those headcount reductions which were probable and could be reasonably estimated.

Accelerated depreciation costs primarily relate to manufacturing, research and administrative facilities and equipment to be sold or closed as part of the programs. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the asset, based upon the anticipated date the site will be closed or divested or the equipment disposed of, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. All the sites have and will continue to operate up through the respective closure dates and, since future undiscounted cash flows are sufficient to recover the respective book values, Merck is recording accelerated depreciation over the revised useful life of the site assets. Anticipated site closure dates, particularly related to manufacturing locations, have been and may continue to be adjusted to reflect changes resulting from regulatory or other factors.

Other activity in 2019, 2018 and 2017 includes asset abandonment, facility shut-down and other related costs, as well as pretax gains and losses resulting from the sales of facilities and related assets. Additionally, other activity includes certain employee-related costs associated with pension and other postretirement benefit plans (see Note 13) and share-based compensation.

The following table summarizes the charges and spending relating to restructuring program activities:

	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2018	$ 619	$ —	$ 128	$ 747
Expenses	473	(1)	186	658
(Payments) receipts, net	(649)	—	(238)	(887)
Non-cash activity	—	1	15	16
Restructuring reserves December 31, 2018	443	—	91	534
Expenses	**572**	**233**	**122**	**927**
(Payments) receipts, net	**(325)**	**—**	**(136)**	**(461)**
Non-cash activity	**—**	**(233)**	**(8)**	**(241)**
Restructuring reserves December 31, 2019 *(1)*	**$ 690**	**$ —**	**$ 69**	**$ 759**

(1) *The remaining cash outlays are expected to be substantially completed by the end of 2023.*

6. Financial Instruments

Derivative Instruments and Hedging Activities

The Company manages the impact of foreign exchange rate movements and interest rate movements on its earnings, cash flows and fair values of assets and liabilities through operational means and through the use of various financial instruments, including derivative instruments.

A significant portion of the Company's revenues and earnings in foreign affiliates is exposed to changes in foreign exchange rates. The objectives and accounting related to the Company's foreign currency risk management program, as well as its interest rate risk management activities are discussed below.

Foreign Currency Risk Management

The Company has established revenue hedging, balance sheet risk management and net investment hedging programs to protect against volatility of future foreign currency cash flows and changes in fair value caused by changes in foreign exchange rates.

The objective of the revenue hedging program is to reduce the variability caused by changes in foreign exchange rates that would affect the U.S. dollar value of future cash flows derived from foreign currency denominated sales, primarily the euro, Japanese yen and Chinese renminbi. To achieve this objective, the Company will hedge a portion of its forecasted foreign currency denominated third-party and intercompany distributor entity sales (forecasted sales) that are expected to occur over its planning cycle, typically no more than two years into the future. The Company will layer in hedges over time, increasing the portion of forecasted sales hedged as it gets closer to the expected date of the forecasted sales. The portion of forecasted sales hedged is based on assessments of cost-benefit profiles that consider natural offsetting exposures, revenue and exchange rate volatilities and correlations, and the cost of hedging instruments. The Company manages its anticipated transaction exposure principally with purchased local currency put options, forward contracts, and purchased collar options.

The fair values of these derivative contracts are recorded as either assets (gain positions) or liabilities (loss positions) in the Consolidated Balance Sheet. Changes in the fair value of derivative contracts are recorded each period in either current earnings or *OCI*, depending on whether the derivative is designated as part of a hedge transaction and, if so, the type of hedge transaction. For derivatives that are designated as cash flow hedges, the unrealized gains or losses on these contracts is recorded in *AOCI* and reclassified into *Sales* when the hedged anticipated revenue is recognized. For those derivatives which are not designated as cash flow hedges, but serve as economic hedges of forecasted sales, unrealized gains or losses are recorded in *Sales* each period. The cash flows from both designated and non-designated contracts are reported as operating activities in the Consolidated Statement of Cash Flows. The Company does not enter into derivatives for trading or speculative purposes.

The Company manages operating activities and net asset positions at each local subsidiary in order to mitigate the effects of exchange on monetary assets and liabilities. The Company also uses a balance sheet risk management program to mitigate the exposure of net monetary assets that are denominated in a currency other than a subsidiary's functional currency from the effects of volatility in foreign exchange. In these instances, Merck principally utilizes forward exchange contracts to offset the effects of exchange on exposures denominated in developed country currencies, primarily the euro and Japanese yen. For exposures in developing country currencies, the Company will enter into forward contracts to partially offset the effects of exchange on exposures when it is deemed economical to do so based on a cost-benefit analysis that considers the magnitude of the exposure, the volatility of the exchange rate and the cost of the hedging instrument. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

Monetary assets and liabilities denominated in a currency other than the functional currency of a given subsidiary are remeasured at spot rates in effect on the balance sheet date with the effects of changes in spot rates reported in *Other (income) expense, net*. The forward contracts are not designated as hedges and are marked to market through *Other (income) expense, net*. Accordingly, fair value changes in the forward contracts help mitigate the changes in the value of the remeasured assets and liabilities attributable to changes in foreign currency exchange rates, except to the extent of the spot-forward differences. These differences are not significant due to the short-term nature of the contracts, which typically have average maturities at inception of less than one year.

The Company also uses forward exchange contracts to hedge a portion of its net investment in foreign operations against movements in exchange rates. The forward contracts are designated as hedges of the net investment in a foreign operation. The unrealized gains or losses on these contracts are recorded in foreign currency translation adjustment within *OCI*, and remain in *AOCI* until either the sale or complete or substantially complete liquidation of the subsidiary. The Company excludes certain portions of the change in fair value of its derivative instruments from the assessment of hedge effectiveness (excluded component). Changes in fair value of the excluded components are recognized in *OCI*. The Company recognizes in earnings the initial value of the excluded component on a straight-line basis over the life of the derivative instrument, rather than using the mark-to-market approach. The cash flows from these contracts are reported as investing activities in the Consolidated Statement of Cash Flows.

Foreign exchange risk is also managed through the use of foreign currency debt. The Company's senior unsecured euro-denominated notes have been designated as, and are effective as, economic hedges of the net investment in a foreign operation. Accordingly, foreign currency transaction gains or losses due to spot rate fluctuations on the euro-denominated debt instruments are included in foreign currency translation adjustment within *OCI*.

The effects of the Company's net investment hedges on *OCI* and the Consolidated Statement of Income are shown below:

	Amount of Pretax (Gain) Loss Recognized in Other Comprehensive Income [1]			Amount of Pretax (Gain) Loss Recognized in *Other (income) expense, net* for Amounts Excluded from Effectiveness Testing		
Years Ended December 31	**2019**	2018	2017	**2019**	2018	2017
Net Investment Hedging Relationships						
Foreign exchange contracts	**$ (10)**	$ (18)	$ —	**$ (31)**	$ (11)	$ —
Euro-denominated notes	**(75)**	(183)	520	**—**	—	—

[1] *No amounts were reclassified from AOCI into income related to the sale of a subsidiary.*

Interest Rate Risk Management

The Company may use interest rate swap contracts on certain investing and borrowing transactions to manage its net exposure to interest rate changes and to reduce its overall cost of borrowing. The Company does not use leveraged swaps and, in general, does not leverage any of its investment activities that would put principal capital at risk.

At December 31, 2019, the Company was a party to 19 pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes as detailed in the table below.

	2019		
Debt Instrument	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
1.85% notes due 2020	$ 1,250	5	$ 1,250
3.875% notes due 2021	1,150	5	1,150
2.40% notes due 2022	1,000	4	1,000
2.35% notes due 2022	1,250	5	1,250

The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in the benchmark London Interbank Offered Rate (LIBOR) swap rate. The fair value changes in the notes attributable to changes in the LIBOR swap rate are recorded in interest expense along with the offsetting fair value changes in the swap contracts. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

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The table below presents the location of amounts recorded on the Consolidated Balance Sheet related to cumulative basis adjustments for fair value hedges as of December 31:

	Carrying Amount of Hedged Liabilities		Cumulative Amount of Fair Value Hedging Adjustment Increase (Decrease) Included in the Carrying Amount	
	2019	2018	**2019**	2018
Balance Sheet Line Item in which Hedged Item is Included				
Loans payable and current portion of long-term debt	**$ 1,249**	$ —	**$ (1)**	$ —
Long-Term Debt	**3,409**	4,560	**14**	(82)

Presented in the table below is the fair value of derivatives on a gross basis segregated between those derivatives that are designated as hedging instruments and those that are not designated as hedging instruments as of December 31:

		2019			2018		
		Fair Value of Derivative			Fair Value of Derivative		
	Balance Sheet Caption	**Asset**	**Liability**	**U.S. Dollar Notional**	Asset	Liability	U.S. Dollar Notional
Derivatives Designated as Hedging Instruments							
Interest rate swap contracts	Other Assets	**$ 15**	**$ —**	**$ 3,400**	$ —	$ —	$ —
Interest rate swap contracts	Accrued and other current liabilities	**—**	**1**	**1,250**	—	—	—
Interest rate swap contracts	Other Noncurrent Liabilities	**—**	**—**	**—**	—	81	4,650
Foreign exchange contracts	Other current assets	**152**	**—**	**6,117**	263	—	6,222
Foreign exchange contracts	Other Assets	**55**	**—**	**2,160**	75	—	2,655
Foreign exchange contracts	Accrued and other current liabilities	**—**	**22**	**1,748**	—	7	774
Foreign exchange contracts	Other Noncurrent Liabilities	**—**	**1**	**53**	—	1	89
		$ 222	**$ 24**	**$ 14,728**	$ 338	$ 89	$ 14,390
Derivatives Not Designated as Hedging Instruments							
Foreign exchange contracts	Other current assets	**$ 66**	**$ —**	**$ 7,245**	$ 116	$ —	$ 5,430
Foreign exchange contracts	Accrued and other current liabilities	**—**	**73**	**8,693**	—	71	9,922
		$ 66	**$ 73**	**$ 15,938**	$ 116	$ 71	$ 15,352
		$ 288	**$ 97**	**$ 30,666**	$ 454	$ 160	$ 29,742

As noted above, the Company records its derivatives on a gross basis in the Consolidated Balance Sheet. The Company has master netting agreements with several of its financial institution counterparties (see *Concentrations of Credit Risk* below). The following table provides information on the Company's derivative positions subject to these master netting arrangements as if they were presented on a net basis, allowing for the right of offset by counterparty and cash collateral exchanged per the master agreements and related credit support annexes at December 31:

	2019		2018	
	Asset	**Liability**	Asset	Liability
Gross amounts recognized in the consolidated balance sheet	**$ 288**	**$ 97**	$ 454	$ 160
Gross amounts subject to offset in master netting arrangements not offset in the consolidated balance sheet	**(84)**	**(84)**	(121)	(121)
Cash collateral received	**(34)**	**—**	(107)	—
Net amounts	**$ 170**	**$ 13**	$ 226	$ 39

The table below provides information regarding the location and amount of pretax (gains) losses of derivatives designated in fair value or cash flow hedging relationships:

	Sales			Other (income) expense, net *(1)*			Other comprehensive income (loss)		
Years Ended December 31	**2019**	2018	2017	**2019**	2018	2017	**2019**	2018	2017
Financial Statement Line Items in which Effects of Fair Value or Cash Flow Hedges are Recorded	**$ 46,840**	$ 42,294	$ 40,122	**$ 139**	(402)	(500)	**$ (648)**	$ (361)	$ 316
(Gain) loss on fair value hedging relationships									
Interest rate swap contracts									
Hedged items	**—**	—	—	**95**	(27)	(48)	**—**	—	—
Derivatives designated as hedging instruments	**—**	—	—	**(65)**	50	12	**—**	—	—
Impact of cash flow hedging relationships									
Foreign exchange contracts									
Amount of gain (loss) recognized in *OCI* on derivatives	**—**	—	—	**—**	—	—	**87**	228	(562)
(Decrease) increase in *Sales* as a result of *AOCI* reclassifications	**255**	(160)	138	**—**	—	—	**(255)**	160	(138)
Interest rate contracts									
Amount of gain recognized in *Other (income) expense, net* on derivatives	**—**	—	—	**(4)**	(4)	(3)	**—**	—	—
Amount of loss recognized in *OCI* on derivatives	**—**	—	—	**—**	—	—	**(6)**	(4)	(3)

(1) *Interest expense is a component of* Other (income) expense, net.

The table below provides information regarding the income statement effects of derivatives not designated as hedging instruments:

		Amount of Derivative Pretax (Gain) Loss Recognized in Income		
Years Ended December 31	Income Statement Caption	**2019**	2018	2017
Derivatives Not Designated as Hedging Instruments				
Foreign exchange contracts (1)	Other (income) expense, net	**$ 174**	$ (260)	$ 110
Foreign exchange contracts (2)	Sales	**1**	(8)	(3)

(1) *These derivative contracts mitigate changes in the value of remeasured foreign currency denominated monetary assets and liabilities attributable to changes in foreign currency exchange rates.*

(2) *These derivative contracts serve as economic hedges of forecasted transactions.*

At December 31, 2019, the Company estimates $31 million of pretax net unrealized gains on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from *AOCI* to *Sales*. The amount ultimately reclassified to *Sales* may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.

Investments in Debt and Equity Securities

Information on investments in debt and equity securities at December 31 is as follows:

	2019				2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$ 668	$ —	$ —	$ 668	$ —	$ —	$ —	$ —
Corporate notes and bonds	608	13	—	621	4,985	3	(68)	4,920
U.S. government and agency securities	266	3	—	269	895	2	(5)	892
Asset-backed securities	226	1	—	227	1,285	1	(11)	1,275
Foreign government bonds	—	—	—	—	167	—	(1)	166
Mortgage-backed securities	—	—	—	—	8	—	—	8
Total debt securities	1,768	17	—	1,785	7,340	6	(85)	7,261
Publicly traded equity securities [(1)]				838				456
Total debt and publicly traded equity securities				$ 2,623				$ 7,717

[(1)] *Unrealized net gains recognized in* Other (income) expense, net *on equity securities still held at December 31, 2019 were $160 million during 2019. Unrealized net losses recognized in* Other (income) expense, net *on equity securities still held at December 31, 2018 were $35 million during 2018.*

At December 31, 2019 and 2018, the Company also had $420 million and $568 million, respectively, of equity investments without readily determinable fair values included in *Other Assets*. During 2019 and 2018, the Company recognized unrealized gains of $20 million and $167 million, respectively, in *Other (income) expense, net*, on certain of these equity investments based on favorable observable price changes from transactions involving similar investments of the same investee. In addition, during 2019 and 2018, the Company recognized unrealized losses of $13 million and $26 million, respectively, in *Other (income) expense, net*, related to certain of these investments based on unfavorable observable price changes. Cumulative unrealized gains and cumulative unrealized losses based on observable prices changes for investments in equity investments without readily determinable fair values were $109 million and $21 million, respectively.

Available-for-sale debt securities included in *Short-term investments* totaled $749 million at December 31, 2019. Of the remaining debt securities, $933 million mature within five years. At December 31, 2019 and 2018, there were no debt securities pledged as collateral.

Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company uses a fair value hierarchy which maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest:

Level 1 — Quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 — Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity. Level 3 assets or liabilities are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as assets or liabilities for which the determination of fair value requires significant judgment or estimation. If the inputs used to measure the financial assets and liabilities fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

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Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

Financial assets and liabilities measured at fair value on a recurring basis at December 31 are summarized below:

	Fair Value Measurements Using				Fair Value Measurements Using			
	Level 1	**Level 2**	**Level 3**	**Total**	Level 1	Level 2	Level 3	Total
		2019				2018		
Assets								
Investments								
Commercial paper	**$ —**	**$ 668**	**$ —**	**$ 668**	$ —	$ —	$ —	$ —
Corporate notes and bonds	**—**	**621**	**—**	**621**	—	4,835	—	4,835
Asset-backed securities [1]	**—**	**227**	**—**	**227**	—	1,253	—	1,253
U.S. government and agency securities	**—**	**209**	**—**	**209**	—	731	—	731
Foreign government bonds	**—**	**—**	**—**	**—**	—	166	—	166
Publicly traded equity securities	**518**	**—**	**—**	**518**	147	—	—	147
	518	**1,725**	**—**	**2,243**	147	6,985	—	7,132
Other assets [2]								
U.S. government and agency securities	**60**	**—**	**—**	**60**	55	106	—	161
Corporate notes and bonds	**—**	**—**	**—**	**—**	—	85	—	85
Asset-backed securities [1]	**—**	**—**	**—**	**—**	—	22	—	22
Mortgage-backed securities	**—**	**—**	**—**	**—**	—	8	—	8
Publicly traded equity securities	**320**	**—**	**—**	**320**	309	—	—	309
	380	**—**	**—**	**380**	364	221	—	585
Derivative assets [3]								
Forward exchange contracts	**—**	**169**	**—**	**169**	—	241	—	241
Purchased currency options	**—**	**104**	**—**	**104**	—	213	—	213
Interest rate swaps	**—**	**15**	**—**	**15**	—	—	—	—
	—	**288**	**—**	**288**	—	454	—	454
Total assets	**$ 898**	**$ 2,013**	**$ —**	**$ 2,911**	$ 511	$ 7,660	$ —	$ 8,171
Liabilities								
Other liabilities								
Contingent consideration	**$ —**	**$ —**	**$ 767**	**$ 767**	$ —	$ —	$ 788	$ 788
Derivative liabilities [3]								
Forward exchange contracts	**—**	**95**	**—**	**95**	—	74	—	74
Interest rate swaps	**—**	**1**	**—**	**1**	—	81	—	81
Written currency options	**—**	**1**	**—**	**1**	—	5	—	5
	—	**97**	**—**	**97**	—	160	—	160
Total liabilities	**$ —**	**$ 97**	**$ 767**	**$ 864**	$ —	$ 160	$ 788	$ 948

[1] *Primarily all of the asset-backed securities are highly-rated (Standard & Poor's rating of AAA and Moody's Investors Service rating of Aaa), secured primarily by auto loan, credit card and student loan receivables, with weighted-average lives of primarily 5 years or less.*

[2] *Investments included in other assets are restricted as to use, including for the payment of benefits under employee benefit plans.*

[3] *The fair value determination of derivatives includes the impact of the credit risk of counterparties to the derivatives and the Company's own credit risk, the effects of which were not significant.*

As of December 31, 2019, *Cash and cash equivalents* of $9.7 billion include $8.9 billion of cash equivalents (which would be considered Level 2 in the fair value hierarchy).

Contingent Consideration

Summarized information about the changes in liabilities for contingent consideration associated with business acquisitions is as follows:

	2019	2018
Fair value January 1	**$ 788**	$ 935
Changes in estimated fair value [1]	**64**	89
Additions	**—**	8
Payments	**(85)**	(244)
Fair value December 31 [2][3]	**$ 767**	$ 788

[1] *Recorded in* Cost of sales, Research and development *expenses, and* Other (income) expense, net. *Includes cumulative translation adjustments.*

[2] *Balance at December 31, 2019 includes $114 million recorded as a current liability for amounts expected to be paid within the next 12 months.*

[3] *At December 31, 2019 and 2018, $625 million and $614 million, respectively, of the liabilities relate to the termination of the SPMSD joint venture in 2016. As part of the termination, Merck recorded a liability for contingent future royalty payments of 11.5% on net sales of all Merck products that were previously sold by the joint venture through December 31, 2024. The fair value of this liability is determined utilizing the estimated amount and timing of projected cash flows and a risk-adjusted discount rate of 8% is used to present value the cash flows.*

The changes in the estimated fair value of liabilities for contingent consideration in 2019 and 2018 were largely attributable to increases in the liabilities recorded in connection with the termination of the Sanofi Pasteur MSD (SPMSD) joint venture in 2016. In 2018, these increases were partially offset by the reversal of a liability related to the discontinuation of a program obtained in connection with the acquisition of SmartCells (see Note 8). The payments of contingent consideration in both years relate to the SPMSD termination liabilities described above. The payments of contingent consideration in 2018 also include $175 million related to the achievement of a clinical development milestone for MK-7264 (gefapixant), a program obtained in connection with the acquisition of Afferent Pharmaceuticals.

Other Fair Value Measurements

Some of the Company's financial instruments, such as cash and cash equivalents, receivables and payables, are reflected in the balance sheet at carrying value, which approximates fair value due to their short-term nature.

The estimated fair value of loans payable and long-term debt (including current portion) at December 31, 2019, was $28.8 billion compared with a carrying value of $26.3 billion and at December 31, 2018, was $25.6 billion compared with a carrying value of $25.1 billion. Fair value was estimated using recent observable market prices and would be considered Level 2 in the fair value hierarchy.

Concentrations of Credit Risk

On an ongoing basis, the Company monitors concentrations of credit risk associated with corporate and government issuers of securities and financial institutions with which it conducts business. Credit exposure limits are established to limit a concentration with any single issuer or institution. Cash and investments are placed in instruments that meet high credit quality standards, as specified in the Company's investment policy guidelines.

The majority of the Company's accounts receivable arise from product sales in the United States, Europe and China and are primarily due from drug wholesalers and retailers, hospitals, government agencies, managed health care providers and pharmacy benefit managers. The Company monitors the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in their credit profile. The Company also continues to monitor global economic conditions, including the volatility associated with international sovereign economies, and associated impacts on the financial markets and its business.

The Company's customers with the largest accounts receivable balances are: McKesson Corporation, AmerisourceBergen Corporation and Cardinal Health, Inc., which represented, in aggregate, approximately 35% of total accounts receivable at December 31, 2019. The Company monitors the creditworthiness of its customers to which it grants credit terms in the normal course of business. Bad debts have been minimal. The Company does not normally require collateral or other security to support credit sales.

The Company has accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable. In 2019, the Company expanded its factoring arrangements in China and entered into factoring agreements to sell accounts receivable from the Company's major U.S. distributors. The Company factored

$2.7 billion and $1.1 billion of accounts receivable in the fourth quarter of 2019 and 2018, respectively, under these factoring arrangements, which reduced outstanding accounts receivable. The cash received from the financial institutions is reported within operating activities in the Consolidated Statement of Cash Flows. In certain of these factoring arrangements, for ease of administration, the Company will collect customer payments related to the factored receivables, which it then remits to the financial institutions. At December 31, 2019, the Company had collected $256 million on behalf of the financial institutions, which is reflected as restricted cash in *Other current assets* and the related obligation to remit the cash within *Accrued and other current liabilities*. The Company remitted the cash to the financial institutions in January 2020. The net cash flows relating to these collections are reported as financing activities in the Consolidated Statement of Cash Flows. The costs of factoring such accounts receivable were *de minimis*.

Derivative financial instruments are executed under International Swaps and Derivatives Association master agreements. The master agreements with several of the Company's financial institution counterparties also include credit support annexes. These annexes contain provisions that require collateral to be exchanged depending on the value of the derivative assets and liabilities, the Company's credit rating, and the credit rating of the counterparty. Cash collateral received by the Company from various counterparties was $34 million and $107 million at December 31, 2019 and 2018, respectively. The obligation to return such collateral is recorded in *Accrued and other current liabilities*. No cash collateral was advanced by the Company to counterparties as of December 31, 2019 or 2018.

7. Inventories

Inventories at December 31 consisted of:

	2019	2018
Finished goods	**$ 1,772**	$ 1,658
Raw materials and work in process	**5,650**	5,004
Supplies	**207**	194
Total (approximates current cost)	**7,629**	6,856
(Decrease) increase to LIFO cost	**(171)**	1
	$ 7,458	$ 6,857
Recognized as:		
Inventories	**$ 5,978**	$ 5,440
Other assets	**1,480**	1,417

Inventories valued under the LIFO method comprised approximately $2.6 billion and $2.5 billion at December 31, 2019 and 2018, respectively. Amounts recognized as *Other assets* are comprised almost entirely of raw materials and work in process inventories. At December 31, 2019 and 2018, these amounts included $1.3 billion and $1.4 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included $168 million and $7 million at December 31, 2019 and 2018, respectively, of inventories produced in preparation for product launches.

8. Goodwill and Other Intangibles

The following table summarizes goodwill activity by segment:

	Pharmaceutical	Animal Health	All Other	Total
Balance January 1, 2018	$ 16,066	$ 1,877	$ 341	$ 18,284
Acquisitions	—	17	24	41
Impairments	—	—	(144)	(144)
Other [1]	96	(24)	—	72
Balance December 31, 2018 [2]	16,162	1,870	221	18,253
Acquisitions	**19**	**1,322**	**—**	**1,341**
Impairments	**—**	**—**	**(162)**	**(162)**
Other [1]	**—**	**—**	**(7)**	**(7)**
Balance December 31, 2019 [2]	**$ 16,181**	**$ 3,192**	**$ 52**	**$ 19,425**

[1] *Other includes cumulative translation adjustments on goodwill balances and certain other adjustments.*

[2] *Accumulated goodwill impairment losses at December 31, 2019 and 2018 were $531 million and $369 million, respectively.*

The additions to goodwill within the Animal Health segment in 2019 primarily relate to the acquisition of Antelliq (see Note 3). The impairments of goodwill within other non-reportable segments in 2019 and 2018 relate to certain businesses within the Healthcare Services segment.

Other intangibles at December 31 consisted of:

	2019			2018		
	Gross Carrying Amount	**Accumulated Amortization**	**Net**	Gross Carrying Amount	Accumulated Amortization	Net
Products and product rights	**$ 45,947**	**$ 38,852**	**$ 7,095**	$ 46,615	$ 37,585	$ 9,030
Licenses	**3,185**	**824**	**2,361**	2,081	408	1,673
IPR&D	**1,032**	**—**	**1,032**	1,064	—	1,064
Trade names	**2,899**	**217**	**2,682**	209	107	102
Other	**2,261**	**1,235**	**1,026**	2,403	1,168	1,235
	$ 55,324	**$ 41,128**	**$ 14,196**	$ 52,372	$ 39,268	$ 13,104

Acquired intangibles include products and product rights, licenses, trade names and patents, which are initially recorded at fair value, assigned an estimated useful life, and amortized primarily on a straight-line basis over their estimated useful lives. Some of the Company's more significant acquired intangibles, on a net basis, related to human health marketed products (included in products and product rights above) at December 31, 2019 include *Zerbaxa*, $2.4 billion; *Implanon/Nexplanon,* $412 million; *Gardasil/Gardasil* 9, $314 million; *Dificid*, $312 million; *Bridion*, $230 million; *Sivextro*, $171 million; and *Simponi*, $163 million. Additionally, the Company had $2.4 billion of acquired intangibles related to animal health marketed products at December 31, 2019. Some of the Company's more significant intangible assets included in licenses above at December 31, 2019 include Lenvima, $956 million and Lynparza, $955 million as a result of collaborations with Eisai and AstraZeneca (see Note 4). The increase in trade names in 2019 reflects $2.7 billion of intangibles acquired in the Antelliq acquisition in 2019 (see Note 3). The Company has an intangible asset related to Adempas as a result of a collaboration with Bayer (see Note 4) that had a carrying value of $883 million at December 31, 2019 reflected in "Other" in the table above.

In 2019, the Company recorded impairment charges related to marketed products and other intangibles of $705 million within *Cost of sales*. Of this amount, $612 million related to *Sivextro*, a product for the treatment of acute bacterial skin and skin structure infections caused by designated susceptible Gram-positive organisms. As part of a reorganization and reprioritization of its internal sales force, the Company made the decision to cease promotion of *Sivextro* in the U.S. market by the end of 2019. This decision resulted in reduced cash flow projections for *Sivextro*, which indicated that the *Sivextro* intangible asset value was not fully recoverable on an undiscounted cash

flows basis. The Company utilized market participant assumptions to determine its best estimate of the fair value of the intangible

asset related to *Sivextro* that, when compared with its related carrying value, resulted in the impairment charge noted above.

In 2017, the Company recorded impairment charges related to marketed products and other intangibles of $58 million. Of this amount, $47 million related to *Intron A*, a treatment for certain types of cancers. Sales of *Intron A* were being adversely affected by the availability of new therapeutic options. In 2017, sales of *Intron A* in the United States eroded more rapidly than previously anticipated by the Company, which led to changes in the cash flow assumptions for *Intron A*. These revisions to cash flows indicated that the *Intron A* intangible asset value was not fully recoverable on an undiscounted cash flows basis. The Company utilized market participant assumptions to determine its best estimate of the fair value of the intangible asset related to *Intron A* that, when compared with its related carrying value, resulted in the impairment charge noted above. The remaining charges in 2017 relate to the impairment of customer relationship, tradename and developed technology intangibles for certain businesses in the Healthcare Services segment.

IPR&D that the Company acquires through business combinations represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. Amounts capitalized as IPR&D are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, the Company will make a separate determination as to the then useful life of the asset and begin amortization.

In 2019, the Company recorded $172 million of IPR&D impairment charges within *Research and development* expenses. Of this amount, $155 million relates to the write-off of the intangible asset balance for programs obtained in connection with the acquisition of IOmet Pharma Ltd following a review of clinical trial results conducted by Merck, along with external clinical trial results for similar compounds. The discontinuation of this clinical development program resulted in a reversal of the related liability for contingent consideration of $11 million.

In 2018, the Company recorded $152 million of IPR&D impairment charges. Of this amount, $139 million relates to the write-off of the remaining intangible asset balance for a program obtained in connection with the SmartCells acquisition following a decision to terminate the program due to product development issues. The discontinuation of this clinical development program resulted in a reversal of the related liability for contingent consideration of $60 million (see Note 6).

In 2017, the Company recorded $483 million of IPR&D impairment charges. Of this amount, $240 million resulted from a strategic decision to discontinue the development of the investigational combination regimens MK-3682B (grazoprevir/ruzasvir/uprifosbuvir) and MK-3682C (ruzasvir/uprifosbuvir) for the treatment of chronic hepatitis C virus (HCV) infection. This decision was made based on a review of available Phase 2 efficacy data and in consideration of the evolving marketplace and the growing number of treatment options available for patients with chronic HCV infection, including *Zepatier*, which is marketed by the Company for the treatment of adult patients with chronic HCV infection. As a result of this decision, the Company recorded an IPR&D impairment charge to write-off the remaining intangible asset related to uprifosbuvir. The IPR&D impairment charges in 2017 also include a charge of $226 million to write-off the intangible asset related to verubecestat, an investigational small molecule inhibitor of the beta-site amyloid precursor protein cleaving enzyme 1 (BACE1), resulting from a decision in February 2018 to stop a Phase 3 study evaluating verubecestat in people with prodromal Alzheimer's disease. The decision to stop the study followed a recommendation by the external Data Monitoring Committee (eDMC), which assessed overall benefit/risk during an interim safety analysis. The eDMC concluded that it was unlikely that positive benefit/risk could be established if the trial continued.

The IPR&D projects that remain in development are subject to the inherent risks and uncertainties in drug development and it is possible that the Company will not be able to successfully develop and complete the IPR&D programs and profitably commercialize the underlying product candidates.

The Company may recognize additional non-cash impairment charges in the future related to other marketed products or pipeline programs and such charges could be material.

Aggregate amortization expense recorded within *Cost of sales* was $2.0 billion in 2019, $3.1 billion in 2018 and $3.2 billion in 2017. The estimated aggregate amortization expense for each of the next five years is as follows: 2020, $1.6 billion; 2021, $1.5 billion; 2022, $1.5 billion; 2023, $1.5 billion; 2024, $1.4 billion.

9. Loans Payable, Long-Term Debt and Leases

Loans Payable

Loans payable at December 31, 2019 included $1.9 billion of notes due in 2020, $1.4 billion of commercial paper and $226 million of long-dated notes that are subject to repayment at the option of the holders. Loans payable at December 31, 2018 included $5.1 billion of commercial paper and $149 million of long-dated notes that are subject to repayment at the option of the holders. The weighted-average interest rate of commercial paper borrowings was 2.23% and 2.09% for the years ended December 31, 2019 and 2018, respectively.

Long-Term Debt

Long-term debt at December 31 consisted of:

	2019	2018
2.75% notes due 2025	**$ 2,492**	$ 2,490
3.70% notes due 2045	**1,975**	1,974
2.80% notes due 2023	**1,747**	1,745
3.40% notes due 2029	**1,732**	—
4.00% notes due 2049	**1,468**	—
2.35% notes due 2022	**1,248**	1,214
4.15% notes due 2043	**1,238**	1,237
3.875% notes due 2021	**1,151**	1,132
1.125% euro-denominated notes due 2021	**1,113**	1,134
1.875% euro-denominated notes due 2026	**1,107**	1,127
2.40% notes due 2022	**1,010**	983
3.90% notes due 2039	**982**	—
2.90% notes due 2024	**745**	—
6.50% notes due 2033	**722**	726
0.50% euro-denominated notes due 2024	**555**	565
1.375% euro-denominated notes due 2036	**551**	561
2.50% euro-denominated notes due 2034	**550**	560
3.60% notes due 2042	**490**	490
6.55% notes due 2037	**412**	414
5.75% notes due 2036	**338**	338
5.95% debentures due 2028	**306**	306
5.85% notes due 2039	**271**	270
6.40% debentures due 2028	**250**	250
6.30% debentures due 2026	**135**	135
1.85% notes due 2020	**—**	1,231
Floating-rate notes due 2020	**—**	699
Other	**148**	225
	$ 22,736	$ 19,806

Other (as presented in the table above) includes $147 million and $223 million at December 31, 2019 and 2018, respectively, of borrowings at variable rates that resulted in effective interest rates of 2.54% and 2.27% for 2019 and 2018, respectively.

With the exception of the 6.30% debentures due 2026, the notes listed in the table above are redeemable in whole or in part, at Merck's option at any time, at varying redemption prices.

In March 2019, the Company issued $5.0 billion principal amount of senior unsecured notes consisting of $750 million of 2.90% notes due 2024, $1.75 billion of 3.40% notes due 2029, $1.0 billion of 3.90% notes due 2039, and $1.5 billion of 4.00% notes due 2049. The Company used the net proceeds from the offering of $5.0 billion for general corporate purposes, including the repayment of outstanding commercial paper borrowings.

Effective as of November 3, 2009, the Company executed a full and unconditional guarantee of the then existing debt of its subsidiary Merck Sharp & Dohme Corp. (MSD) and MSD executed a full and unconditional guarantee of the then existing debt of the Company (excluding commercial paper), including for payments of principal and interest. These guarantees do not extend to debt issued subsequent to that date.

Certain of the Company's borrowings require that Merck comply with covenants and, at December 31, 2019, the Company was in compliance with these covenants.

The aggregate maturities of long-term debt for each of the next five years are as follows: 2020, $1.9 billion; 2021, $2.3 billion; 2022, $2.3 billion; 2023, $1.7 billion; 2024, $1.3 billion.

The Company has a $6.0 billion credit facility that matures in June 2024. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

Leases

As discussed in Note 1, on January 1, 2019, Merck adopted new guidance for the accounting and reporting of leases. The Company has operating leases primarily for manufacturing facilities, research and development facilities, corporate offices, employee housing, vehicles and certain equipment. As permitted under the transition guidance in ASC 842, the Company elected a package of practical expedients which, among other provisions, allowed the Company to carry forward historical lease classifications. The Company determines if an arrangement is a lease at inception. When evaluating contracts for embedded leases, the Company exercises judgment to determine if there is an explicit or implicit identified asset in the contract and if Merck controls the use of that asset. Embedded leases, primarily associated with contract manufacturing organizations, are immaterial.

Under ASC 842 transition guidance, Merck elected the hindsight practical expedient to determine the lease term for existing leases, which permits companies to consider available information prior to the effective date of the new guidance as to the actual or likely exercise of options to extend or terminate the lease. The lease term includes options to extend or terminate the lease when it is reasonably certain that Merck will exercise that option. Real estate leases for facilities have an average remaining lease term of eight years, which include options to extend the leases for up to four years where applicable. Vehicle leases are generally in effect for four years. The Company has made an accounting policy election not to record short-term leases (leases with an initial term of 12 months or less) on the balance sheet; however, Merck currently has no short-term leases.

Lease expense for operating lease payments is recognized on a straight-line basis over the term of the lease. Operating lease assets and liabilities are recognized based on the present value of lease payments over the lease term. Since the Company's leases do not have a readily determinable implicit discount rate, the Company uses its incremental borrowing rate to calculate the present value of lease payments by asset class. On a quarterly basis, an updated incremental borrowing rate is determined based on the average remaining lease term of each asset class and the Company's pretax cost of debt for that same term. The updated rates for each asset class are applied prospectively to new leases. As a practical expedient, the Company has made an accounting policy election for all asset classes not to separate lease components (e.g. payments for rent, real estate taxes and insurance costs) from non-lease components (e.g. common-area maintenance costs) in the event that the agreement contains both. Merck includes both the lease and non-lease components for purposes of calculating the right-of-use asset and related lease liability (if the non-lease components are fixed). For vehicle leases and employee housing, the Company applies a portfolio approach to effectively account for the operating lease assets and liabilities.

Certain of the Company's lease agreements contain variable lease payments that are adjusted periodically for inflation or for actual operating expense true-ups compared with estimated amounts; however, these amounts are immaterial. Sublease income and activity related to sale and leaseback transactions are immaterial. Merck's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

Operating lease cost was $339 million in 2019. Cash paid for amounts included in the measurement of operating lease liabilities was $281 million in 2019. Operating lease assets obtained in exchange for lease obligations was $129 million in 2019.

Supplemental balance sheet information related to operating leases is as follows:

December 31		**2019**
Assets		
Other Assets [1]	**$**	**1,073**
Liabilities		
Accrued and other current liabilities		**236**
Other Noncurrent Liabilities		**768**
	$	**1,004**
Weighted-average remaining lease term (years)		**7.4**
Weighted-average discount rate		**3.2 %**

[1] *Includes prepaid leases that have no related lease liability.*

Maturities of operating leases liabilities are as follows:

2020	$	264
2021		200
2022		168
2023		113
2024		89
Thereafter		297
Total lease payments		1,131
Less: Imputed interest		127
	$	1,004

At December 31, 2019, the Company had entered into additional real estate operating leases that had not yet commenced. The obligations associated with these leases total $538 million, of which $221 million relates to a lease that will commence in April 2020 and has a lease term of 10 years.

As of December 31, 2018, prior to the adoption of ASC 842, the minimum aggregate rental commitments under noncancellable leases were as follows: 2019, $188 million; 2020, $198 million; 2021, $150 million; 2022, $134 million; 2023, $84 million and thereafter, $243 million.

10. Contingencies and Environmental Liabilities

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property, and commercial litigation, as well as certain additional matters including governmental and environmental matters. In the opinion of the Company, it is unlikely that the resolution of these matters will be material to the Company's financial condition, results of operations or cash flows.

Given the nature of the litigation discussed below and the complexities involved in these matters, the Company is unable to reasonably estimate a possible loss or range of possible loss for such matters until the Company knows, among other factors, (i) what claims, if any, will survive dispositive motion practice, (ii) the extent of the claims, including the size of any potential class, particularly when damages are not specified or are indeterminate, (iii) how the discovery process will affect the litigation, (iv) the settlement posture of the other parties to the litigation and (v) any other factors that may have a material effect on the litigation.

The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. For product liability claims, a portion of the overall accrual is actuarially determined and considers such factors as past experience, number of claims reported and estimates of claims incurred but not yet reported. Individually significant contingent losses are accrued when probable and reasonably estimable. Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable.

The Company's decision to obtain insurance coverage is dependent on market conditions, including cost and availability, existing at the time such decisions are made. The Company has evaluated its risks and has determined that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and, as such, has no insurance for most product liabilities.

Product Liability Litigation

Fosamax

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Fosamax* (*Fosamax* Litigation). As of December 31, 2019, approximately 3,750 cases are pending against Merck in either federal or state court. Plaintiffs in the vast majority of these cases generally allege that they sustained femur fractures and/or other bone injuries (Femur Fractures) in association with the use of *Fosamax*.

All federal cases involving allegations of Femur Fractures have been or will be transferred to a multidistrict litigation in the District of New Jersey (Femur Fracture MDL). In the only bellwether case tried to date in the Femur Fracture MDL, *Glynn v. Merck*, the jury returned a verdict in Merck's favor. In addition, in June 2013, the Femur Fracture MDL court granted Merck's motion for judgment as a matter of law in the *Glynn* case and held that the plaintiff's failure to warn claim was preempted by federal law.

In August 2013, the Femur Fracture MDL court entered an order requiring plaintiffs in the Femur Fracture MDL to show cause why those cases asserting claims for a femur fracture injury that took place prior to September 14, 2010, should not be dismissed based on the court's preemption decision in the *Glynn* case. Pursuant to the show cause order, in March 2014, the Femur Fracture MDL court dismissed with prejudice approximately 650 cases on preemption grounds. Plaintiffs in approximately 515 of those cases appealed that decision to the U.S. Court of Appeals for the Third Circuit (Third Circuit). In March 2017, the Third Circuit issued a decision reversing the Femur Fracture MDL court's preemption ruling and remanding the appealed cases back to the Femur Fracture MDL court. Merck filed a petition for a writ of certiorari to the U.S. Supreme Court in August 2017, seeking review of the Third Circuit's decision. The Supreme Court granted Merck's petition in June 2018, and in May 2019, the Supreme Court issued its opinion and decided that the Third Circuit had incorrectly concluded that the issue of preemption should be resolved by a jury, and accordingly vacated the judgment of the Third Circuit and remanded the proceedings back to the Third Circuit to address the issue in a manner consistent with the Supreme Court's opinion. On November 15, 2019, the Third Circuit remanded the cases back to the District Court in order to allow that court to determine in the first instance whether the plaintiffs' state law claims are preempted by federal law under the standards described by the Supreme Court in its opinion. On December 13, 2019, the District Court ordered Merck to serve its opening brief on or before February 21, 2020, and plaintiffs to file their responsive brief on or before April 22, 2020. Merck may then file a reply on or before May 22, 2020.

Accordingly, as of December 31, 2019, approximately 970 cases were actively pending in the Femur Fracture MDL.

As of December 31, 2019, approximately 2,510 cases alleging Femur Fractures have been filed in New Jersey state court and are pending before Judge James Hyland in Middlesex County. The parties selected an initial group of cases to be reviewed through fact discovery, and Merck has continued to select additional cases to be reviewed.

As of December 31, 2019, approximately 275 cases alleging Femur Fractures have been filed and are pending in California state court. All of the Femur Fracture cases filed in California state court have been coordinated before a single judge in Orange County, California.

Additionally, there are four Femur Fracture cases pending in other state courts.

Discovery is presently stayed in the Femur Fracture MDL and in the state court in California. Merck intends to defend against these lawsuits.

Januvia/Janumet

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Januvia* and/or *Janumet*. As of December 31, 2019, Merck is aware of approximately 1,380 product users alleging that *Januvia* and/or *Janumet* caused the development of pancreatic cancer and other injuries.

Most claims have been filed in multidistrict litigation before the U.S. District Court for the Southern District of California (MDL). Outside of the MDL, the majority of claims have been filed in coordinated proceedings before the Superior Court of California, County of Los Angeles (California State Court).

In November 2015, the MDL and California State Court-in separate opinions-granted summary judgment to defendants on grounds of federal preemption.

Plaintiffs appealed in both forums. In November 2017, the U.S. Court of Appeals for the Ninth Circuit vacated the judgment and remanded for further discovery. In November 2018, the California state appellate court reversed and remanded on similar grounds. In March 2019, the parties in the MDL and the California coordinated proceeding agreed to coordinate and adopt a schedule for completing discovery on general causation and preemption issues and for renewing summary judgment and *Daubert* motions. Under the stipulated case management schedule, the hearings for *Daubert* and summary judgment motions are expected to take place in June 2020.

As of December 31, 2019, six product users have claims pending against Merck in state courts other than California, including Illinois. In June 2017, the Illinois trial court denied Merck's motion for summary judgment based on federal preemption. Merck appealed, and the Illinois appellate court affirmed in December 2018. Merck filed a petition for leave to appeal to the Illinois Supreme Court in February 2019. In April 2019, the Illinois Supreme Court stayed consideration of the pending petition to appeal until the U.S. Supreme Court issued its opinion in *Merck Sharp & Dohme Corp. v. Albrecht* (relating to the *Fosamax* matter discussed above). Merck filed the opinion in *Albrecht* with the Illinois Supreme Court in June 2019. The petition for leave to appeal was decided on September 25, 2019, in which the Illinois Supreme Court directed the intermediate appellate court to reconsider its earlier ruling. The Illinois Appellate Court issued a favorable decision concluding, consistent with *Albrecht*, that preemption presents a legal question to be resolved by the court.

In addition to the claims noted above, the Company has agreed to toll the statute of limitations for approximately 50 additional claims. The Company intends to continue defending against these lawsuits.

Vioxx

As previously disclosed, Merck is a defendant in a lawsuit brought by the Attorney General of Utah alleging that Merck misrepresented the safety of *Vioxx*. The lawsuit is pending in Utah state court. Utah seeks damages and penalties under the Utah False Claims Act. A bench trial in this matter is currently scheduled for April 20, 2020.

Governmental Proceedings

As previously disclosed, in the fall of 2018, the Company received a records subpoena from the U.S. Attorney's Office for the District of Vermont (VT USAO) pursuant to Section 248 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) relating to an investigation of potential health care offenses. The subpoena sought information relating to any actual or potential business relationship or arrangement Merck has had with Practice Fusion, Inc. (PFI), a cloud-based, electronic health records (EHR) company that was acquired by Allscripts in January 2018. The Company cooperated with the government and responded to that subpoena. Subsequently, on May 21, 2019, Merck received a second records subpoena from the VT USAO that broadened the government's information request by seeking information relating to Merck's relationship with any EHR company. Shortly thereafter, the VT USAO served a Civil Investigation Demand (CID) upon Merck similarly seeking information on the Company's relationships with EHR vendors. The CID explains that the government is conducting a False Claims Act investigation concerning whether Merck and/or PFI submitted claims to federal healthcare programs that violate the Federal Anti-Kickback Statute. Merck is cooperating with the government's investigation.

As previously disclosed, on April 15, 2019, Merck received a set of investigative interrogatories from the California Attorney General's Office pursuant to its investigation of conduct and agreements that allegedly affected or delayed competition to Lantus in the insulin market. The interrogatories seek information concerning Merck's development of an insulin glargine product, and its subsequent termination, as well as Merck's patent litigation against Sanofi S.A. concerning Lantus and the resolution of that litigation. Merck is cooperating with the California Attorney General's investigation.

As previously disclosed, the Company's subsidiaries in China have received and may continue to receive inquiries regarding their operations from various Chinese governmental agencies. Some of these inquiries may be

related to matters involving other multinational pharmaceutical companies, as well as Chinese entities doing business with such companies. The Company's policy is to cooperate with these authorities and to provide responses as appropriate.

As previously disclosed, from time to time, the Company receives inquiries and is the subject of preliminary investigation activities from competition and other governmental authorities in markets outside the United States. These authorities may include regulators, administrative authorities, and law enforcement and other similar officials, and these preliminary investigation activities may include site visits, formal or informal requests or demands for documents or materials, inquiries or interviews and similar matters. Certain of these preliminary inquiries or activities may lead to the commencement of formal proceedings. Should those proceedings be determined adversely to the Company, monetary fines and/or remedial undertakings may be required.

Commercial and Other Litigation

Zetia Antitrust Litigation

As previously disclosed, Merck, MSD, Schering Corporation and MSP Singapore Company LLC (collectively, the Merck Defendants) are defendants in putative class action and opt-out lawsuits filed in 2018 on behalf of direct and indirect purchasers of *Zetia* alleging violations of federal and state antitrust laws, as well as other state statutory and common law causes of action. The cases have been consolidated for pretrial purposes in a federal multidistrict litigation before Judge Rebecca Beach Smith in the Eastern District of Virginia. In December 2018, the court denied the Merck Defendants' motions to dismiss or stay the direct purchaser putative class actions pending bilateral arbitration. On August 9, 2019, the district court adopted in full the report and recommendation of the magistrate judge with respect to the Merck Defendants' motions to dismiss on non-arbitration issues, thereby granting in part and denying in part Merck Defendants' motions to dismiss. In addition, on June 27, 2019, the representatives of the putative direct purchaser class filed an amended complaint and, on August 1, 2019, retailer opt-out plaintiffs filed an amended complaint. The Merck Defendants moved to dismiss the new allegations in both complaints. On October 15, 2019, the magistrate judge issued a report and recommendation recommending that the district judge grant the motions in their entirety. On December 20, 2019, the district court adopted this report and recommendation in part. The district court granted the Merck Defendants' motion to dismiss to the extent the motion sought dismissal of claims for overcharges paid by entities that purchased generic ezetimibe from Par Pharmaceutical, Inc. (Par Pharmaceutical) and dismissed any claims for such overcharges. Trial is currently scheduled to begin on October 28, 2020.

Rotavirus Vaccines Antitrust Litigation

As previously disclosed, MSD is a defendant in putative class action lawsuits filed in 2018 on behalf of direct purchasers of *RotaTeq*, alleging violations of federal antitrust laws. The cases were consolidated in the Eastern District of Pennsylvania. On January 23, 2019, the court denied MSD's motions to compel arbitration and to dismiss the consolidated complaint. On February 19, 2019, MSD appealed the court's order on arbitration to the Third Circuit. On October 28, 2019, the Third Circuit vacated the district court's order and remanded for limited discovery on the issue of arbitrability, after which MSD may file a renewed motion to compel arbitration.

Sales Force Litigation

As previously disclosed, in May 2013, Ms. Kelli Smith filed a complaint against the Company in the U.S. District Court for the District of New Jersey on behalf of herself and a putative class of female sales representatives and a putative sub-class of female sales representatives with children, claiming (a) discriminatory policies and practices in selection, promotion and advancement, (b) disparate pay, (c) differential treatment, (d) hostile work environment and (e) retaliation under federal and state discrimination laws. In April 2016, the Magistrate Judge granted plaintiffs' request to amend the complaint to add the following: (i) a Company subsidiary as a corporate defendant; (ii) an ERISA claim and (iii) an individual constructive discharge claim for one of the named plaintiffs. Approximately 700 individuals opted-in to this action; the opt-in period has closed. In August 2017, plaintiffs filed their motion to certify a Title VII pay discrimination class and also sought final collective action certification of plaintiffs' Equal Pay Act claim.

On October 1, 2018, the parties entered into an agreement to fully resolve the Smith sales force litigation. As part of the settlement and in exchange for a full and general release of all individual and class claims, the Company agreed to pay $8.5 million. On December 3, 2019, the court approved the settlement.

Qui Tam Litigation

As previously disclosed, in June 2012, the U.S. District Court for the Eastern District of Pennsylvania unsealed a complaint that has been filed against the Company under the federal False Claims Act by two former employees alleging, among other things, that the Company defrauded the U.S. government by falsifying data in connection with a clinical study conducted on the mumps component of the Company's *M-M-R* II vaccine. The complaint alleges the fraud took place between 1999 and 2001. The U.S. government had the right to participate in and take over the prosecution of this lawsuit but notified the court that it declined to exercise that right. The two former employees are pursuing the lawsuit without the involvement of the U.S. government. In addition, as previously disclosed, two putative class action lawsuits on behalf of direct purchasers of the *M-M-R* II vaccine, which charge that the Company misrepresented the efficacy of the *M-M-R* II vaccine in violation of federal antitrust laws and various state consumer protection laws, are pending in the Eastern District of Pennsylvania. In September 2014, the court denied Merck's motion to dismiss the False Claims Act suit and granted in part and denied in part its motion to dismiss the then-pending antitrust suit. As a result, both the False Claims Act suit and the antitrust suits have proceeded into discovery, which is now complete, and the parties have filed and briefed cross-motions for summary judgment, which are currently pending before the Court. The Company continues to defend against these lawsuits.

Merck KGaA Litigation

As previously disclosed, in January 2016, to protect its long-established brand rights in the United States, the Company filed a lawsuit against Merck KGaA, Darmstadt, Germany (KGaA), historically operating as the EMD Group in the United States, alleging it improperly uses the name "Merck" in the United States. KGaA has filed suit against the Company in France, the UK, Germany, Switzerland, Mexico, India, Australia, Singapore, Hong Kong, and China alleging, among other things, unfair competition, trademark infringement and/or corporate name infringement. In the UK, Australia, Singapore, Hong Kong, and India, KGaA also alleges breach of the parties' coexistence agreement. The litigation is ongoing in the United States with no trial date set, and also ongoing in numerous jurisdictions outside of the United States; the Company is defending those suits in each jurisdiction.

Patent Litigation

From time to time, generic manufacturers of pharmaceutical products file abbreviated New Drug Applications (NDAs) with the U.S. Food and Drug Administration (FDA) seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned by the Company. To protect its patent rights, the Company may file patent infringement lawsuits against such generic companies. Similar lawsuits defending the Company's patent rights may exist in other countries. The Company intends to vigorously defend its patents, which it believes are valid, against infringement by companies attempting to market products prior to the expiration of such patents. As with any litigation, there can be no assurance of the outcomes, which, if adverse, could result in significantly shortened periods of exclusivity for these products and, with respect to products acquired through acquisitions, potentially significant intangible asset impairment charges.

Januvia, Janumet, Janumet XR — In February 2019, Par Pharmaceutical filed suit against the Company in the U.S. District Court for the District of New Jersey, seeking a declaratory judgment of invalidity of a patent owned by the Company covering certain salt and polymorphic forms of sitagliptin that expires in 2026. In response, the Company filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Par Pharmaceutical and additional companies that also indicated an intent to market generic versions of *Januvia*, *Janumet*, and *Janumet XR* following expiration of key patent protection in 2022, but prior to the expiration of the later-granted patent owned by the Company covering certain salt and polymorphic forms of sitagliptin that expires in 2026, and a later granted patent owned by the Company covering the *Janumet* formulation which expires in 2028. Par Pharmaceutical dismissed its case in the U.S. District Court for the District of New Jersey against the Company and will litigate the action in the U.S. District Court for the District of Delaware. The Company filed a patent infringement lawsuit against Mylan Pharmaceuticals Inc. and Mylan Inc. (Mylan) in the Northern District of West Virginia. The Judicial Panel of Multidistrict Litigation entered an order transferring the Company's lawsuit against Mylan to the U.S. District Court for the District of Delaware for coordinated and consolidated pretrial proceedings with the other cases pending in that district. The U.S. District Court for the District of Delaware has scheduled the lawsuits for a single 3-day trial on invalidity issues in October 2021. The Court will schedule separate 1-day trials on infringement issues if necessary. In October 2019, Mylan filed a petition for *Inter Partes* Review (IPR) at the United States Patent and Trademark Office

(USPTO) seeking invalidity of the 2026 patent. The USPTO has six months from filing to determine whether it will institute the requested IPR proceeding.

Other Litigation

There are various other pending legal proceedings involving the Company, principally product liability and intellectual property lawsuits. While it is not feasible to predict the outcome of such proceedings, in the opinion of the Company, either the likelihood of loss is remote or any reasonably possible loss associated with the resolution of such proceedings is not expected to be material to the Company's financial condition, results of operations or cash flows either individually or in the aggregate.

Legal Defense Reserves

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of December 31, 2019 and 2018 of approximately $240 million and $245 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

Environmental Matters

The Company and its subsidiaries are parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund, and other federal and state equivalents. These proceedings seek to require the operators of hazardous waste disposal facilities, transporters of waste to the sites and generators of hazardous waste disposed of at the sites to clean up the sites or to reimburse the government for cleanup costs. The Company has been made a party to these proceedings as an alleged generator of waste disposed of at the sites. In each case, the government alleges that the defendants are jointly and severally liable for the cleanup costs. Although joint and several liability is alleged, these proceedings are frequently resolved so that the allocation of cleanup costs among the parties more nearly reflects the relative contributions of the parties to the site situation. The Company's potential liability varies greatly from site to site. For some sites the potential liability is *de minimis* and for others the final costs of cleanup have not yet been determined. While it is not feasible to predict the outcome of many of these proceedings brought by federal or state agencies or private litigants, in the opinion of the Company, such proceedings should not ultimately result in any liability which would have a material adverse effect on the financial condition, results of operations or liquidity of the Company. The Company has taken an active role in identifying and accruing for these costs and such amounts do not include any reduction for anticipated recoveries of cleanup costs from former site owners or operators or other recalcitrant potentially responsible parties.

In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $67 million and $71 million at December 31, 2019 and 2018, respectively. These liabilities are undiscounted, do not consider potential recoveries from other parties and will be paid out over the periods of remediation for the applicable sites, which are expected to occur primarily over the next 15 years. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed $58 million in the aggregate. Management also does not believe that these expenditures should result in a material adverse effect on the Company's financial condition, results of operations or liquidity for any year.

11. Equity

The Merck certificate of incorporation authorizes 6,500,000,000 shares of common stock and 20,000,000 shares of preferred stock.

Capital Stock

A summary of common stock and treasury stock transactions (shares in millions) is as follows:

	2019		2018		2017	
	Common Stock	**Treasury Stock**	Common Stock	Treasury Stock	Common Stock	Treasury Stock
Balance January 1	**3,577**	**985**	3,577	880	3,577	828
Purchases of treasury stock	**—**	**66**	—	122	—	67
Issuances [(1)]	**—**	**(13)**	—	(17)	—	(15)
Balance December 31	**3,577**	**1,038**	3,577	985	3,577	880

[(1)] *Issuances primarily reflect activity under share-based compensation plans.*

On October 25, 2018, the Company entered into accelerated share repurchase (ASR) agreements with two third-party financial institutions (Dealers). Under the ASR agreements, Merck agreed to purchase $5 billion of Merck's common stock, in total, with an initial delivery of 56.7 million shares of Merck's common stock, based on the then-current market price, made by the Dealers to Merck, and payments of $5 billion made by Merck to the Dealers on October 29, 2018, which were funded with existing cash and investments, as well as short-term borrowings. The payments to the Dealers were recorded as reductions to shareholders' equity, consisting of a $4 billion increase in treasury stock, which reflected the value of the initial 56.7 million shares received on October 29, 2018, and a $1 billion decrease in other-paid-in capital, which reflected the value of the stock held back by the Dealers pending final settlement. Upon settlement of the ASR agreements in April 2019, Merck received an additional 7.7 million shares as determined by the average daily volume weighted-average price of Merck's common stock during the term of the ASR program, less a negotiated discount, bringing the total shares received by Merck under this program to 64.4 million.

12. Share-Based Compensation Plans

The Company has share-based compensation plans under which the Company grants restricted stock units (RSUs) and performance share units (PSUs) to certain management level employees. In addition, employees and non-employee directors may be granted options to purchase shares of Company common stock at the fair market value at the time of grant. These plans were approved by the Company's shareholders.

At December 31, 2019, 111 million shares collectively were authorized for future grants under the Company's share-based compensation plans. These awards are settled with treasury shares.

Employee stock options are granted to purchase shares of Company stock at the fair market value at the time of grant. These awards generally vest one-third each year over a three-year period, with a contractual term of 7-10 years. RSUs are stock awards that are granted to employees and entitle the holder to shares of common stock as the awards vest. The fair value of the stock option and RSU awards is determined and fixed on the grant date based on the Company's stock price. PSUs are stock awards where the ultimate number of shares issued will be contingent on the Company's performance against a pre-set objective or set of objectives. The fair value of each PSU is determined on the date of grant based on the Company's stock price. For RSUs and PSUs, dividends declared during the vesting period are payable to the employees only upon vesting. Over the PSU performance period, the number of shares of stock that are expected to be issued will be adjusted based on the probability of achievement of a performance target and final compensation expense will be recognized based on the ultimate number of shares issued. RSU and PSU distributions will be in shares of Company stock after the end of the vesting or performance period, subject to the terms applicable to such awards. PSU awards generally vest after three years. Prior to 2018, RSU awards generally vested after three years; beginning with awards granted in 2018, RSU awards generally vest one-third each year over a three-year period.

Total pretax share-based compensation cost recorded in 2019, 2018 and 2017 was $417 million, $348 million and $312 million, respectively, with related income tax benefits of $57 million, $55 million and $57 million, respectively.

The Company uses the Black-Scholes option pricing model for determining the fair value of option grants. In applying this model, the Company uses both historical data and current market data to estimate the fair value of its options. The Black-Scholes model requires several assumptions including expected dividend yield, risk-free interest rate, volatility, and term of the options. The expected dividend yield is based on historical patterns of dividend payments. The risk-free interest rate is based on the rate at grant date of zero-coupon U.S. Treasury Notes with a term equal to the expected term of the option. Expected volatility is estimated using a blend of historical and implied volatility. The historical component is based on historical monthly price changes. The implied volatility is obtained from market data on the Company's traded options. The expected life represents the amount of time that options granted are expected to be outstanding, based on historical and forecasted exercise behavior.

The weighted average exercise price of options granted in 2019, 2018 and 2017 was $80.05, $58.15 and $63.88 per option, respectively. The weighted average fair value of options granted in 2019, 2018 and 2017 was $10.63, $8.26 and $7.04 per option, respectively, and were determined using the following assumptions:

Years Ended December 31	**2019**	2018	2017
Expected dividend yield	**3.2 %**	3.4 %	3.6 %
Risk-free interest rate	**2.4 %**	2.9 %	2.0 %
Expected volatility	**18.7 %**	19.1 %	17.8 %
Expected life (years)	**5.9**	6.1	6.1

Summarized information relative to stock option plan activity (options in thousands) is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2019	23,807	$ 51.89		
Granted	**2,796**	**80.05**		
Exercised	**(8,119)**	**44.48**		
Forfeited	**(616)**	**45.48**		
Outstanding December 31, 2019	**17,868**	**$ 59.88**	**6.48**	**$ 555**
Exercisable December 31, 2019	**11,837**	**$ 55.40**	**5.45**	**$ 421**

Additional information pertaining to stock option plans is provided in the table below:

Years Ended December 31	**2019**	2018	2017
Total intrinsic value of stock options exercised	**$ 295**	$ 348	$ 236
Fair value of stock options vested	**27**	29	30
Cash received from the exercise of stock options	**361**	591	499

A summary of nonvested RSU and PSU activity (shares in thousands) is as follows:

	RSUs		PSUs	
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested January 1, 2019	16,128	$ 58.85	2,039	$ 59.42
Granted	**4,811**	**80.08**	**763**	**83.90**
Vested	**(6,594)**	**55.70**	**(748)**	**57.87**
Forfeited	**(818)**	**64.75**	**(82)**	**66.68**

Nonvested December 31, 2019	**13,527**	**$**	**67.58**	**1,972**	**$**	**69.18**

At December 31, 2019, there was $603 million of total pretax unrecognized compensation expense related to nonvested stock options, RSU and PSU awards which will be recognized over a weighted average period of 1.9 years. For segment reporting, share-based compensation costs are unallocated expenses.

13. Pension and Other Postretirement Benefit Plans

The Company has defined benefit pension plans covering eligible employees in the United States and in certain of its international subsidiaries. In addition, the Company provides medical benefits, principally to its eligible U.S. retirees and their dependents, through its other postretirement benefit plans. The Company uses December 31 as the year-end measurement date for all of its pension plans and other postretirement benefit plans.

Net Periodic Benefit Cost

The net periodic benefit cost (credit) for pension and other postretirement benefit plans consisted of the following components:

	Pension Benefits								
	U.S.			International			Other Postretirement Benefits		
Years Ended December 31	**2019**	2018	2017	**2019**	2018	2017	**2019**	2018	2017
Service cost	**$ 293**	$ 326	$ 312	**$ 238**	$ 238	$ 252	**$ 48**	$ 57	$ 57
Interest cost	**458**	432	454	**177**	178	172	**69**	69	81
Expected return on plan assets	**(817)**	(851)	(862)	**(426)**	(431)	(393)	**(72)**	(83)	(78)
Amortization of unrecognized prior service cost	**(49)**	(50)	(53)	**(12)**	(13)	(11)	**(78)**	(84)	(98)
Net loss amortization	**151**	232	180	**64**	84	98	**(10)**	1	1
Termination benefits	**31**	19	44	**8**	2	4	**5**	3	8
Curtailments	**14**	10	3	**6**	1	(4)	**(11)**	(8)	(31)
Settlements	**—**	5	—	**1**	13	5	**—**	—	—
Net periodic benefit cost (credit)	**$ 81**	$ 123	$ 78	**$ 56**	$ 72	$ 123	**$ (49)**	$ (45)	$ (60)

The changes in net periodic benefit cost (credit) year over year for pension plans are largely attributable to changes in the discount rate affecting net loss amortization.

In connection with restructuring actions (see Note 5), termination charges were recorded in 2019, 2018 and 2017 on pension and other postretirement benefit plans related to expanded eligibility for certain employees exiting Merck. Also, in connection with these restructuring activities, curtailments were recorded on pension and other postretirement benefit plans and settlements were recorded on certain U.S. and international pension plans as reflected in the table above.

The components of net periodic benefit cost (credit) other than the service cost component are included in *Other (income) expense, net* (see Note 14), with the exception of certain amounts for termination benefits, curtailments and settlements, which are recorded in *Restructuring costs* if the event giving rise to the termination benefits, curtailment or settlement is related to restructuring actions as noted above.

Obligations and Funded Status

Summarized information about the changes in plan assets and benefit obligations, the funded status and the amounts recorded at December 31 is as follows:

	Pension Benefits				Other Postretirement Benefits	
	U.S.		International			
	2019	2018	**2019**	2018	**2019**	2018
Fair value of plan assets January 1	**$ 9,648**	$ 10,896	**$ 8,580**	$ 9,339	**$ 968**	$ 1,114
Actual return on plan assets	**2,165**	(810)	**1,505**	(289)	**203**	(72)
Company contributions	**130**	378	**262**	167	**14**	6
Effects of exchange rate changes	**—**	—	**31**	(352)	**—**	—
Benefits paid	**(582)**	(772)	**(230)**	(202)	**(104)**	(80)
Settlements	**—**	(44)	**(12)**	(106)	**—**	—
Other	**—**	—	**27**	23	**21**	—
Fair value of plan assets December 31	**$ 11,361**	$ 9,648	**$ 10,163**	$ 8,580	**$ 1,102**	$ 968
Benefit obligation January 1	**$ 10,620**	$ 11,904	**$ 9,083**	$ 9,483	**$ 1,615**	$ 1,922
Service cost	**293**	326	**238**	238	**48**	57
Interest cost	**458**	432	**177**	178	**69**	69
Actuarial losses (gains) [1]	**2,165**	(1,258)	**1,313**	(154)	**21**	(341)
Benefits paid	**(582)**	(772)	**(230)**	(202)	**(104)**	(80)
Effects of exchange rate changes	**—**	—	**4**	(387)	**1**	(6)
Plan amendments	**—**	—	**1**	10	**—**	(9)
Curtailments	**18**	13	**3**	(2)	**—**	—
Termination benefits	**31**	19	**8**	2	**5**	3
Settlements	**—**	(44)	**(12)**	(106)	**—**	—
Other	**—**	—	**27**	23	**18**	—
Benefit obligation December 31	**$ 13,003**	$ 10,620	**$ 10,612**	$ 9,083	**$ 1,673**	$ 1,615
Funded status December 31	**$ (1,642)**	$ (972)	**$ (449)**	$ (503)	**$ (571)**	$ (647)
Recognized as:						
Other Assets	**$ —**	$ —	**$ 837**	$ 659	**$ —**	$ —
Accrued and other current liabilities	**(92)**	(47)	**(18)**	(14)	**(10)**	(10)
Other Noncurrent Liabilities	**(1,550)**	(925)	**(1,268)**	(1,148)	**(561)**	(637)

[1] *Actuarial losses (gains) primarily reflect changes in discount rates.*

At December 31, 2019 and 2018, the accumulated benefit obligation was $22.8 billion and $19.0 billion, respectively, for all pension plans, of which $12.8 billion and $10.4 billion, respectively, related to U.S. pension plans.

Information related to the funded status of selected pension plans at December 31 is as follows:

	U.S.		International	
	2019	2018	**2019**	2018
Pension plans with a projected benefit obligation in excess of plan assets				
Projected benefit obligation	**$ 13,003**	$ 10,620	**$ 7,421**	$ 6,251
Fair value of plan assets	**11,361**	9,648	**6,135**	5,089
Pension plans with an accumulated benefit obligation in excess of plan assets				
Accumulated benefit obligation	**$ 12,009**	$ 9,702	**$ 2,476**	$ 5,936
Fair value of plan assets	**10,484**	8,966	**1,501**	5,071

Plan Assets

Entities are required to use a fair value hierarchy which maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest:

Level 1 — Quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 — Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity. The Level 3 assets are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as instruments for which the determination of fair value requires significant judgment or estimation. At December 31, 2019 and 2018, $860 million and $826 million, respectively, or approximately 4% and 5%, respectively, of the Company's pension investments were categorized as Level 3 assets.

If the inputs used to measure the financial assets fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

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The fair values of the Company's pension plan assets at December 31 by asset category are as follows:

	Fair Value Measurements Using					Fair Value Measurements Using				
	Level 1	**Level 2**	**Level 3**	**NAV [1]**	**Total**	Level 1	Level 2	Level 3	NAV [1]	Total
	2019					2018				
U.S. Pension Plans										
Assets										
Cash and cash equivalents	**$ 3**	**$ —**	**$ —**	**$ 236**	**$ 239**	$ 40	$ —	$ —	$ 182	$ 222
Investment funds										
Developed markets equities	**205**	**—**	**—**	**3,542**	**3,747**	169	—	—	3,021	3,190
Emerging markets equities	**165**	**—**	**—**	**723**	**888**	121	—	—	720	841
Government and agency obligations	**—**	**—**	**—**	**173**	**173**	—	—	—	161	161
Corporate obligations	**—**	**—**	**—**	**—**	**—**	—	—	—	32	32
Equity securities										
Developed markets	**2,451**	**—**	**—**	**—**	**2,451**	2,172	—	—	—	2,172
Fixed income securities										—
Government and agency obligations	**—**	**2,094**	**—**	**—**	**2,094**	—	1,509	—	—	1,509
Corporate obligations	**—**	**1,582**	**—**	**—**	**1,582**	—	1,246	—	—	1,246
Mortgage and asset-backed securities	**—**	**178**	**—**	**—**	**178**	—	262	—	—	262
Other investments	**—**	**—**	**9**	**—**	**9**	—	—	13	—	13
Plan assets at fair value	**$ 2,824**	**$ 3,854**	**$ 9**	**$ 4,674**	**$ 11,361**	$ 2,502	$ 3,017	$ 13	$ 4,116	$ 9,648
International Pension Plans										
Assets										
Cash and cash equivalents	**$ 70**	**$ 1**	**$ —**	**$ 15**	**$ 86**	$ 50	$ 3	$ —	$ 16	$ 69
Investment funds										
Developed markets equities	**546**	**3,761**	**—**	**96**	**4,403**	461	3,071	—	75	3,607
Government and agency obligations	**462**	**2,534**	**—**	**207**	**3,203**	372	2,082	—	180	2,634
Emerging markets equities	**66**	**96**	**—**	**90**	**252**	56	112	—	83	251
Corporate obligations	**5**	**11**	**—**	**109**	**125**	4	7	—	94	105
Fixed income obligations	**9**	**6**	**—**	**—**	**15**	7	4	—	—	11
Real estate	**—**	**1**	**—**	**—**	**1**	—	1	1	—	2
Equity securities										
Developed markets	**565**	**—**	**—**	**—**	**565**	544	—	—	—	544
Fixed income securities										
Government and agency obligations	**3**	**376**	**—**	**—**	**379**	2	291	—	—	293
Corporate obligations	**1**	**135**	**—**	**—**	**136**	1	113	—	—	114
Mortgage and asset-backed securities	**—**	**61**	**—**	**—**	**61**	—	55	—	—	55
Other investments										
Insurance contracts [2]	**—**	**65**	**851**	**—**	**916**	—	66	811	—	877
Other	**—**	**5**	**—**	**16**	**21**	—	4	1	13	18
Plan assets at fair value	**$ 1,727**	**$ 7,052**	**$ 851**	**$ 533**	**$ 10,163**	$ 1,497	$ 5,809	$ 813	$ 461	$ 8,580

[1] *Certain investments that were measured at net asset value (NAV) per share or its equivalent have not been classified in the fair value hierarchy. The NAV amounts presented in this table are intended to permit reconciliation of the fair value hierarchy to the fair value of plan assets at December 31, 2019 and 2018.*

[2] *The plans' Level 3 investments in insurance contracts are generally valued using a crediting rate that approximates market returns and invest in underlying securities whose market values are unobservable and determined using pricing models, discounted cash flow methodologies, or similar techniques.*

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The table below provides a summary of the changes in fair value, including transfers in and/or out, of all financial assets measured at fair value using significant unobservable inputs (Level 3) for the Company's pension plan assets:

	2019				2018			
	Insurance Contracts	Real Estate	Other	Total	Insurance Contracts	Real Estate	Other	Total
U.S. Pension Plans								
Balance January 1	$ —	$ —	$ 13	$ 13	$ —	$ —	$ 15	$ 15
Actual return on plan assets:								
Relating to assets still held at December 31	—	—	(8)	(8)	—	—	(3)	(3)
Relating to assets sold during the year	—	—	8	8	—	—	4	4
Purchases and sales, net	—	—	(4)	(4)	—	—	(3)	(3)
Balance December 31	$ —	$ —	$ 9	$ 9	$ —	$ —	$ 13	$ 13
International Pension Plans								
Balance January 1	$ 811	$ 1	$ 1	$ 813	$ 470	$ 2	$ 1	$ 473
Actual return on plan assets:								
Relating to assets still held at December 31	54	—	—	54	(32)	—	—	(32)
Purchases and sales, net	(14)	(1)	(1)	(16)	380	(1)	—	379
Transfers out of Level 3	—	—	—	—	(7)	—	—	(7)
Balance December 31	$ 851	$ —	$ —	$ 851	$ 811	$ 1	$ 1	$ 813

The fair values of the Company's other postretirement benefit plan assets at December 31 by asset category are as follows:

	Fair Value Measurements Using					Fair Value Measurements Using				
	Level 1	Level 2	Level 3	NAV [1]	Total	Level 1	Level 2	Level 3	NAV [1]	Total
	2019					2018				
Assets										
Cash and cash equivalents	$ 52	$ —	$ —	$ 22	$ 74	$ 78	$ —	$ —	$ 16	$ 94
Investment funds										
Developed markets equities	19	—	—	324	343	16	—	—	279	295
Emerging markets equities	15	—	—	66	81	12	—	—	67	79
Government and agency obligations	1	—	—	16	17	1	—	—	15	16
Corporate obligations	—	—	—	—	—	—	—	—	3	3
Equity securities										—
Developed markets	225	—	—	—	225	200	—	—	—	200
Fixed income securities										
Government and agency obligations	—	196	—	—	196	—	141	—	—	141
Corporate obligations	—	149	—	—	149	—	116	—	—	116
Mortgage and asset-backed securities	—	17	—	—	17	—	24	—	—	24
Plan assets at fair value	$ 312	$ 362	$ —	$ 428	$ 1,102	$ 307	$ 281	$ —	$ 380	$ 968

[1] *Certain investments that were measured at net asset value (NAV) per share or its equivalent have not been classified in the fair value hierarchy. The NAV amounts presented in this table are intended to permit reconciliation of the fair value hierarchy to the fair value of plan assets at December 31, 2019 and 2018.*

The Company has established investment guidelines for its U.S. pension and other postretirement plans to create an asset allocation that is expected to deliver a rate of return sufficient to meet the long-term obligation of each

plan, given an acceptable level of risk. The target investment portfolio of the Company's U.S. pension and other postretirement benefit plans is allocated 30% to 45% in U.S. equities, 15% to 30% in international equities, 35% to 45% in fixed-income investments, and up to 5% in cash and other investments. The portfolio's equity weighting is consistent with the long-term nature of the plans' benefit obligations. The expected annual standard deviation of returns

of the target portfolio, which approximates 10%, reflects both the equity allocation and the diversification benefits among the asset classes in which the portfolio invests. For international pension plans, the targeted investment portfolio varies based on the duration of pension liabilities and local government rules and regulations. Although a significant percentage of plan assets are invested in U.S. equities, concentration risk is mitigated through the use of strategies that are diversified within management guidelines.

Expected Contributions

Expected contributions during 2020 are approximately $100 million for U.S. pension plans, approximately $150 million for international pension plans and approximately $15 million for other postretirement benefit plans.

Expected Benefit Payments

Expected benefit payments are as follows:

	U.S. Pension Benefits	International Pension Benefits	Other Postretirement Benefits
2020	$ 747	$ 242	$ 88
2021	717	225	92
2022	710	243	94
2023	718	250	98
2024	708	250	100
2025 — 2029	3,943	1,417	540

Expected benefit payments are based on the same assumptions used to measure the benefit obligations and include estimated future employee service.

Amounts Recognized in Other Comprehensive Income

Net loss amounts reflect experience differentials primarily relating to differences between expected and actual returns on plan assets as well as the effects of changes in actuarial assumptions. Net loss amounts in excess of certain thresholds are amortized into net periodic benefit cost over the average remaining service life of employees. The following amounts were reflected as components of *OCI*:

	Pension Plans						Other Postretirement Benefit Plans		
	U.S.			International					
Years Ended December 31	**2019**	2018	2017	**2019**	2018	2017	**2019**	2018	2017
Net (loss) gain arising during the period	**$ (816)**	$ (397)	$ (19)	**$ (227)**	$ (505)	$ 309	**$ 112**	$ 186	$ 170
Prior service (cost) credit arising during the period	**(4)**	(4)	(13)	**(1)**	(10)	22	**(11)**	2	(31)
	$ (820)	$ (401)	$ (32)	**$ (228)**	$ (515)	$ 331	**$ 101**	$ 188	$ 139
Net loss amortization included in benefit cost	**$ 151**	$ 232	$ 180	**$ 64**	$ 84	$ 98	**$ (10)**	$ 1	$ 1
Prior service credit amortization included in benefit cost	**(49)**	(50)	(53)	**(12)**	(13)	(11)	**(78)**	(84)	(98)
	$ 102	$ 182	$ 127	**$ 52**	$ 71	$ 87	**$ (88)**	$ (83)	$ (97)

Actuarial Assumptions

The Company reassesses its benefit plan assumptions on a regular basis. The weighted average assumptions used in determining U.S. pension and other postretirement benefit plan and international pension plan information are as follows:

	U.S. Pension and Other Postretirement Benefit Plans			International Pension Plans		
December 31	**2019**	2018	2017	**2019**	2018	2017
Net periodic benefit cost						
Discount rate	**4.40 %**	3.70 %	4.30 %	**2.20 %**	2.10 %	2.20 %
Expected rate of return on plan assets	**8.10 %**	8.20 %	8.70 %	**4.90 %**	5.10 %	5.10 %
Salary growth rate	**4.30 %**	4.30 %	4.30 %	**2.80 %**	2.90 %	2.90 %
Interest crediting rate	**3.40 %**	3.30 %	3.30 %	**2.90 %**	2.80 %	3.00 %
Benefit obligation						
Discount rate	**3.40 %**	4.40 %	3.70 %	**1.50 %**	2.20 %	2.10 %
Salary growth rate	**4.20 %**	4.30 %	4.30 %	**2.80 %**	2.80 %	2.90 %
Interest crediting rate	**4.90 %**	3.40 %	3.30 %	**2.80 %**	2.90 %	2.80 %

For both the pension and other postretirement benefit plans, the discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due. The expected rate of return for both the pension and other postretirement benefit plans represents the average rate of return to be earned on plan assets over the period the benefits included in the benefit obligation are to be paid and is determined on a plan basis. The expected rate of return for each plan is developed considering long-term historical returns data, current market conditions, and actual returns on the plan assets. Using this reference information, the long-term return expectations for each asset category and a weighted-average expected return for each plan's target portfolio is developed, according to the allocation among those investment categories. The expected portfolio performance reflects the contribution of active management as appropriate. For 2020, the expected rate of return for the Company's U.S. pension and other postretirement benefit plans will range from 7.00% to 7.30%, as compared to a range of 7.70% to 8.10% in 2019. The decrease reflects lower expected asset returns and a modest shift in asset allocation. The change in the weighted-average expected return on U.S. pension and other postretirement benefit plan assets from 2017 to 2019 is due to the relative weighting of the referenced plans' assets.

The health care cost trend rate assumptions for other postretirement benefit plans are as follows:

December 31	**2019**	2018
Health care cost trend rate assumed for next year	**6.8 %**	7.0 %
Rate to which the cost trend rate is assumed to decline	**4.5 %**	4.5 %
Year that the trend rate reaches the ultimate trend rate	**2032**	2032

Savings Plans

The Company also maintains defined contribution savings plans in the United States. The Company matches a percentage of each employee's contributions consistent with the provisions of the plan for which the employee is eligible. Total employer contributions to these plans in 2019, 2018 and 2017 were $149 million, $136 million and $131 million, respectively.

14. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

Years Ended December 31	**2019**	2018	2017
Interest income	**$ (274)**	$ (343)	$ (385)
Interest expense	**893**	772	754
Exchange losses (gains)	**187**	145	(11)
Income from investments in equity securities, net [1]	**(170)**	(324)	(352)
Net periodic defined benefit plan (credit) cost other than service cost	**(545)**	(512)	(512)
Other, net	**48**	(140)	6
	$ 139	$ (402)	$ (500)

[1] *Includes net realized and unrealized gains and losses from investments in equity securities either owned directly or through ownership interests in investment funds.*

Other, net (as presented in the table above) in 2019 includes $162 million of goodwill impairment charges related to certain businesses in the Healthcare Services segment (see Note 8).

Other, net in 2018 includes a gain of $115 million related to the settlement of certain patent litigation, income of $99 million related to AstraZeneca's option exercise in 2014 in connection with the termination of the Company's relationship with AstraZeneca LP (AZLP), and a gain of $85 million resulting from the receipt of a milestone payment for an out-licensed migraine clinical development program. Other, net in 2018 also includes $144 million of goodwill impairment charges related to certain businesses in the Healthcare Services segment (see Note 8), as well as $41 million of charges related to the write-down of assets held for sale to fair value in anticipation of the dissolution of the Company's joint venture with Supera Farma Laboratorios S.A. in Brazil.

Other, net in 2017 includes income of $232 million related to AstraZeneca's option exercise and a $191 million loss on extinguishment of debt.

Interest paid was $841 million in 2019, $777 million in 2018 and $723 million in 2017.

15. Taxes on Income

A reconciliation between the effective tax rate and the U.S. statutory rate is as follows:

	2019		2018		2017	
	Amount	**Tax Rate**	Amount	Tax Rate	Amount	Tax Rate
U.S. statutory rate applied to income before taxes	**$ 2,408**	**21.0 %**	$ 1,827	21.0 %	$ 2,282	35.0 %
Differential arising from:						
Foreign earnings	**(1,020)**	**(8.9)**	(245)	(2.8)	(1,654)	(25.4)
GILTI and the foreign-derived intangible income deduction	**336**	**2.9**	(25)	(0.3)	—	—
Tax settlements	**(403)**	**(3.5)**	(22)	(0.3)	(356)	(5.5)
R&D tax credit	**(118)**	**(1.0)**	(96)	(1.1)	(71)	(1.1)
State taxes	**(2)**	**—**	201	2.3	77	1.2
Acquisition of Peloton	**209**	**1.8**	—	—	—	—
TCJA	**117**	**1.0**	289	3.3	2,625	40.3
Valuation allowances	**113**	**1.0**	269	3.1	632	9.7
Acquisition-related costs, including amortization	**95**	**0.8**	267	3.1	713	10.9
Restructuring	**39**	**0.3**	56	0.6	142	2.2
Other [1]	**(87)**	**(0.7)**	(13)	(0.1)	(287)	(4.4)
	$ 1,687	**14.7 %**	$ 2,508	28.8 %	$ 4,103	62.9 %

[1] *Other includes the tax effects of losses on foreign subsidiaries and miscellaneous items.*

The Tax Cuts and Jobs Act (TCJA) was enacted in December 2017. Among other provisions, the TCJA reduced the U.S. federal corporate statutory tax rate from 35% to 21% effective January 1, 2018, required companies to pay a one-time transition tax on undistributed earnings of certain foreign subsidiaries, and created new taxes on certain foreign sourced earnings. The Company reflected the impact of the TCJA in its 2017 financial statements. However, since application of certain provisions of the TCJA remained subject to further interpretation, in certain instances the Company made reasonable estimates of the effects of the TCJA, which were since finalized as described below.

The one-time transition tax is based on the Company's post-1986 undistributed earnings and profits (E&P). For a substantial portion of these undistributed E&P, the Company had not previously provided deferred taxes as these earnings were deemed by Merck to be retained indefinitely by subsidiary companies for reinvestment. The Company recorded a provisional amount in 2017 for its one-time transition tax liability of $5.3 billion. This provisional amount was reduced by the reversal of $2.0 billion of deferred taxes that were previously recorded in connection with the merger of Schering-Plough Corporation in 2009 for certain undistributed foreign E&P. On the basis of revised calculations of post-1986 undistributed foreign E&P and finalization of the amounts held in cash or other specified assets, the Company recognized a measurement-period adjustment of $124 million in 2018 related to the transition tax obligation, with a corresponding adjustment to income tax expense during the period, resulting in a revised transition tax obligation of $5.5 billion. In 2019, the Company recorded additional charges of $117 million related to the finalization of treasury regulations associated with the TCJA. As permitted under the TCJA, the Company has elected to pay the one-time transition tax over a period of eight years through 2025. The Company's remaining transition tax liability, which has been reduced by payments and the utilization of foreign tax credits, was $3.4 billion at December 31, 2019, of which $390 million is included in *Income taxes payable* and the remainder of $3.0 billion is included in *Other Noncurrent Liabilities*. In 2017, the Company remeasured its deferred tax assets and liabilities at the new federal statutory tax rate of 21%, which resulted in a provisional deferred tax benefit of $779 million. On the basis of clarifications to the deferred tax benefit calculation, the Company recorded measurement-period adjustments in 2018 of $32 million related to deferred income taxes.

The foreign earnings tax rate differentials in the tax rate reconciliation above primarily reflect the impacts of operations in jurisdictions with different tax rates than the United States, particularly Ireland and Switzerland, as well as Singapore and Puerto Rico which operate under tax incentive grants (which begin to expire in 2022), where the earnings had been indefinitely reinvested, thereby yielding a favorable impact on the effective tax rate compared with the U.S. statutory rate of 21% in 2019 and 2018 and 35% in 2017. The foreign earnings tax rate differentials do not include the impact of intangible asset impairment charges, amortization of purchase accounting adjustments or restructuring costs. These items are presented separately as they each represent a significant, separately disclosed pretax cost or charge, and a substantial portion of each of these items relates to jurisdictions with lower tax rates than the United States. Therefore, the impact of recording these expense items in lower tax rate jurisdictions is an unfavorable impact on the effective tax rate compared to the U.S. statutory rate.

Income before taxes consisted of:

Years Ended December 31	**2019**	2018	2017
Domestic	**$ 439**	$ 3,717	$ 3,483
Foreign	**11,025**	4,984	3,038
	$ 11,464	$ 8,701	$ 6,521

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Taxes on income consisted of:

Years Ended December 31	**2019**	2018	2017
Current provision			
Federal	**$ 514**	$ 536	$ 5,585
Foreign	**1,806**	2,281	1,229
State	**(77)**	200	(90)
	2,243	3,017	6,724
Deferred provision			
Federal	**(330)**	(402)	(2,958)
Foreign	**(240)**	(64)	75
State	**14**	(43)	262
	(556)	(509)	(2,621)
	$ 1,687	$ 2,508	$ 4,103

Deferred income taxes at December 31 consisted of:

	2019		2018	
	Assets	**Liabilities**	Assets	Liabilities
Product intangibles and licenses	**$ 442**	**$ 1,778**	$ 720	$ 1,640
Inventory related	**32**	**354**	32	377
Accelerated depreciation	**—**	**594**	—	582
Pensions and other postretirement benefits	**785**	**191**	565	151
Compensation related	**322**	**—**	291	—
Unrecognized tax benefits	**109**	**—**	174	—
Net operating losses and other tax credit carryforwards	**897**	**—**	715	—
Other	**764**	**84**	621	66
Subtotal	**3,351**	**3,001**	3,118	2,816
Valuation allowance	**(1,100)**		(1,348)	
Total deferred taxes	**$ 2,251**	**$ 3,001**	$ 1,770	$ 2,816
Net deferred income taxes		**$ 750**		$ 1,046
Recognized as:				
Other Assets	**$ 719**		$ 656	
Deferred Income Taxes		**$ 1,470**		$ 1,702

The Company has net operating loss (NOL) carryforwards in several jurisdictions. As of December 31, 2019, $762 million of deferred taxes on NOL carryforwards relate to foreign jurisdictions. Valuation allowances of $1.1 billion have been established on these foreign NOL carryforwards and other foreign deferred tax assets. In addition, the Company has $135 million of deferred tax assets relating to various U.S. tax credit carryforwards and NOL carryforwards, all of which are expected to be fully utilized prior to expiry.

Income taxes paid in 2019, 2018 and 2017 were $4.5 billion, $1.5 billion and $4.9 billion, respectively. Tax benefits relating to stock option exercises were $65 million in 2019, $77 million in 2018 and $73 million in 2017.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	2019	2018	2017
Balance January 1	**$ 1,893**	$ 1,723	$ 3,494
Additions related to current year positions	**199**	221	146
Additions related to prior year positions	**46**	142	520

Reductions for tax positions of prior years [1]	**(454)**	(73)	(1,038)
Settlements [1]	**(356)**	(91)	(1,388)
Lapse of statute of limitations [2]	**(103)**	(29)	(11)
Balance December 31	**$ 1,225**	$ 1,893	$ 1,723

(1) Amounts reflect the settlements with the IRS as discussed below.

(2) Amount in 2019 includes $78 million related to the divestiture of Merck's Consumer Care business in 2014.

If the Company were to recognize the unrecognized tax benefits of $1.2 billion at December 31, 2019, the income tax provision would reflect a favorable net impact of $1.1 billion.

The Company is under examination by numerous tax authorities in various jurisdictions globally. The Company believes that it is reasonably possible that the total amount of unrecognized tax benefits as of December 31, 2019 could decrease by up to approximately $40 million in the next 12 months as a result of various audit closures, settlements or the expiration of the statute of limitations. The ultimate finalization of the Company's examinations with relevant taxing authorities can include formal administrative and legal proceedings, which could have a significant impact on the timing of the reversal of unrecognized tax benefits. The Company believes that its reserves for uncertain tax positions are adequate to cover existing risks or exposures.

Interest and penalties associated with uncertain tax positions amounted to a (benefit) expense of $(101) million in 2019, $51 million in 2018 and $183 million in 2017. These amounts reflect the beneficial impacts of various tax settlements, including those discussed below. Liabilities for accrued interest and penalties were $243 million and $372 million as of December 31, 2019 and 2018, respectively.

In 2019, the Internal Revenue Service (IRS) concluded its examinations of Merck's 2012-2014 U.S. federal income tax returns. As a result, the Company was required to make a payment of $107 million. The Company's reserves for unrecognized tax benefits for the years under examination exceeded the adjustments relating to this examination period and therefore the Company recorded a $364 million net tax benefit in 2019. This net benefit reflects reductions in reserves for unrecognized tax benefits for tax positions relating to the years that were under examination, partially offset by additional reserves for tax positions not previously reserved for.

In 2017, the IRS concluded its examinations of Merck's 2006-2011 U.S. federal income tax returns. As a result, the Company was required to make a payment of approximately $2.8 billion. The Company's reserves for unrecognized tax benefits for the years under examination exceeded the adjustments relating to this examination period and therefore the Company recorded a net $234 million tax benefit in 2017. This net benefit reflects reductions in reserves for unrecognized tax benefits for tax positions relating to the years that were under examination, partially offset by additional reserves for tax positions not previously reserved for, as well as adjustments to reserves for unrecognized tax benefits relating to years which remain open to examination that are affected by this settlement.

The IRS is currently conducting examinations of the Company's tax returns for the years 2015 and 2016. In addition, various state and foreign tax examinations are in progress and for these jurisdictions, the Company's income tax returns are open for examination for the period 2003 through 2019.

16. Earnings per Share

The calculations of earnings per share (shares in millions) are as follows:

Years Ended December 31	**2019**	2018	2017
Net income attributable to Merck & Co., Inc.	**$ 9,843**	$ 6,220	$ 2,394
Average common shares outstanding	**2,565**	2,664	2,730
Common shares issuable [(1)]	**15**	15	18
Average common shares outstanding assuming dilution	**2,580**	2,679	2,748
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	**$ 3.84**	$ 2.34	$ 0.88
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	**$ 3.81**	$ 2.32	$ 0.87

[(1)] *Issuable primarily under share-based compensation plans.*

In 2019, 2018 and 2017, 2 million, 6 million and 5 million, respectively, of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

17. Other Comprehensive Income (Loss)

Changes in *AOCI* by component are as follows:

	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance January 1, 2017, net of taxes	$ 338	$ (3)	$ (3,206)	$ (2,355)	$ (5,226)
Other comprehensive income (loss) before reclassification adjustments, pretax	(561)	212	438	235	324
Tax	207	(35)	(106)	166	232
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(354)	177	332	401	556
Reclassification adjustments, pretax	(141) [1]	(291) [2]	117 [3]	—	(315)
Tax	49	56	(30)	—	75
Reclassification adjustments, net of taxes	(92)	(235)	87	—	(240)
Other comprehensive income (loss), net of taxes	(446)	(58)	419	401	316
Balance at December 31, 2017, net of taxes	(108)	(61)	(2,787)	(1,954)	(4,910)
Other comprehensive income (loss) before reclassification adjustments, pretax	228	(108)	(728)	(84)	(692)
Tax	(55)	1	169	(139)	(24)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	173	(107)	(559)	(223)	(716)
Reclassification adjustments, pretax	157 [1]	97 [2]	170 [3]	—	424
Tax	(33)	—	(36)	—	(69)
Reclassification adjustments, net of taxes	124	97	134	—	355
Other comprehensive income (loss), net of taxes	297	(10)	(425)	(223)	(361)
Adoption of ASU 2018-02	(23)	1	(344)	100	(266)
Adoption of ASU 2016-01	—	(8)	—	—	(8)
Balance at December 31, 2018, net of taxes	166	(78)	(3,556) [4]	(2,077)	(5,545)
Other comprehensive income (loss) before reclassification adjustments, pretax	**86**	**140**	**(948)**	**112**	**(610)**
Tax	**(15)**	**—**	**192**	**(16)**	**161**
Other comprehensive income (loss) before reclassification adjustments, net of taxes	**71**	**140**	**(756)**	**96**	**(449)**
Reclassification adjustments, pretax	**(261)** [1]	**(44)** [2]	**66** [3]	**—**	**(239)**
Tax	**55**	**—**	**(15)**	**—**	**40**
Reclassification adjustments, net of taxes	**(206)**	**(44)**	**51**	**—**	**(199)**
Other comprehensive income (loss), net of taxes	**(135)**	**96**	**(705)**	**96**	**(648)**
Balance at December 31, 2019, net of taxes	**$ 31**	**$ 18**	**$ (4,261)** [4]	**$ (1,981)**	**$ (6,193)**

[1] *Relates to foreign currency cash flow hedges that were reclassified from* AOCI *to* Sales.

[2] *Represents net realized (gains) losses on the sales of available-for-sale investments that were reclassified from* AOCI *to* Other (income) expense, net. *In 2017, these amounts included both investments in debt and equity securities; however, as a result of the adoption of ASU 2016-01 in 2018, these amounts relate only to investments in available-for-sale debt securities.*

[3] *Includes net amortization of prior service cost and actuarial gains and losses included in net periodic benefit cost (see Note 13).*

[4] *Includes pension plan net loss of $5.1 billion and $4.4 billion at December 31, 2019 and 2018, respectively, and other postretirement benefit plan net gain of $247 million and $170 million at December 31, 2019 and 2018, respectively, as well as pension plan prior service credit of $263 million and $314 million at December 31, 2019 and 2018, respectively, and other postretirement benefit plan prior service credit of $305 million and $375 million at December 31, 2019 and 2018, respectively.*

18. Segment Reporting

The Company's operations are principally managed on a products basis and include four operating segments, which are the Pharmaceutical, Animal Health, Healthcare Services and Alliances segments. The Pharmaceutical and Animal Health segments are the only reportable segments.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. A large component of pediatric and adolescent vaccine sales are made to the U.S. Centers for Disease Control and Prevention Vaccines for Children program, which is funded by the U.S. government. Additionally, the Company sells vaccines to the Federal government for placement into vaccine stockpiles. During 2019, as a result of changes to the Company's internal reporting structure, certain costs that were previously included in the Pharmaceutical segment are now being included as part of non-segment expenses within Merck Research Laboratories. Prior period Pharmaceutical segment profits have been recast to reflect these changes on a comparable basis.

The Animal Health segment discovers, develops, manufactures and markets a wide range of veterinary pharmaceutical and vaccine products, as well as health management solutions and services, for the prevention, treatment and control of disease in all major livestock and companion animal species. The Company also offers an extensive suite of digitally connected identification, traceability and monitoring products. The Company sells its products to veterinarians, distributors and animal producers.

The Healthcare Services segment provides services and solutions that focus on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company has recently sold certain businesses in the Healthcare Services segment and is in the process of divesting the remaining businesses.

The Alliances segment primarily includes activity from the Company's relationship with AstraZeneca LP related to sales of Nexium and Prilosec, which concluded in 2018.

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Sales of the Company's products were as follows:

Years Ended December 31	**2019**			2018			2017		
	U.S.	**Int'l**	**Total**	U.S.	Int'l	Total	U.S.	Int'l	Total
Pharmaceutical:									
Oncology									
Keytruda	**$ 6,305**	**$ 4,779**	**$ 11,084**	$ 4,150	$ 3,021	$ 7,171	$ 2,309	$ 1,500	$ 3,809
Alliance revenue - Lynparza [(1)]	**269**	**176**	**444**	127	61	187	—	20	20
Alliance revenue - Lenvima [(1)]	**239**	**165**	**404**	95	54	149	—	—	—
Emend	**183**	**205**	**388**	312	210	522	342	213	556
Vaccines									
Gardasil/Gardasil 9	**1,831**	**1,905**	**3,737**	1,873	1,279	3,151	1,565	743	2,308
ProQuad/M-M-R II/Varivax	**1,683**	**592**	**2,275**	1,430	368	1,798	1,374	303	1,676
Pneumovax 23	**679**	**247**	**926**	627	281	907	581	240	821
RotaTeq	**506**	**284**	**791**	496	232	728	481	204	686
Vaqta	**130**	**108**	**238**	127	112	239	94	124	218
Hospital Acute Care									
Bridion	**533**	**598**	**1,131**	386	531	917	239	465	704
Noxafil	**282**	**380**	**662**	353	389	742	309	327	636
Primaxin	**2**	**271**	**273**	7	258	265	10	270	280
Invanz	**30**	**233**	**263**	253	243	496	361	241	602
Cubicin	**92**	**165**	**257**	191	176	367	189	193	382
Cancidas	**6**	**242**	**249**	12	314	326	20	402	422
Immunology									
Simponi	**—**	**830**	**830**	—	893	893	—	819	819
Remicade	**—**	**411**	**411**	—	582	582	—	837	837
Neuroscience									
Belsomra	**92**	**214**	**306**	96	164	260	98	112	210
Virology									
Isentress/Isentress HD	**398**	**576**	**975**	513	627	1,140	565	639	1,204
Zepatier	**118**	**252**	**370**	8	447	455	771	888	1,660
Cardiovascular									
Zetia	**14**	**575**	**590**	45	813	857	352	992	1,344
Vytorin	**16**	**269**	**285**	10	487	497	124	627	751
Atozet	**—**	**391**	**391**	—	347	347	—	225	225
Adempas	**—**	**419**	**419**	—	329	329	—	300	300
Diabetes									
Januvia	**1,724**	**1,758**	**3,482**	1,969	1,718	3,686	2,153	1,584	3,737
Janumet	**589**	**1,452**	**2,041**	811	1,417	2,228	863	1,296	2,158
Women's Health									
NuvaRing	**742**	**136**	**879**	722	180	902	564	197	761
Implanon/Nexplanon	**568**	**219**	**787**	495	208	703	496	191	686
Diversified Brands									
Singulair	**29**	**669**	**698**	20	688	708	40	692	732
Cozaar/Hyzaar	**24**	**418**	**442**	23	431	453	18	466	484
Nasonex	**9**	**284**	**293**	23	353	376	54	333	387
Arcoxia	**—**	**288**	**288**	—	335	335	—	363	363
Follistim AQ	**103**	**138**	**241**	115	153	268	123	174	298
Other pharmaceutical [(2)]	**1,563**	**3,343**	**4,901**	1,319	3,380	4,705	1,759	3,556	5,314
Total Pharmaceutical segment sales	**18,759**	**22,992**	**41,751**	16,608	21,081	37,689	15,854	19,536	35,390

Animal Health:									
Livestock	**582**	**2,201**	**2,784**	528	2,102	2,630	471	2,013	2,484
Companion Animals	**724**	**885**	**1,609**	710	872	1,582	619	772	1,391
Total Animal Health segment sales	**1,306**	**3,086**	**4,393**	1,238	2,974	4,212	1,090	2,785	3,875
Other segment sales [3]	**174**	**1**	**175**	248	2	250	396	1	397
Total segment sales	**20,239**	**26,079**	**46,319**	18,094	24,057	42,151	17,340	22,322	39,662
Other [4]	**86**	**436**	**521**	118	26	143	84	376	460
	$ 20,325	**$ 26,515**	**$ 46,840**	$ 18,212	$ 24,083	$ 42,294	$ 17,424	$ 22,698	$ 40,122

U.S. plus international may not equal total due to rounding.

[1] *Alliance revenue represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs (see Note 4).*

[2] *Other pharmaceutical primarily reflects sales of other human health pharmaceutical products, including products within the franchises not listed separately.*

[3] *Represents the non-reportable segments of Healthcare Services and Alliances.*

[4] *Other is primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, as well as third-party manufacturing sales. Other in 2019, 2018 and 2017 also includes approximately $80 million, $95 million and $85 million, respectively, related to the sale of the marketing rights to certain products.*

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Consolidated sales by geographic area where derived are as follows:

Years Ended December 31	**2019**	2018	2017
United States	**$ 20,325**	$ 18,212	$ 17,424
Europe, Middle East and Africa	**12,707**	12,213	11,478
Japan	**3,583**	3,212	3,122
China	**3,207**	2,184	1,586
Asia Pacific (other than Japan and China)	**2,943**	2,909	2,751
Latin America	**2,469**	2,415	2,339
Other	**1,606**	1,149	1,422
	$ 46,840	$ 42,294	$ 40,122

A reconciliation of segment profits to *Income before taxes* is as follows:

Years Ended December 31	**2019**	2018	2017
Segment profits:			
Pharmaceutical segment	**$ 28,324**	$ 24,871	$ 23,018
Animal Health segment	**1,609**	1,659	1,552
Other segments	**(7)**	103	275
Total segment profits	**29,926**	26,633	24,845
Other profits	**363**	6	26
Unallocated:			
Interest income	**274**	343	385
Interest expense	**(893)**	(772)	(754)
Depreciation and amortization	**(1,573)**	(1,334)	(1,378)
Research and development	**(9,499)**	(9,432)	(10,004)
Amortization of purchase accounting adjustments	**(1,419)**	(2,664)	(3,056)
Restructuring costs	**(638)**	(632)	(776)
Charge related to the termination of a collaboration with Samsung	**—**	(423)	—
Loss on extinguishment of debt	**—**	—	(191)
Other unallocated, net	**(5,077)**	(3,024)	(2,576)
Income Before Taxes	**$ 11,464**	$ 8,701	$ 6,521

Pharmaceutical segment profits are comprised of segment sales less standard costs, as well as selling, general and administrative expenses directly incurred by the segment. Animal Health segment profits are comprised of segment sales, less all cost of sales, as well as selling, general and administrative expenses and research and development costs directly incurred by the segment. For internal management reporting presented to the chief operating decision maker, Merck does not allocate the remaining cost of sales not included in segment profits as described above, research and development expenses incurred in Merck Research Laboratories, the Company's research and development division that focuses on human health-related activities, or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. In addition, costs related to restructuring activities, as well as the amortization of purchase accounting adjustments are not allocated to segments.

Other profits are primarily comprised of miscellaneous corporate profits, as well as operating profits related to third-party manufacturing sales.

Other unallocated, net includes expenses from corporate and manufacturing cost centers, goodwill and other intangible asset impairment charges, gains or losses on sales of businesses, expense or income related to changes in the estimated fair value of liabilities for contingent consideration, and other miscellaneous income or expense items.

Equity (income) loss from affiliates and depreciation and amortization included in segment profits is as follows:

	Pharmaceutical	Animal Health	All Other	Total
Year Ended December 31, 2019				
Included in segment profits:				
Equity (income) loss from affiliates	**$ —**	**$ —**	**$ —**	**$ —**
Depreciation and amortization	**137**	**109**	**10**	**256**
Year Ended December 31, 2018				
Included in segment profits:				
Equity (income) loss from affiliates	$ 4	$ —	$ —	$ 4
Depreciation and amortization	243	82	10	335
Year Ended December 31, 2017				
Included in segment profits:				
Equity (income) loss from affiliates	$ 7	$ —	$ —	$ 7
Depreciation and amortization	125	75	12	212

Property, plant and equipment, net, by geographic area where located is as follows:

December 31	**2019**	2018	2017
United States	**$ 8,974**	$ 8,306	$ 8,070
Europe, Middle East and Africa	**4,767**	3,706	3,151
Asia Pacific (other than Japan and China)	**714**	684	632
Latin America	**266**	264	271
China	**174**	167	150
Japan	**152**	159	158
Other	**6**	5	7
	$ 15,053	$ 13,291	$ 12,439

The Company does not disaggregate assets on a products and services basis for internal management reporting and, therefore, such information is not presented.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Merck & Co., Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheet of Merck & Co., Inc. and its subsidiaries (the "Company") as of December 31, 2019 and 2018, and the related consolidated statements of income, of comprehensive income, of equity and of cash flows for each of the three years in the period ended December 31, 2019, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable

assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Customer Discount Accruals in the U.S. - Medicaid, Managed Care and Medicare Part D Rebates

As described in Note 2 to the consolidated financial statements, the Company records certain variable consideration including discounts, which are estimated at the time of sale generally using the expected value method. Amounts accrued for aggregate customer discounts as of December 31, 2019 in the U.S. are $2.4 billion and are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal and state agencies, and other customers to the amounts accrued. Certain of these discounts take the form of rebates, which are amounts owed based upon definitive contractual agreements or legal requirements with private sector (Managed Care) and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. Management uses historical customer segment utilization mix, sales forecasts, changes to product mix and price, inventory levels in the distribution channel, government pricing calculations and prior payment history in order to estimate the expected provision.

The principal considerations for our determination that performing procedures relating to customer discount accruals in the U.S. - Medicaid, Managed Care, and Medicare Part D rebates is a critical audit matter are that there was significant judgment required by management with significant measurement uncertainty, as the calculation of the rebate accruals includes assumptions related to price and customer segment utilization, pertaining to forecasted customer claims that may not be fully paid until a subsequent period. This in turn led to a high degree of auditor judgment, subjectivity and effort in applying the procedures related to those assumptions.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to customer discount accruals in the U.S. - Medicaid, Managed Care, and Medicare Part D rebates, including management's controls over the assumptions used to estimate the corresponding rebate accruals. These procedures also included, among others, developing an independent estimate of the rebate accruals by utilizing third party data on customer segment utilization, changes to price, the terms of the specific rebate programs, and the historical trend of actual rebate claims paid. The independent estimate was compared to the rebate accruals recorded by management to evaluate the reasonableness of the estimate. Additionally, these procedures included testing actual rebate claims paid and evaluating the contractual terms of the Company's rebate agreements.

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PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 26, 2020

We have served as the Company's auditor since 2002.

(b) Supplementary Data

Selected quarterly financial data for 2019 and 2018 are contained in the Condensed Interim Financial Data table below.

Condensed Interim Financial Data (Unaudited)

($ in millions except per share amounts)	4th Q	3rd Q [1]	2nd Q	1st Q [2]
2019 [3]				
Sales	**$ 11,868**	**$ 12,397**	**$ 11,760**	**$ 10,816**
Cost of sales	**3,669**	**3,990**	**3,401**	**3,052**
Selling, general and administrative	**2,888**	**2,589**	**2,712**	**2,425**
Research and development	**2,548**	**3,204**	**2,189**	**1,931**
Restructuring costs	**194**	**232**	**59**	**153**
Other (income) expense, net	**(223)**	**35**	**140**	**188**
Income before taxes	**2,792**	**2,347**	**3,259**	**3,067**
Net income attributable to Merck & Co., Inc.	**2,357**	**1,901**	**2,670**	**2,915**
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	**$ 0.93**	**$ 0.74**	**$ 1.04**	**$ 1.13**
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	**$ 0.92**	**$ 0.74**	**$ 1.03**	**$ 1.12**
2018 [3]				
Sales	$ 10,998	$ 10,794	$ 10,465	$ 10,037
Cost of sales	3,289	3,619	3,417	3,184
Selling, general and administrative	2,643	2,443	2,508	2,508
Research and development	2,214	2,068	2,274	3,196
Restructuring costs	138	171	228	95
Other (income) expense, net	110	(172)	(48)	(291)
Income before taxes	2,604	2,665	2,086	1,345
Net income attributable to Merck & Co., Inc.	1,827	1,950	1,707	736
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	$ 0.70	$ 0.73	$ 0.64	$ 0.27
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	$ 0.69	$ 0.73	$ 0.63	$ 0.27

[1] *Amounts for 2019 include a charge related to the acquisition of Peloton Therapeutics, Inc. (see Note 3).*

[2] *Amounts for 2018 include a charge related to the formation of a collaboration with Eisai (see Note 4).*

[3] *Amounts for 2019 and 2018 reflect acquisition and divestiture-related costs (see Note 8) and the impact of restructuring actions (see Note 5).*

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures. Based on their evaluation, as of the end of the period covered by this Form 10-K, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Act)) are effective. For the fourth quarter of 2019, there have been no changes in internal control over financial reporting that materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Act. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control — Integrated Framework* issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2019. PricewaterhouseCoopers LLP, an independent registered public accounting firm, has performed its own assessment of the effectiveness of the Company's internal control over financial reporting and its attestation report is included in this Form 10-K filing.

Management's Report

Management's Responsibility for Financial Statements

Responsibility for the integrity and objectivity of the Company's financial statements rests with management. The financial statements report on management's stewardship of Company assets. These statements are prepared in conformity with generally accepted accounting principles and, accordingly, include amounts that are based on management's best estimates and judgments. Nonfinancial information included in the Annual Report on Form 10-K has also been prepared by management and is consistent with the financial statements.

To assure that financial information is reliable and assets are safeguarded, management maintains an effective system of internal controls and procedures, important elements of which include: careful selection, training and development of operating and financial managers; an organization that provides appropriate division of responsibility; and communications aimed at assuring that Company policies and procedures are understood throughout the organization. A staff of internal auditors regularly monitors the adequacy and application of internal controls on a worldwide basis.

To ensure that personnel continue to understand the system of internal controls and procedures, and policies concerning good and prudent business practices, annually all employees of the Company are required to complete Code of Conduct training. This training reinforces the importance and understanding of internal controls by reviewing key corporate policies, procedures and systems. In addition, the Company has compliance programs, including an ethical business practices program to reinforce the Company's long-standing commitment to high ethical standards in the conduct of its business.

The financial statements and other financial information included in the Annual Report on Form 10-K fairly present, in all material respects, the Company's financial condition, results of operations and cash flows. Our formal certification to the Securities and Exchange Commission is included in this Form 10-K filing.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control — Integrated Framework* issued

in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2019.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2019, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

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Kenneth C. Frazier
Chairman, President
and Chief Executive Officer

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Robert M. Davis
Executive Vice President, Global Services,
and Chief Financial Officer

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The required information on directors and nominees is incorporated by reference from the discussion under Proposal 1. Election of Directors of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 26, 2020. Information on executive officers is set forth in Part I of this document on page 35.

The required information on compliance with Section 16(a) of the Securities Exchange Act of 1934, if applicable, is incorporated by reference from the discussion under the heading "Stock Ownership Information" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 26, 2020.

The Company has a Code of Conduct — *Our Values and Standards* applicable to all employees, including the principal executive officer, principal financial officer, principal accounting officer and Controller. The Code of Conduct is available on the Company's website at http://www.msd.com/about/how-we-operate/code-of-conduct/values-and-standards.html. The Company intends to disclose future amendments to certain provisions of the Code of Conduct, and waivers of the Code of Conduct granted to executive officers and directors, if any, on the website within four business days following the date of any amendment or waiver. Every Merck employee is responsible for adhering to business practices that are in accordance with the law and with ethical principles that reflect the highest standards of corporate and individual behavior.

The required information on the identification of the audit committee and the audit committee financial expert is incorporated by reference from the discussion under the heading "Board Meetings and Committees" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 26, 2020.

Item 11. Executive Compensation.

The information required on executive compensation is incorporated by reference from the discussion under the headings "Compensation Discussion and Analysis," "Summary Compensation Table," "All Other Compensation" table, "Grants of Plan-Based Awards" table, "Outstanding Equity Awards" table, "Option Exercises and Stock Vested" table, "Pension Benefits" table, "Nonqualified Deferred Compensation" table, Potential Payments Upon Termination or a Change in Control, including the discussion under the subheadings "Separation" and "Change in Control," as well as all footnote information to the various tables, of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 26, 2020.

The required information on director compensation is incorporated by reference from the discussion under the heading "Director Compensation" and related "Director Compensation" table and "Schedule of Director Fees" table of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 26, 2020.

The required information under the headings "Compensation and Benefits Committee Interlocks and Insider Participation" and "Compensation and Benefits Committee Report" is incorporated by reference from the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 26, 2020.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information with respect to security ownership of certain beneficial owners and management is incorporated by reference from the discussion under the heading "Stock Ownership Information" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 26, 2020.

Equity Compensation Plan Information

The following table summarizes information about the options, warrants and rights and other equity compensation under the Company's equity compensation plans as of the close of business on December 31, 2019. The table does not include information about tax qualified plans such as the Merck U.S. Savings Plan.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders[1]	17,867,551[2]	$ 59.88	110,842,998
Equity compensation plans not approved by security holders	—	—	—
Total	17,867,551	$ 59.88	110,842,998

[1] *Includes options to purchase shares of Company Common Stock and other rights under the following shareholder-approved plans: the Merck & Co., Inc. 2010 and 2019 Incentive Stock Plans, and the Merck & Co., Inc. 2010 Non-Employee Directors Stock Option Plan.*

[2] *Excludes approximately 13,527,086 shares of restricted stock units and 1,927,145 performance share units (assuming maximum payouts) under the Merck Sharp & Dohme 2004, 2007 and 2010 Incentive Stock Plans. Also excludes 197,485 shares of phantom stock deferred under the MSD Employee Deferral Program and 557,132 shares of phantom stock deferred under the Merck & Co., Inc. Plan for Deferred Payment of Directors' Compensation.*

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The required information on transactions with related persons is incorporated by reference from the discussion under the heading "Related Person Transactions" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 26, 2020.

The required information on director independence is incorporated by reference from the discussion under the heading "Independence of Directors" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 26, 2020.

Item 14. Principal Accountant Fees and Services.

The information required for this item is incorporated by reference from the discussion under Proposal 3. Ratification of Appointment of Independent Registered Public Accounting Firm for 2020 beginning with the caption "Pre-Approval Policy for Services of Independent Registered Public Accounting Firm" through "Fees for Services Provided by the Independent Registered Public Accounting Firm" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 26, 2020.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this Form 10-K

1. Financial Statements

Consolidated statement of income for the years ended December 31, 2019, 2018 and 2017

Consolidated statement of comprehensive income for the years ended December 31, 2019, 2018 and 2017

Consolidated balance sheet as of December 31, 2019 and 2018

Consolidated statement of equity for the years ended December 31, 2019, 2018 and 2017

Consolidated statement of cash flows for the years ended December 31, 2019, 2018 and 2017

Notes to consolidated financial statements

Report of PricewaterhouseCoopers LLP, independent registered public accounting firm

2. Financial Statement Schedules

Schedules are omitted because they are either not required or not applicable.

Financial statements of affiliates carried on the equity basis have been omitted because, considered individually or in the aggregate, such affiliates do not constitute a significant subsidiary.

3. Exhibits

Exhibit Number		Description
3.1	—	Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) — Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
3.2	—	By-Laws of Merck & Co., Inc. (effective July 22, 2015) — Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed July 28, 2015 (No. 1-6571)
4.1	—	Indenture, dated as of April 1, 1991, between Merck Sharp & Dohme Corp. (f/k/a Schering Corporation) and U.S. Bank Trust National Association (as successor to Morgan Guaranty Trust Company of New York), as Trustee (the 1991 Indenture) — Incorporated by reference to Exhibit 4 to MSD's Registration Statement on Form S-3 (No. 33-39349)
4.2	—	First Supplemental Indenture to the 1991 Indenture, dated as of October 1, 1997 — Incorporated by reference to Exhibit 4(b) to MSD's Registration Statement on Form S-3 filed September 25, 1997 (No. 333-36383)
4.3	—	Second Supplemental Indenture to the 1991 Indenture, dated November 3, 2009 — Incorporated by reference to Exhibit 4.3 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No.1-6571)
4.4	—	Third Supplemental Indenture to the 1991 Indenture, dated May 1, 2012 — Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the period ended March 31, 2012 (No. 1-6571)
4.5	—	Indenture, dated November 26, 2003, between Merck & Co., Inc. (f/k/a Schering-Plough Corporation) and The Bank of New York as Trustee (the 2003 Indenture) — Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed November 28, 2003 (No. 1-6571)
4.6	—	Second Supplemental Indenture to the 2003 Indenture (including Form of Note), dated November 26, 2003 — Incorporated by reference to Exhibit 4.3 to Schering-Plough's Current Report on Form 8-K filed November 28, 2003 (No. 1-6571)
4.7	—	Third Supplemental Indenture to the 2003 Indenture (including Form of Note), dated September 17, 2007 — Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed September 17, 2007 (No. 1-6571)

Exhibit Number		Description
4.8	—	Fifth Supplemental Indenture to the 2003 Indenture, dated November 3, 2009 — Incorporated by reference to Exhibit 4.4 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
4.9	—	Indenture, dated as of January 6, 2010, between Merck & Co., Inc. and U.S. Bank Trust National Association, as Trustee — Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed December 10, 2010 (No. 1-6571)
4.10	—	2.900% Notes due 2024 Officers' Certificate of the Company dated March 7, 2019, including form of the 2024 Notes - Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed March 7, 2019 (No. 1-6571)
4.11	—	3.400% Notes due 2029 Officers' Certificate of the Company dated March 7, 2019, including form of the 2029 Notes - Incorporated by reference to Exhibit 4.2 to Merck & Co., Inc.'s Current Report on Form 8-K filed March 7, 2019 (No. 1-6571)
4.12	—	3.900% Notes due 2039 Officers' Certificate of the Company dated March 7, 2019, including form of the 2039 Notes - Incorporated by reference to Exhibit 4.3 to Merck & Co., Inc.'s Current Report on Form 8-K filed March 7, 2019 (No. 1-6571)
4.13	—	4.000% Notes due 2049 Officers' Certificate of the Company dated March 7, 2019, including form of the 2049 Notes - Incorporated by reference to Exhibit 4.4 to Merck & Co., Inc.'s Current Report on Form 8-K filed March 7, 2019 (No. 1-6571)
*10.1	—	Merck & Co., Inc. Executive Incentive Plan (as amended and restated effective June 1, 2015) — Incorporated by reference to Merck & Co., Inc.'s Schedule 14A filed April 13, 2015 (No. 1-6571)
*10.2	—	Merck & Co., Inc. Deferral Program Including the Base Salary Deferral Plan (Amended and Restated effective December 1, 2019)
*10.3	—	Merck & Co., Inc. 2010 Incentive Stock Plan (as amended and restated June 1, 2015) — Incorporated by reference to Merck & Co., Inc.'s Schedule 14A filed April 13, 2015 (No. 1-6571)
*10.4	—	Form of stock option terms for 2011 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.2 to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the period ended March 31, 2011 filed May 9, 2011 (No. 1-6571)
*10.5	—	Form of stock option terms for 2012 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.20 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2011 filed February 28, 2012 (No. 1-6571)
*10.6	—	Form of stock option terms for 2013 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.19 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2012 filed February 28, 2013 (No. 1-6571)
*10.7	—	Form of stock option terms for 2014 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.18 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2014 filed February 27, 2015 (No. 1-6571)
*10.8	—	Form of stock option terms for 2015 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.20 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2015 filed February 26, 2016 (No. 1-6571)
*10.9	—	Form of stock option terms for 2018 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by referent to Exhibit 10.12 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2017 filed February 27, 2018 (No. 1-6571)

Exhibit Number		Description
*10.10	—	Form of stock option terms for 2016 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.19 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2016 filed February 28, 2017 (No. 1-6571)
*10.11	—	Form of restricted stock unit terms for 2018 quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.17 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2017 filed on February 28, 2018 (No. 1-6571)
*10.12	—	2018 Performance Share Unit Award Terms under the Merck & Co., Inc. 2010 Stock Incentive Plan — Incorporated by reference to Exhibit 10 to Merck & Co., Inc.'s Current Report on Form 10-Q Quarterly Report for the period ended March 31, 2018 filed May 8, 2018 (No. 1-6571)
*10.13	—	Merck & Co., Inc. 2019 Incentive Stock Plan - Incorporated by reference to Appendix C to Merck & Co., Inc.'s Schedule 14A filed April 8, 2019 (No. 1-6571)
*10.14	—	Merck & Co., Inc. Change in Control Separation Benefits Plan (effective as amended and restated, as of January 1, 2013) — Incorporated by reference to Exhibit 10.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 29, 2012 (No. 1-6571)
*10.15	—	Merck & Co., Inc. U.S. Separation Benefits Plan (amended and restated as of January 1, 2019) - Incorporated by reference to Exhibit 10.19 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2018 filed February 27, 2019 (No. 1-6571)
*10.16	—	Merck & Co., Inc. 2010 Non-Employee Directors Stock Option Plan (amended and restated as of December 1, 2010) — Incorporated by reference to Exhibit 10.17 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2010 filed February 28, 2011 (No. 1-6571)
*10.17	—	Retirement Plan for the Directors of Merck & Co., Inc. (amended and restated June 21, 1996) — Incorporated by reference to Exhibit 10.C to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1996 filed August 13, 1996 (No. 1-3305)
*10.18	—	Merck & Co., Inc. Plan for Deferred Payment of Directors' Compensation (Amended and Restated effective as of January 1, 2020)
10.19	—	Distribution agreement between Schering-Plough and Centocor, Inc., dated April 3, 1998 — Incorporated by reference to Exhibit 10(u) to Schering-Plough's Amended 10-K for the year ended December 31, 2003 filed May 3, 2004 (No. 1-6571)†
10.20	—	Amendment Agreement to the Distribution Agreement between Centocor, Inc., CAN Development, LLC, and Schering-Plough (Ireland) Company — Incorporated by reference to Exhibit 10.1 to Schering-Plough's Current Report on Form 8-K filed December 21, 2007 (No. 1-6571)†
10.21	—	Severance Agreement and General Release between Merck & Co., Inc. and Adam H. Schechter, dated December 1, 2018 - Incorporated by reference to Exhibit 10.27 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2018 filed February 27, 2019 (No. 1-6571)
10.22	—	Offer Letter between Merck & Co., Inc. and Jennifer Zachary, dated March 16, 2018 - Incorporated by reference to Exhibit 10.28 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2018 filed February 27, 2019 (No. 1-6571)
21	—	Subsidiaries of Merck & Co., Inc.
23	—	Consent of Independent Registered Public Accounting Firm
24.1	—	Power of Attorney
24.2	—	Certified Resolution of Board of Directors
31.1	—	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
31.2	—	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer
32.1	—	Section 1350 Certification of Chief Executive Officer
32.2	—	Section 1350 Certification of Chief Financial Officer

Exhibit Number		Description
101.INS	—	XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	—	XBRL Taxonomy Extension Schema Document.
101.CAL	—	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	—	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	—	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	—	XBRL Taxonomy Extension Presentation Linkbase Document.
104	—	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* *Management contract or compensatory plan or arrangement.*

† *Certain portions of the exhibit have been omitted pursuant to a request for confidential treatment. The non-public information has been filed separately with the Securities and Exchange Commission pursuant to rule 24b-2 under the Securities Exchange Act of 1934, as amended.*

Long-term debt instruments under which the total amount of securities authorized does not exceed 10% of Merck & Co., Inc.'s total consolidated assets are not filed as exhibits to this report. Merck & Co., Inc. will furnish a copy of these agreements to the Securities and Exchange Commission on request.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: February 26, 2020

MERCK & CO., INC.

By: KENNETH C. FRAZIER
(Chairman, President and Chief Executive Officer)

By: /s/ JENNIFER ZACHARY
Jennifer Zachary
(Attorney-in-Fact)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signatures	Title	Date
KENNETH C. FRAZIER	Chairman, President and Chief Executive Officer; Principal Executive Officer; Director	February 26, 2020
ROBERT M. DAVIS	Executive Vice President, Global Services, and Chief Financial Officer; Principal Financial Officer	February 26, 2020
RITA A. KARACHUN	Senior Vice President Finance-Global Controller; Principal Accounting Officer	February 26, 2020
LESLIE A. BRUN	Director	February 26, 2020
THOMAS R. CECH	Director	February 26, 2020
MARY ELLEN COE	Director	February 26, 2020
PAMELA J. CRAIG	Director	February 26, 2020
THOMAS H. GLOCER	Director	February 26, 2020
ROCHELLE B. LAZARUS	Director	February 26, 2020
PAUL B. ROTHMAN	Director	February 26, 2020
PATRICIA F. RUSSO	Director	February 26, 2020
INGE G. THULIN	Director	February 26, 2020
WENDELL P. WEEKS	Director	February 26, 2020
PETER C. WENDELL	Director	February 26, 2020

Jennifer Zachary, by signing her name hereto, does hereby sign this document pursuant to powers of attorney duly executed by the persons named, filed with the Securities and Exchange Commission as an exhibit to this document, on behalf of such persons, all in the capacities and on the date stated, such persons including a majority of the directors of the Company.

By: /S/ JENNIFER ZACHARY
Jennifer Zachary
(Attorney-in-Fact)

10-K 1 mrk1231201810k.htm 2018 FORM 10-K
As filed with the Securities and Exchange Commission on February 27, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549

FORM 10-K

(MARK ONE)

☒ **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the Fiscal Year Ended December 31, 2018

or

☐ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the transition period from _____ to _____

Commission File No. 1-6571

Merck & Co., Inc.

2000 Galloping Hill Road
Kenilworth, N. J. 07033
(908) 740-4000

Incorporated in New Jersey — *I.R.S. Employer Identification No. 22-1918501*

Securities Registered pursuant to Section 12(b) of the Act:

Title of Each Class	*Name of Each Exchange on which Registered*
Common Stock ($0.50 par value)	New York Stock Exchange
1.125% Notes due 2021	New York Stock Exchange
0.500% Notes due 2024	New York Stock Exchange
1.875% Notes due 2026	New York Stock Exchange
2.500% Notes due 2034	New York Stock Exchange
1.375% Notes due 2036	New York Stock Exchange

Number of shares of Common Stock ($0.50 par value) outstanding as of January 31, 2019: 2,581,220,308.

Aggregate market value of Common Stock ($0.50 par value) held by non-affiliates on June 30, 2018 based on closing price on June 30, 2018: $161,991,000,000.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. **Yes** ☒ **No** ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. **Yes** ☐ **No** ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. **Yes** ☒ **No** ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). **Yes** ☒ **No** ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check One):

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

Documents Incorporated by Reference:

Document	*Part of Form 10-K*

Proxy Statement for the Annual Meeting of Shareholders to be held May 28, 2019, to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this report	Part III

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PART I

Item 1. Business.

Merck & Co., Inc. (Merck or the Company) is a global health care company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies and animal health products. The Company's operations are principally managed on a products basis and include four operating segments, which are the Pharmaceutical, Animal Health, Healthcare Services and Alliances segments.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities.

The Animal Health segment discovers, develops, manufactures and markets animal health products, including pharmaceutical and vaccine products, for the prevention, treatment and control of disease in all major livestock and companion animal species, which the Company sells to veterinarians, distributors and animal producers.

The Healthcare Services segment provides services and solutions that focus on engagement, health analytics and clinical services to improve the value of care delivered to patients.

The Alliances segment primarily includes results from the Company's relationship with AstraZeneca LP related to sales of Nexium and Prilosec, which concluded in 2018.

The Company was incorporated in New Jersey in 1970.

All product or service marks appearing in type form different from that of the surrounding text are trademarks or service marks owned, licensed to, promoted or distributed by Merck, its subsidiaries or affiliates, except as noted. All other trademarks or services marks are those of their respective owners.

Product Sales

Total Company sales, including sales of the Company's top pharmaceutical products, as well as sales of animal health products, were as follows:

($ in millions)	**2018**	2017	2016
Total Sales	**$ 42,294**	$ 40,122	$ 39,807
Pharmaceutical	**37,689**	35,390	35,151
Keytruda	**7,171**	3,809	1,402
Januvia/Janumet	**5,914**	5,896	6,109
Gardasil/Gardasil 9	**3,151**	2,308	2,173
ProQuad/M-M-R II/*Varivax*	**1,798**	1,676	1,640
Zetia/Vytorin	**1,355**	2,095	3,701
Isentress/Isentress HD	**1,140**	1,204	1,387
Bridion	**917**	704	482
Pneumovax 23	**907**	821	641
NuvaRing	**902**	761	777
Simponi	**893**	819	766
Animal Health	**4,212**	3,875	3,478
Livestock	**2,630**	2,484	2,287
Companion Animals	**1,582**	1,391	1,191
Other Revenues[(1)]	**393**	857	1,178

[(1)] *Other revenues are primarily comprised of Healthcare Services segment revenue, third-party manufacturing sales, and miscellaneous corporate revenues, including revenue hedging activities.*

Pharmaceutical

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. Certain of the products within the Company's franchises are as follows:

Oncology

Keytruda (pembrolizumab), the Company's anti-PD-1 (programmed death receptor-1) therapy, as monotherapy for the treatment of certain patients with non-small-cell lung cancer (NSCLC), melanoma, classical Hodgkin Lymphoma (cHL), urothelial carcinoma, head and neck squamous cell carcinoma (HNSCC), gastric or gastroesophageal junction adenocarcinoma, and microsatellite instability-high (MSI-H) or mismatch repair deficient cancer, and in combination with chemotherapy in certain patients with NSCLC. *Keytruda* is also used in the United States for monotherapy treatment of certain patients with cervical cancer, primary mediastinal large B-cell lymphoma (PMBCL), hepatocellular carcinoma, and Merkel cell carcinoma, and in combination with chemotherapy for patients with squamous NSCLC; *Emend* (aprepitant) for the prevention of chemotherapy-induced and post-operative nausea and vomiting; and *Temodar* (temozolomide) (marketed as *Temodal* outside the United States), a treatment for certain types of brain tumors. In addition, the Company recognizes alliance revenue related to sales of Lynparza (olaparib), an oral poly (ADP-ribose) polymerase (PARP) inhibitor, for certain types of ovarian and breast cancer; and Lenvima (lenvatinib) for certain types of thyroid cancer, hepatocellular carcinoma, and in combination for certain patients with renal cell carcinoma.

Vaccines

Gardasil (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant)/ *Gardasil* 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), vaccines to help prevent certain diseases caused by certain types of human papillomavirus (HPV)*; ProQuad* (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella; *M-M-R* II (Measles, Mumps and Rubella Virus Vaccine Live), a vaccine to help prevent measles, mumps and rubella; *Varivax* (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox (varicella); *Pneumovax* 23 (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease; *RotaTeq* (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children; and *Zostavax* (Zoster Vaccine Live), a vaccine to help prevent shingles (herpes zoster).

Hospital Acute Care

Bridion (sugammadex) Injection, a medication for the reversal of two types of neuromuscular blocking agents used during surgery; *Noxafil* (posaconazole) for the prevention of invasive fungal infections; *Invanz* (ertapenem sodium) for the treatment of certain infections; *Cubicin (*daptomycin for injection), an I.V. antibiotic for complicated skin and skin structure infections or bacteremia, when caused by designated susceptible organisms; *Cancidas* (caspofungin acetate), an anti-fungal product; *Primaxin* (imipenem and cilastatin sodium), an anti-bacterial product; and *Zerbaxa* (ceftolozane and tazobactam) is currently approved in the United States for the treatment of adult patients with complicated urinary tract infections caused by certain susceptible Gram-negative microorganisms, and is also indicated, in combination with metronidazole, for the treatment of adult patients with complicated intra-abdominal infections caused by certain susceptible Gram-negative and Gram-positive microorganisms.

Immunology

Simponi (golimumab), a once-monthly subcutaneous treatment for certain inflammatory diseases; and *Remicade* (infliximab), a treatment for inflammatory diseases, which the Company markets in Europe, Russia and Turkey.

Neuroscience

Belsomra (suvorexant), an orexin receptor antagonist indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

Virology

Isentress/Isentress HD (raltegravir), an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection; and *Zepatier* (elbasvir and grazoprevir) for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype (GT) 1 or GT4 infection, with ribavirin in certain patient populations.

Cardiovascular

Zetia (ezetimibe) (marketed as *Ezetrol* in most countries outside the United States); *Vytorin* (ezetimibe/simvastatin) (marketed as *Inegy* outside the United States); *Atozet* (ezetimibe and atorvastatin) (marketed in certain countries outside of the United States) and *Rosuzet* (ezetimibe and rosuvastatin) (marketed in certain countries outside of the United States), cholesterol modifying medicines; and Adempas (riociguat), a cardiovascular drug for the treatment of pulmonary arterial hypertension.

Diabetes

Januvia (sitagliptin) and *Janumet* (sitagliptin/metformin HCl) for the treatment of type 2 diabetes.

Women's Health

NuvaRing (etonogestrel/ethinyl estradiol vaginal ring), a vaginal contraceptive product; and *Implanon* (etonogestrel implant), a single-rod subdermal contraceptive implant/*Nexplanon* (etonogestrel implant), a single, radiopaque, rod-shaped subdermal contraceptive implant.

Animal Health

The Animal Health segment discovers, develops, manufactures and markets animal health products, including pharmaceutical and vaccine products, for the prevention, treatment and control of disease in all major livestock and companion animal species. Principal products in this segment include:

Livestock Products

Nuflor (Florfenicol) antibiotic range for use in cattle and swine; *Bovilis*/*Vista* vaccine lines for infectious diseases in cattle; *Banamine* (Flunixin meglumine) bovine and swine anti-inflammatory; *Estrumate* (cloprostenol sodium) for the treatment of fertility disorders in cattle; *Matrix* (altrenogest) fertility management for swine; *Resflor* (florfenicol and flunixin meglumine), a combination broad-spectrum antibiotic and non-steroidal anti-inflammatory drug for bovine respiratory disease; *Zuprevo* (Tildipirosin) for bovine respiratory disease; *Zilmax* (zilpaterol hydrochloride) and *Revalor* (trenbolone acetate and estradiol) to improve production efficiencies in beef cattle; *Safe-Guard* (fenbendazole) de-wormer for cattle; *M+Pac* (Mycoplasma Hyopneumoniae Bacterin) swine pneumonia vaccine; *Porcilis* (Lawsonia intracellularis baterin) and *Circumvent* (Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector) vaccine lines for infectious diseases in swine; *Nobilis*/*Innovax* (Live Marek's Disease Vector), vaccine lines for poultry; *Paracox* and *Coccivac* coccidiosis vaccines; *Exzolt*, a systemic treatment for poultry red mite infestations; *Slice* (Emamectin benzoate) parasiticide for sea lice in salmon; *Aquavac* (Avirulent Live Culture)/*Norvax* vaccines against bacterial and viral disease in fish; *Compact PD* vaccine for salmon; and *Aquaflor* (Florfenicol) antibiotic for farm-raised fish.

Companion Animal Products

Bravecto (fluralaner), a line of oral and topical products that kills fleas and ticks in dogs and cats for up to 12 weeks; *Nobivac* vaccine lines for flexible dog and cat vaccination; *Otomax* (Gentamicin sulfate, USP; Betamethasone valerate USP; and Clotrimazole USP ointment)/*Mometamax* (Gentamicin sulfate, USP, Mometasone Furoate Monohydrate and Clotrimazole, USP, Otic Suspension)/*Posatex* (Orbifloxacin, Mometasone Furoate Monohydrate and Posaconazole, Suspension) ear ointments for acute and chronic otitis; *Caninsulin*/*Vetsulin* (porcine insulin zinc suspension) diabetes mellitus treatment for dogs and cats; *Panacur* (fenbendazole)/*Safeguard* (fenbendazole) broad-spectrum anthelmintic (de-wormer) for use in many animals; *Regumate* (altrenogest) fertility management for horses; *Prestige* vaccine line for horses; and *Scalibor* (Deltamethrin)/*Exspot* for protecting against bites from fleas, ticks, mosquitoes and sandflies.

For a further discussion of sales of the Company's products, see Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" below.

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2018 Product Approvals

Set forth below is a summary of significant product approvals received by the Company in 2018.

Product	Date	Approval
Keytruda	December 2018	The Japanese Ministry of Health, Labor and Welfare (JMHLW) approved *Keytruda* for three expanded uses in unresectable, advanced or recurrent NSCLC, one in malignant melanoma, as well as a new indication in high microsatellite instability solid tumors.
	December 2018	The U.S. Food and Drug Administration (FDA) approved *Keytruda* for the treatment of adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma.
	December 2018	The European Commission (EC) approved *Keytruda* for the adjuvant treatment of adults with stage III melanoma and lymph node involvement who have undergone complete resection.
	November 2018	FDA approved *Keytruda* for the treatment of patients with hepatocellular carcinoma who have been previously treated with sorafenib.
	October 2018	FDA approved *Keytruda*, in combination with carboplatin and either paclitaxel or nab-paclitaxel, for the first-line treatment of patients with metastatic squamous non-small cell lung cancer (NSCLC).
	September 2018	EC approved *Keytruda* in combination with pemetrexed and platinum chemotherapy for the first-line treatment of metastatic nonsquamous NSCLC in adults whose tumors have no EGFR or ALK positive mutations.
	September 2018	EC approved *Keytruda* for the treatment of recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) in adults whose tumors express PD-L1 with a ≥ 50% TPS and progressing on or after platinum-containing chemotherapy.
	August 2018	FDA approved *Keytruda* in combination with pemetrexed and platinum chemotherapy for the first-line treatment of metastatic nonsquamous NSCLC patients with no EGFR or ALK genomic tumor aberrations.
	July 2018	The China National Drug Administration (CNDA) approved *Keytruda* for the treatment of adult patients with unresectable or metastatic melanoma following failure of one prior line of therapy.
	June 2018	FDA approved *Keytruda* for the treatment of adult and pediatric patients with refractory primary mediastinal large B-cell lymphoma (PMBCL), or who have relapsed after two or more prior lines of therapy.
	June 2018	FDA approved *Keytruda* for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 as determined by an FDA-approved test.
Lynparza[(1)]	December 2018	FDA approved Lynparza for use as maintenance treatment of certain patients with advanced ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy.
	July 2018	JMHLW approved Lynparza for use in patients with unresectable or recurrent *BRCA*-mutated, human epidermal growth factor receptor 2 (HER2)-negative breast cancer who have received prior chemotherapy.
	May 2018	EC approved Lynparza for use as a maintenance therapy in patients with platinum-sensitive relapsed high grade epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in response (complete or partial) to platinum based chemotherapy regardless of *BRCA* mutation status.
	January 2018	FDA approved Lynparza for use in patients with *BRCA*-mutated, HER2-negative metastatic breast cancer who have been previously treated with chemotherapy.
	January 2018	

		JMHLW approved Lynparza for use as a maintenance therapy in patients with platinum-sensitive relapsed ovarian cancer, regardless of *BRCA* mutation status.

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Lenvima[2]	September 2018	CNDA approved Lenvima for the treatment of certain patients with hepatocellular carcinoma.
	August 2018	FDA approved Lenvima for the treatment of certain patients with hepatocellular carcinoma.
	August 2018	EC approved Lenvima for the treatment of certain patients with hepatocellular carcinoma.
	March 2018	JMHLW approved Lenvima for the treatment of certain patients with unresectable hepatocellular carcinoma.
Gardasil 9	October 2018	FDA approved *Gardasil* 9 for an expanded age indication for use in women and men ages 27 to 45 for the prevention of certain cancers and diseases caused by the nine HPV types covered by the vaccine.
	April 2018	CNDA approved *Gardasil* 9 for use in girls and women ages 16 to 26.
Delstrigo	November 2018	EC approved *Delstrigo* (doravirine, lamivudine, and tenofovir disoproxil fumarate) for the treatment of adults infected with human immunodeficiency virus (HIV-1) without past or present evidence of resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, lamivudine, or tenofovir.
	August 2018	FDA approved *Delstrigo* for the treatment of HIV-1 infection in adult patients with no prior antiretroviral treatment experience.
Pifeltro	November 2018	EC approved *Pifeltro* (doravirine), in combination with other antiretroviral medicinal products, for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the NNRTI class.
	August 2018	FDA approved *Pifeltro* for the treatment of HIV-1 infection in adult patients with no prior antiretroviral treatment experience.
Isentress	March 2018	EC approved *Isentress* for an extension to the existing indication to cover treatment of neonates. *Isentress* is now indicated in combination with other anti-retroviral medicinal products for the treatment of HIV-1 infection.
Prevymis	January 2018	EC approved *Prevymis* (letermovir) for the prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant.
Steglatro, Steglujan and *Segluromet*[3]	March 2018	EC approved *Steglatro* (ertugliflozin), *Steglujan* (ertugliflozin and sitagliptin) and *Segluromet* (ertugliflozin and metformin hydrochloride) for the treatment of adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control (as monotherapy in patients for whom the use of metformin is considered inappropriate due to intolerance or contraindications, and in addition to other medicinal products for the treatment of diabetes).
Vaxelis	December 2018	FDA approved *Vaxelis* (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus, Haemophilus b Conjugate [Meningococcal Protein Conjugate] and Hepatitis B [Recombinant] Vaccine) for use in children from 6 weeks through 4 years of age (prior to the 5th birthday)

(1) *In July 2017, Merck and AstraZeneca entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza.*

(2) *In March 2018, Merck and Eisai Co., Ltd. announced a strategic collaboration for the worldwide co-development and co-commercialization of Eisai's Lenvima.*

(3)

In 2013, Merck and Pfizer Inc. announced that they entered into a worldwide collaboration, except Japan, for the co-development and co-promotion of ertugliflozin.

Competition and the Health Care Environment

Competition

The markets in which the Company conducts its business and the pharmaceutical industry in general are highly competitive and highly regulated. The Company's competitors include other worldwide research-based pharmaceutical companies, smaller research companies with more limited therapeutic focus, generic drug manufacturers and animal health care companies. The Company's operations may be adversely affected by generic and biosimilar competition as the Company's products mature, as well as technological advances of competitors, industry consolidation,

patents granted to competitors, competitive combination products, new products of competitors, the generic availability of competitors' branded products, and new information from clinical trials of marketed products or post-marketing surveillance. In addition, patent rights are increasingly being challenged by competitors, and the outcome can be highly uncertain. An adverse result in a patent dispute can preclude commercialization of products or negatively affect sales of existing products and could result in the payment of royalties or in the recognition of an impairment charge with respect to intangible assets associated with certain products. Competitive pressures have intensified as pressures in the industry have grown.

Pharmaceutical competition involves a rigorous search for technological innovations and the ability to market these innovations effectively. With its long-standing emphasis on research and development, the Company is well-positioned to compete in the search for technological innovations. Additional resources required to meet market challenges include quality control, flexibility to meet customer specifications, an efficient distribution system and a strong technical information service. The Company is active in acquiring and marketing products through external alliances, such as licensing arrangements and collaborations, and has been refining its sales and marketing efforts to address changing industry conditions. However, the introduction of new products and processes by competitors may result in price reductions and product displacements, even for products protected by patents. For example, the number of compounds available to treat a particular disease typically increases over time and can result in slowed sales growth or reduced sales for the Company's products in that therapeutic category.

The highly competitive animal health business is affected by several factors including regulatory and legislative issues, scientific and technological advances, product innovation, the quality and price of the Company's products, effective promotional efforts and the frequent introduction of generic products by competitors.

Health Care Environment and Government Regulation

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access. In the United States, federal and state governments for many years also have pursued methods to reduce the cost of drugs and vaccines for which they pay. For example, federal laws require the Company to pay specified rebates for medicines reimbursed by Medicaid and to provide discounts for outpatient medicines purchased by certain Public Health Service entities and hospitals serving a disproportionate share of low income or uninsured patients.

Against this backdrop, the United States enacted major health care reform legislation in 2010 (the Patient Protection and Affordable Care Act (ACA)). Various insurance market reforms have since advanced and state and federal insurance exchanges were launched in 2014. With respect to the effect of the law on the pharmaceutical industry, the law increased the mandated Medicaid rebate from 15.1% to 23.1%, expanded the rebate to Medicaid managed care utilization, and increased the types of entities eligible for the federal 340B drug discount program. The law also requires pharmaceutical manufacturers to pay a 50% point of service discount to Medicare Part D beneficiaries when they are in the Medicare Part D coverage gap (i.e., the so-called "donut hole"). Approximately $365 million, $385 million and $415 million was recorded by Merck as a reduction to revenue in 2018, 2017 and 2016, respectively, related to the donut hole provision. Beginning in 2019, the 50% point of service discount will increase to a 70% point of service discount in the coverage gap, as a result of the Balanced Budget Act of 2018. In addition, the 70% point of service discount will be extended to biosimilar products. Also, pharmaceutical manufacturers are now required to pay an annual non-tax deductible health care reform fee. The total annual industry fee was $4.1 billion in 2018 and will decrease to $2.8 billion in 2019 and is currently planned to remain at that amount thereafter. The fee is assessed on each company in proportion to its share of prior year branded pharmaceutical sales to certain government programs, such as Medicare and Medicaid. The Company recorded $124 million, $210 million and $193 million of costs within *Selling, general and administrative* expenses in 2018, 2017 and 2016, respectively, for the annual health care reform fee. In February 2016, the Centers for Medicare & Medicaid Services (CMS) issued the Medicaid rebate final rule that implements provisions of the ACA effective April 1, 2016. The rule provides comprehensive guidance on the calculation of Average Manufacturer Price and Best Price; two metrics utilized to determine the rebates drug manufacturers are required to pay to state Medicaid programs. The impact of changes resulting from the issuance of the rule is not material to Merck at this time. However, the Company is still awaiting guidance from CMS on two aspects of the rule that were deferred for later implementation. These include a definition of what constitutes a product 'line extension' and a delay in the participation of the U.S. Territories in the Medicaid Drug Rebate Program until April 1, 2020. The Company will evaluate the financial impact of these two elements when they become effective.

There is significant uncertainty about the future of the ACA in particular and health care laws in general in the United States. The Company is participating in the debate, and monitoring how any proposed changes could affect its business. The Company is unable to predict the likelihood of changes to the ACA. Depending on the nature of any repeal and replacement of the ACA, such actions could have a material adverse effect on the Company's business, cash flow, results of operations, financial position and prospects.

A number of states have passed pharmaceutical price and cost transparency laws. These laws typically require manufacturers to report certain product price information or other financial data to the state. In the case of a California law, manufacturers also are required to provide advance notification of price increases. The Company expects that states will continue their focus on pharmaceutical price transparency and that this focus will continue to exert pressure on product pricing.

The Company also faces increasing pricing pressure globally from managed care organizations, government agencies and programs that could negatively affect the Company's sales and profit margins. In the United States, these include (i) practices of managed care organizations, federal and state exchanges, and institutional and governmental purchasers, and (ii) U.S. federal laws and regulations related to Medicare and Medicaid, including the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and the ACA.

Changes to the health care system enacted as part of health care reform in the United States, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, could result in further pricing pressures. As an example, health care reform is contributing to an increase in the number of patients in the Medicaid program under which sales of pharmaceutical products are subject to substantial rebates.

In addition, in the effort to contain the U.S. federal deficit, the pharmaceutical industry could be considered a potential source of savings via legislative proposals that have been debated but not enacted. These types of revenue generating or cost saving proposals include additional direct price controls in the Medicare prescription drug program (Part D). In addition, Congress may again consider proposals to allow, under certain conditions, the importation of medicines from other countries. It remains very uncertain as to what proposals, if any, may be included as part of future federal budget deficit reduction proposals that would directly or indirectly affect the Company.

In the U.S. private sector, consolidation and integration among health care providers is a major factor in the competitive marketplace for pharmaceutical products. Health plans and pharmacy benefit managers have been consolidating into fewer, larger entities, thus enhancing their purchasing strength and importance. Private third-party insurers, as well as governments, increasingly employ formularies to control costs by negotiating discounted prices in exchange for formulary inclusion. Failure to obtain timely or adequate pricing or formulary placement for Merck's products or obtaining such placement at unfavorable pricing could adversely impact revenue. In addition to formulary tier co-pay differentials, private health insurance companies and self-insured employers have been raising co-payments required from beneficiaries, particularly for branded pharmaceuticals and biotechnology products. Private health insurance companies also are increasingly imposing utilization management tools, such as clinical protocols, requiring prior authorization for a branded product if a generic product is available or requiring the patient to first fail on one or more generic products before permitting access to a branded medicine. These same management tools are also used in treatment areas in which the payer has taken the position that multiple branded products are therapeutically comparable. As the U.S. payer market concentrates further and as more drugs become available in generic form, pharmaceutical companies may face greater pricing pressure from private third-party payers.

In order to provide information about the Company's pricing practices, the Company annually posts on its website its Pricing Transparency Report for the United States. The report provides the Company's average annual list price and net price increases across the Company's U.S. portfolio dating back to 2010.

Efforts toward health care cost containment also remain intense in European countries. The Company faces competitive pricing pressure resulting from generic and biosimilar drugs. In addition, a majority of countries in Europe attempt to contain drug costs by engaging in reference pricing in which authorities examine pre-determined markets for published prices of drugs by brand. The authorities then use price data from those markets to set new local prices for brand-name drugs, including the Company's. Guidelines for examining reference pricing are usually set in local markets and can be changed pursuant to local regulations.

In addition, in Japan, the pharmaceutical industry is subject to government-mandated biennial price reductions of pharmaceutical products and certain vaccines, which occurred in 2018. Furthermore, the government can order repricings for classes of drugs if it determines that it is appropriate under applicable rules.

Certain markets outside of the United States have also implemented other cost management strategies, such as health technology assessments (HTA), which require additional data, reviews and administrative processes, all of which increase the complexity, timing and costs of obtaining product reimbursement and exert downward pressure on available reimbursement. In the United States, HTAs are also being used by government and private payers.

The Company's focus on emerging markets has continued. Governments in many emerging markets are also focused on constraining health care costs and have enacted price controls and related measures, such as compulsory licenses, that aim to put pressure on the price of pharmaceuticals and constrain market access. The Company anticipates that pricing pressures and market access challenges will continue in 2019 to varying degrees in the emerging markets.

Beyond pricing and market access challenges, other conditions in emerging market countries can affect the Company's efforts to continue to grow in these markets, including potential political instability, changes in trade sanctions and embargoes, significant currency fluctuation and controls, financial crises, limited or changing availability of funding for health care, and other developments that may adversely impact the business environment for the Company. Further, the Company may engage third-party agents to assist in operating in emerging market countries, which may affect its ability to realize continued growth and may also increase the Company's risk exposure.

In addressing cost containment pressures, the Company engages in public policy advocacy with policymakers and continues to work to demonstrate that its medicines provide value to patients and to those who pay for health care. The Company advocates with government policymakers to encourage a long-term approach to sustainable health care financing that ensures access to innovative medicines and does not disproportionately target pharmaceuticals as a source of budget savings. In markets with historically low rates of health care spending, the Company encourages those governments to increase their investments and adopt market reforms in order to improve their citizens' access to appropriate health care, including medicines.

Operating conditions have become more challenging under the global pressures of competition, industry regulation and cost containment efforts. Although no one can predict the effect of these and other factors on the Company's business, the Company continually takes measures to evaluate, adapt and improve the organization and its business practices to better meet customer needs and believes that it is well-positioned to respond to the evolving health care environment and market forces.

The pharmaceutical industry is also subject to regulation by regional, country, state and local agencies around the world focused on standards and processes for determining drug safety and effectiveness, as well as conditions for sale or reimbursement.

Of particular importance is the FDA in the United States, which administers requirements covering the testing, approval, safety, effectiveness, manufacturing, labeling, and marketing of prescription pharmaceuticals. In some cases, the FDA requirements and practices have increased the amount of time and resources necessary to develop new products and bring them to market in the United States. At the same time, the FDA has committed to expediting the development and review of products bearing the "breakthrough therapy" designation, which has accelerated the regulatory review process for medicines with this designation. The FDA has also undertaken efforts to bring generic competition to market more efficiently and in a more timely manner.

The European Union (EU) has adopted directives and other legislation concerning the classification, labeling, advertising, wholesale distribution, integrity of the supply chain, enhanced pharmacovigilance monitoring and approval for marketing of medicinal products for human use. These provide mandatory standards throughout the EU, which may be supplemented or implemented with additional regulations by the EU member states. The Company's policies and procedures are already consistent with the substance of these directives; consequently, it is believed that they will not have any material effect on the Company's business.

The Company's business in China has grown rapidly in the past few years, and the importance of China to the Company's overall pharmaceutical and vaccines business has increased accordingly. Continued growth of the Company's business in China is dependent upon ongoing development of a favorable environment for innovative pharmaceutical products and vaccines, sustained access for the Company's current in-line products, and the absence

of trade impediments or adverse pricing controls. In recent years, the Chinese government has introduced and implemented a number of structural reforms to accelerate the shift to innovative products and reduce costs. Since 2017, there have been multiple new policies introduced by the government to improve access to new innovation, reduce the complexity of regulatory filings, and accelerate the review and approval process. This has led to a significant expansion of the new products being approved each year. Additionally, in 2017, the government updated the National Reimbursement Drug List for the first time in eight years. While the mechanism for drugs being added to the list evolves, it is likely that in the future, inclusion will require a price negotiation which could impact the outlook in the market for selected brands. While pricing pressure has always existed in China, health care reform has led to the acceleration of generic substitution, through a pilot tendering process for mature products that have generic substitutes with a Generic Quality Consistency Evaluation approval.

The Company believes that it will continue to be able to conduct its operations, including launching new drugs, in this regulatory environment. (See "Research and Development" below for a discussion of the regulatory approval process.)

Access to Medicines

As a global health care company, Merck's primary role is to discover and develop innovative medicines and vaccines. The Company also recognizes that it has an important role to play in helping to improve access to its products around the world. The Company's efforts in this regard are wide-ranging and include a set of principles that the Company strives to embed into its operations and business strategies to guide the Company's worldwide approach to expanding access to health care. In addition, the Company has many far-reaching philanthropic programs. The Merck Patient Assistance Program provides medicines and adult vaccines for free to people in the United States who do not have prescription drug or health insurance coverage and who, without the Company's assistance, cannot afford their Merck medicine and vaccines. In 2011, Merck launched "Merck for Mothers," a long-term effort with global health partners to end preventable deaths from complications of pregnancy and childbirth. Merck has also provided funds to the Merck Foundation, an independent organization, which has partnered with a variety of organizations dedicated to improving global health.

Privacy and Data Protection

The Company is subject to a significant number of privacy and data protection laws and regulations globally, many of which place restrictions on the Company's ability to transfer, access and use personal data across its business. The legislative and regulatory landscape for privacy and data protection continues to evolve. There has been increased attention to privacy and data protection issues in both developed and emerging markets with the potential to affect directly the Company's business, including the new EU General Data Protection Regulation, which went into effect on May 25, 2018 and imposes penalties up to 4% of global revenue. Additional laws and regulations enacted in the United States, Europe, Asia and Latin America, increases enforcement and litigation activity in the United States and other developed markets, and increases regulatory cooperation among privacy authorities globally. The Company has adopted a comprehensive global privacy program to manage these evolving risks which has been certified as compliant with and approved by the Asia Pacific Economic Cooperation Cross-Border Privacy Rules System, the EU-U.S. Privacy Shield Program, and the Binding Corporate Rules in the EU.

Distribution

The Company sells its human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers, such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccines are sold primarily to physicians, wholesalers, physician distributors and government entities. The Company's professional representatives communicate the effectiveness, safety and value of the Company's pharmaceutical and vaccine products to health care professionals in private practice, group practices, hospitals and managed care organizations. The Company sells its animal health products to veterinarians, distributors and animal producers.

Raw Materials

Raw materials and supplies, which are generally available from multiple sources, are purchased worldwide and are normally available in quantities adequate to meet the needs of the Company's business.

Patents, Trademarks and Licenses

Patent protection is considered, in the aggregate, to be of material importance to the Company's marketing of its products in the United States and in most major foreign markets. Patents may cover products *per se*, pharmaceutical formulations, processes for or intermediates useful in the manufacture of products or the uses of products. Protection for individual products extends for varying periods in accordance with the legal life of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent and its scope of coverage.

The Food and Drug Administration Modernization Act includes a Pediatric Exclusivity Provision that may provide an additional six months of market exclusivity in the United States for indications of new or currently marketed drugs if certain agreed upon pediatric studies are completed by the applicant. Current U.S. patent law provides additional patent term for periods when the patented product was under regulatory review by the FDA. The EU also provides an additional six months of pediatric market exclusivity attached to a product's Supplementary Protection Certificate (SPC). Japan provides the additional term for pediatric studies attached to market exclusivity unrelated to patent rights.

Patent portfolios developed for products introduced by the Company normally provide market exclusivity. The Company has the following key patent protection in the United States, the EU and Japan (including the potential for patent term extensions (PTE) and SPCs where indicated) for the following marketed products:

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Product	Year of Expiration (U.S.)	Year of Expiration (EU)[1]	Year of Expiration (Japan)[3]
Emend	Expired	2019	2019
Emend for Injection	2019	2020[2]	2020
Noxafil	2019	2019	N/A
Vaxelis[4]	2020 (method of making)	2021[5] (SPCs)	Not Marketed
Januvia	2022[2]	2022[2]	2025-2026
Janumet	2022[2]	2023	N/A
Janumet XR	2022[2]	N/A	N/A
Isentress	2024	2022[2]	2022
Simponi	N/A[6]	2025[7]	N/A[6]
Lenvima[8]	2025[2] (with pending PTE)	2021 (patents), 2026[2] (SPCs)	2026
Adempas[9]	2026[2]	2028[2]	2027-2028
Bridion	2026[2] (with pending PTE)	2023	2024
Nexplanon	2027 (device)	2025 (device)	Not Marketed
Bravecto	2027 (with pending PTE)	2025 (patents), 2029 (SPCs)	2029
Gardasil	2028	2021[2]	Expired
Gardasil 9	2028	2025 (patents), 2030[2] (SPCs)	N/A
Keytruda	2028	2028 (patents), 2030[2] (SPCs)	2032
Lynparza[10]	2028[2] (with pending PTE)	2024 (patents), 2029[2] (SPCs)	2028-2029 (with pending PTE)
Zerbaxa	2028[2] (with pending PTE)	2023 (patents), 2028[2] (SPCs)	N/A
Sivextro	2028[2]	2024 (patents), 2029[2] (SPCs)	2029 (with pending PTE)
Belsomra	2029[2]	N/A	2031
Prevymis	2029[2] (with pending PTE)	2024 (patents), 2029[2] (SPCs)	2029 (with pending PTE)
Steglatro[11]	2031[2] (with pending PTE)	2029 (patents), 2034[2] (SPCs)	N/A
Steglujan[11]	2031 (with pending PTE)	2029 (patents), 2034 (SPCs)	N/A
Segluromet[11]	2031 (with pending PTE)	2029 (patents), 2034 (SPCs)	N/A
Delstrigo	2032 (with pending PTE)	2031[12]	N/A
Pifeltro	2032 (with pending PTE)	2031[12]	N/A

N/A: Currently no marketing approval.

Note: Compound patent unless otherwise noted. Certain of the products listed may be the subject of patent litigation. See Item 8. "Financial Statements and Supplementary Data," Note 11. "Contingencies and Environmental Liabilities" below.

(1) The EU date represents the expiration date for the following five countries: France, Germany, Italy, Spain and the United Kingdom (Major EU Markets). If SPC applications have been filed but have not been granted in all Major EU Markets, both the patent expiry date and the SPC expiry date are listed.

(2) Eligible for 6 months Pediatric Exclusivity.

(3) The PTE system in Japan allows for a patent to be extended more than once provided the later approval is directed to a different indication from that of the previous approval. This may result in multiple PTE approvals for a given patent, each with its own expiration date.

(4) Being commercialized in a U.S.-based joint partnership with Sanofi Pasteur.

(5) SPCs are granted in four Major EU Markets and pending in one, based on a patent that expired in 2016.

(6) The Company has no marketing rights in the U.S. and Japan.

(7) Includes Pediatric Exclusivity, which is granted in four Major EU Markets and pending in one.

(8) Being developed and commercialized in a global strategic oncology collaboration with Eisai.

(9) Being commercialized in a worldwide collaboration with Bayer AG.

(10) Being developed and commercialized in a global strategic oncology collaboration with AstraZeneca.

(11) Being developed and promoted in a worldwide, except Japan, collaboration with Pfizer.

(12) SPC applications to be filed by May 2019.

While the expiration of a product patent normally results in a loss of market exclusivity for the covered pharmaceutical product, commercial benefits may continue to be derived from: (i) later-granted patents on processes and intermediates related to the most economical method of manufacture of the active ingredient of such product; (ii) patents relating to the use of such product; (iii) patents relating to novel compositions and formulations; and (iv) in the United States and certain other countries, market exclusivity that may be available under relevant law. The

effect of product patent expiration on pharmaceutical products also depends upon many other factors such as the nature of the market and the position of the product in it, the growth of the market, the complexities and economics of the process for manufacture of the active ingredient of the product and the requirements of new drug provisions of the Federal Food, Drug and Cosmetic Act or similar laws and regulations in other countries.

Additions to market exclusivity are sought in the United States and other countries through all relevant laws, including laws increasing patent life. Some of the benefits of increases in patent life have been partially offset by an

increase in the number of incentives for and use of generic products. Additionally, improvements in intellectual property laws are sought in the United States and other countries through reform of patent and other relevant laws and implementation of international treaties.

The Company has the following key U.S. patent protection for drug candidates under review in the United States by the FDA. Additional patent term may be provided for these pipeline candidates based on Patent Term Restoration and Pediatric Exclusivity.

Under Review (in the U.S.)	Currently Anticipated Year of Expiration (in the U.S.)
V920 (ebola vaccine)	2023
MK-7655A (relebactam + imipenem/cilastatin)	2029

The Company also has the following key U.S. patent protection for drug candidates in Phase 3 development:

Phase 3 Drug Candidate	Currently Anticipated Year of Expiration (in the U.S.)
MK-1242 (vericiguat)[1]	2031
MK-7264 (gefapixant)	2027
V114 (pneumoconjugate vaccine)	2031

[1] *Being developed in a worldwide clinical development collaboration with Bayer AG.*

Unless otherwise noted, the patents in the above charts are compound patents. Each patent is subject to any future patent term restoration of up to five years and six month pediatric market exclusivity, either or both of which may be available. In addition, depending on the circumstances surrounding any final regulatory approval of the compound, there may be other listed patents or patent applications pending that could have relevance to the product as finally approved; the relevance of any such application would depend upon the claims that ultimately may be granted and the nature of the final regulatory approval of the product. Also, regulatory exclusivity tied to the protection of clinical data is complementary to patent protection and, in some cases, may provide more effective or longer lasting marketing exclusivity than a compound's patent estate. In the United States, the data protection generally runs five years from first marketing approval of a new chemical entity, extended to seven years for an orphan drug indication and 12 years from first marketing approval of a biological product.

For further information with respect to the Company's patents, see Item 1A. "Risk Factors" and Item 8. "Financial Statements and Supplementary Data," Note 11. "Contingencies and Environmental Liabilities" below.

Worldwide, all of the Company's important products are sold under trademarks that are considered in the aggregate to be of material importance. Trademark protection continues in some countries as long as used; in other countries, as long as registered. Registration is for fixed terms and can be renewed indefinitely.

Royalty income in 2018 on patent and know-how licenses and other rights amounted to $135 million. Merck also incurred royalty expenses amounting to $1.3 billion in 2018 under patent and know-how licenses it holds.

Research and Development

The Company's business is characterized by the introduction of new products or new uses for existing products through a strong research and development program. At December 31, 2018, approximately 14,500 people were employed in the Company's research activities. The Company prioritizes its research and development efforts and focuses on candidates that it believes represent breakthrough science that will make a difference for patients and payers.

The Company maintains a number of long-term exploratory and fundamental research programs in biology and chemistry as well as research programs directed toward product development. The Company's research and development model is designed to increase productivity and improve the probability of success by prioritizing the Company's research and development resources on candidates the Company believes are capable of providing unambiguous, promotable advantages to patients and payers and delivering the maximum value of its approved medicines and vaccines through new indications and new formulations. Merck is pursuing emerging product opportunities independent of therapeutic area or modality (small molecule, biologics and vaccines) and is building its biologics capabilities. The Company is committed to ensuring that externally sourced programs remain an important

component of its pipeline strategy, with a focus on supplementing its internal research with a licensing and external alliance strategy focused on the entire spectrum of collaborations from early research to late-stage compounds, as well as access to new technologies.

The Company also reviews its pipeline to examine candidates that may provide more value through out-licensing. The Company continues to evaluate certain late-stage clinical development and platform technology assets to determine their out-licensing or sale potential.

The Company's clinical pipeline includes candidates in multiple disease areas, including cancer, cardiovascular diseases, diabetes, infectious diseases, neurosciences, obesity, pain, respiratory diseases, and vaccines.

In the development of human health products, industry practice and government regulations in the United States and most foreign countries provide for the determination of effectiveness and safety of new chemical compounds through preclinical tests and controlled clinical evaluation. Before a new drug or vaccine may be marketed in the United States, recorded data on preclinical and clinical experience are included in the New Drug Application (NDA) for a drug or the Biologics License Application (BLA) for a vaccine or biologic submitted to the FDA for the required approval.

Once the Company's scientists discover a new small molecule compound or biologic that they believe has promise to treat a medical condition, the Company commences preclinical testing with that compound. Preclinical testing includes laboratory testing and animal safety studies to gather data on chemistry, pharmacology, immunogenicity and toxicology. Pending acceptable preclinical data, the Company will initiate clinical testing in accordance with established regulatory requirements. The clinical testing begins with Phase 1 studies, which are designed to assess safety, tolerability, pharmacokinetics, and preliminary pharmacodynamic activity of the compound in humans. If favorable, additional, larger Phase 2 studies are initiated to determine the efficacy of the compound in the affected population, define appropriate dosing for the compound, as well as identify any adverse effects that could limit the compound's usefulness. In some situations, the clinical program incorporates adaptive design methodology to use accumulating data to decide how to modify aspects of the ongoing clinical study as it continues, without undermining the validity and integrity of the trial. One type of adaptive clinical trial is an adaptive Phase 2a/2b trial design, a two-stage trial design consisting of a Phase 2a proof-of-concept stage and a Phase 2b dose-optimization finding stage. If data from the Phase 2 trials are satisfactory, the Company commences large-scale Phase 3 trials to confirm the compound's efficacy and safety. Another type of adaptive clinical trial is an adaptive Phase 2/3 trial design, a study that includes an interim analysis and an adaptation that changes the trial from having features common in a Phase 2 study (e.g. multiple dose groups) to a design similar to a Phase 3 trial. An adaptive Phase 2/3 trial design reduces timelines by eliminating activities which would be required to start a separate study. Upon completion of Phase 3 trials, if satisfactory, the Company submits regulatory filings with the appropriate regulatory agencies around the world to have the product candidate approved for marketing. There can be no assurance that a compound that is the result of any particular program will obtain the regulatory approvals necessary for it to be marketed.

Vaccine development follows the same general pathway as for drugs. Preclinical testing focuses on the vaccine's safety and ability to elicit a protective immune response (immunogenicity). Pre-marketing vaccine clinical trials are typically done in three phases. Initial Phase 1 clinical studies are conducted in normal subjects to evaluate the safety, tolerability and immunogenicity of the vaccine candidate. Phase 2 studies are dose-ranging studies. Finally, Phase 3 trials provide the necessary data on effectiveness and safety. If successful, the Company submits regulatory filings with the appropriate regulatory agencies.

In the United States, the FDA review process begins once a complete NDA or BLA is submitted, received and accepted for review by the agency. Within 60 days after receipt, the FDA determines if the application is sufficiently complete to permit a substantive review. The FDA also assesses, at that time, whether the application will be granted a priority review or standard review. Pursuant to the Prescription Drug User Fee Act V (PDUFA), the FDA review period target for NDAs or original BLAs is either six months, for priority review, or ten months, for a standard review, from the time the application is deemed sufficiently complete. Once the review timelines are determined, the FDA will generally act upon the application within those timelines, unless a major amendment has been submitted (either at the Company's own initiative or the FDA's request) to the pending application. If this occurs, the FDA may extend the review period to allow for review of the new information, but by no more than three months. Extensions to the review period are communicated to the Company. The FDA can act on an application either by issuing an approval letter or by issuing a Complete Response Letter (CRL) stating that the application will not be approved in its present form and describing all deficiencies that the FDA has identified. Should the Company wish to pursue an application after receiving

a CRL, it can resubmit the application with information that addresses the questions or issues identified by the FDA in order to support approval. Resubmissions are subject to review period targets, which vary depending on the underlying submission type and the content of the resubmission.

The FDA has four program designations — Fast Track, Breakthrough Therapy, Accelerated Approval, and Priority Review — to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening conditions. The Fast Track designation provides pharmaceutical manufacturers with opportunities for frequent interactions with FDA reviewers during the product's development and the ability for the manufacturer to do a rolling submission of the NDA/BLA. A rolling submission allows completed portions of the application to be submitted and reviewed by the FDA on an ongoing basis. The Breakthrough Therapy designation provides manufacturers with all of the features of the Fast Track designation as well as intensive guidance on implementing an efficient development program for the product and a commitment by the FDA to involve senior managers and experienced staff in the review. The Accelerated Approval designation allows the FDA to approve a product based on an effect on a surrogate or intermediate endpoint that is reasonably likely to predict a product's clinical benefit and generally requires the manufacturer to conduct required post-approval confirmatory trials to verify the clinical benefit. The Priority Review designation means that the FDA's goal is to take action on the NDA/BLA within six months, compared to ten months under standard review.

In addition, under the Generating Antibiotic Incentives Now Act, the FDA may grant Qualified Infectious Disease Product (QIDP) status to antibacterial or antifungal drugs intended to treat serious or life threatening infections including those caused by antibiotic or antifungal resistant pathogens, novel or emerging infectious pathogens, or other qualifying pathogens. QIDP designation offers certain incentives for development of qualifying drugs, including Priority Review of the NDA when filed, eligibility for Fast Track designation, and a five-year extension of applicable exclusivity provisions under the Food, Drug and Cosmetic Act.

The primary method the Company uses to obtain marketing authorization of pharmaceutical products in the EU is through the "centralized procedure." This procedure is compulsory for certain pharmaceutical products, in particular those using biotechnological processes, and is also available for certain new chemical compounds and products. A company seeking to market an innovative pharmaceutical product through the centralized procedure must file a complete set of safety data and efficacy data as part of a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA). After the EMA evaluates the MAA, it provides a recommendation to the EC and the EC then approves or denies the MAA. It is also possible for new chemical products to obtain marketing authorization in the EU through a "mutual recognition procedure" in which an application is made to a single member state and, if the member state approves the pharmaceutical product under a national procedure, the applicant may submit that approval to the mutual recognition procedure of some or all other member states.

Outside of the United States and the EU, the Company submits marketing applications to national regulatory authorities. Examples of such are the Pharmaceuticals and Medical Devices Agency in Japan, Health Canada, Agência Nacional de Vigilância Sanatária in Brazil, Korea Food and Drug Administration in South Korea, Therapeutic Goods Administration in Australia and China Food and Drug Administration. Each country has a separate and independent review process and timeline. In many markets, approval times can be longer as the regulatory authority requires approval in a major market, such as the United States or the EU, and issuance of a Certificate of Pharmaceutical Product from that market before initiating their local review process.

Research and Development Update

The Company currently has several candidates under regulatory review in the United States and internationally.

Keytruda is an approved anti-PD-1 therapy in clinical development for expanded indications in different cancer types.

In February 2019, the FDA accepted and granted Priority Review for a supplemental BLA for *Keytruda* in combination with Inlyta (axitinib), a tyrosine kinase inhibitor, for the first-line treatment of patients with advanced renal cell carcinoma. This supplemental BLA is based on findings from the Phase 3 KEYNOTE-426 trial, which demonstrated that *Keytruda* in combination with axitinib, as compared to sunitinib, significantly improved overall survival (OS) and progression-free survival (PFS) in the first-line treatment of advanced renal cell carcinoma. These data were presented at the American Society for Clinical Oncology (ASCO) Genitourinary Cancers Symposium in

February 2019. The supplemental BLA also included supporting data from the Phase 1b KEYNOTE-035 trial. The FDA set a PDUFA date of June 20, 2019. Merck has filed data from KEYNOTE-426 with regulatory authorities worldwide.

In February 2019, the Committee for Medicinal Products for Human Use of the EMA adopted a positive opinion recommending *Keytruda,* in combination with carboplatin and either paclitaxel or nab-paclitaxel, for the first-line treatment of metastatic squamous NSCLC in adults. This recommendation is based on results from the pivotal Phase 3 KEYNOTE-407 trial, which enrolled patients regardless of PD-L1 tumor expression status. The trial showed a significant improvement in OS and PFS for patients taking *Keytruda* in combination with chemotherapy (carboplatin and either paclitaxel or nab-paclitaxel) compared with chemotherapy alone. If approved, this would mark the first approval in Europe for an anti-PD-1 therapy in combination with chemotherapy for adults with metastatic squamous NSCLC. In October 2018, the FDA approved *Keytruda* in combination with carboplatin-paclitaxel or nab-paclitaxel as a first-line treatment for metastatic squamous NSCLC, regardless of PD-L1 expression.

In December 2018, the FDA extended the action date for the supplemental BLA seeking approval for *Keytruda* as monotherapy for the first-line treatment of locally advanced or metastatic NSCLC in patients whose tumors express PD-L1 (TPS ≥1%) without EGFR or ALK genomic tumor aberrations. The supplemental BLA is based on results of the Phase 3 KEYNOTE-042 trial where *Keytruda* monotherapy demonstrated a significant improvement in OS compared with chemotherapy in this patient population. The Company submitted additional data and analyses to the FDA, which constituted a major amendment and extended the PDUFA date by three months to April 11, 2019. Merck continues to work closely with the FDA during the review of this supplemental BLA.

In February 2019, the FDA accepted and granted Priority Review for a supplemental BLA for *Keytruda* as monotherapy for the treatment of patients with advanced small-cell lung cancer (SCLC) whose disease has progressed after two or more lines of prior therapy. This supplemental BLA, which is seeking accelerated approval for this new indication, is based on data from the SCLC cohorts of the Phase 2 KEYNOTE-158 and Phase 1b KEYNOTE-028 trials. The FDA set a PDUFA date of June 17, 2019. *Keytruda* is also being studied in combination with chemotherapy in the ongoing Phase 3 KEYNOTE-604 study in patients with newly diagnosed extensive stage SCLC.

In February 2019, the FDA accepted a supplemental BLA for *Keytruda* as monotherapy or in combination with platinum and 5-fluorouracil chemotherapy for the first-line treatment of patients with recurrent or metastatic HNSCC. This supplemental BLA is based in part on data from the pivotal Phase 3 KEYNOTE-048 trial where *Keytruda* demonstrated a significant improvement in OS compared with the standard of care, as monotherapy in patients whose tumors expressed PD-L1 with Combined Positive Score (CPS)≥20 and CPS≥1 and in combination with chemotherapy in the total patient population. These data were presented at the European Society for Medical Oncology (ESMO) 2018 Congress. The FDA granted Priority Review to the supplemental BLA and set a PDUFA date of June 10, 2019. KEYNOTE-048 also serves as the confirmatory trial for KEYNOTE-012, a Phase 1b study which supported the previous accelerated approval for *Keytruda* as monotherapy for the treatment of patients with recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy.

In November 2018, Merck announced that the Phase 3 KEYNOTE-181 trial investigating *Keytruda* as monotherapy in the second-line treatment of advanced or metastatic esophageal or esophagogastric junction carcinoma met a primary endpoint of OS in patients whose tumors expressed PD-L1 (CPS ≥10). In this pivotal study, treatment with *Keytruda* resulted in a statistically significant improvement in OS compared to chemotherapy (paclitaxel, docetaxel or irinotecan) in patients with CPS ≥10, regardless of histology. The primary endpoint of OS was also evaluated in patients with squamous cell histology and in the entire intention-to-treat study population. While directionally favorable, statistical significance for OS was not met in these two patient groups. Per the statistical analysis plan, the key secondary endpoints of PFS and objective response rate (ORR) were not formally tested, as OS was not reached in the full intention-to-treat study population. These results were presented in January 2019 at the ASCO Gastrointestinal Cancers Symposium and have been submitted for regulatory review.

Additionally, *Keytruda* has received Breakthrough Therapy designation from the FDA for the treatment of high-risk early-stage triple-negative breast cancer in combination with neoadjuvant chemotherapy. The FDA's Breakthrough Therapy designation is intended to expedite the development and review of a candidate that is planned for use, alone or in combination, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

In October 2018, Merck announced the first presentation of results from an interim analysis of KEYNOTE-057, a Phase 2 trial evaluating *Keytruda* for previously treated patients with high-risk non-muscle invasive bladder cancer. An interim analysis of the study's primary endpoint showed a complete response rate of nearly 40% at three months with *Keytruda* in patients whose disease was unresponsive to Bacillus Calmette-Guérin therapy, the current standard of care for this disease, and who were ineligible for or who refused to undergo radical cystectomy. These results, as well as other study findings, were presented at the ESMO 2018 Congress.

In February 2019, Merck announced that the pivotal Phase 3 KEYNOTE-240 trial evaluating *Keytruda*, plus best supportive care, for the treatment of patients with advanced hepatocellular carcinoma who were previously treated with systemic therapy, did not meet its co-primary endpoints of OS and PFS compared with placebo plus best supportive care. In the final analysis of the study, there was an improvement in OS for patients treated with *Keytruda* compared to placebo, however these OS results did not meet statistical significance per the pre-specified statistical plan. Results for PFS were also directionally favorable in the *Keytruda* arm compared with placebo but did not reach statistical significance. The key secondary endpoint of ORR was not formally tested, since superiority was not reached for OS or PFS. Results will be presented at an upcoming medical meeting and have been shared with the FDA for discussion.

The *Keytruda* clinical development program consists of more than 900 clinical trials, including more than 600 trials that combine *Keytruda* with other cancer treatments. These studies encompass more than 30 cancer types including: bladder, cervical, colorectal, esophageal, gastric, head and neck, hepatocellular, Hodgkin lymphoma, non-Hodgkin lymphoma, melanoma, mesothelioma, nasopharyngeal, NSCLC, ovarian, PMBCL, prostate, renal, small-cell lung and triple-negative breast, many of which are currently in Phase 3 clinical development. Further trials are being planned for other cancers.

Lynparza, is an oral PARP inhibitor currently approved for certain types of ovarian and breast cancer. In July 2017, Merck and AstraZeneca entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza for multiple cancer types.

In April 2018, Merck and AstraZeneca announced that the EMA validated for review the MAA for Lynparza for use in patients with deleterious or suspected deleterious *BRCA*-mutated, HER2-negative metastatic breast cancer who have been previously treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. This was the first regulatory submission for a PARP inhibitor in breast cancer in Europe.

Lynparza tablets are also under review in the EU as a maintenance treatment in patients with newly-diagnosed, *BRCA*-mutated advanced ovarian cancer who were in complete or partial response following first-line standard platinum-based chemotherapy. This submission was based on positive results from the pivotal Phase 3 SOLO-1 trial. The trial showed a statistically-significant and clinically-meaningful improvement in PFS for Lynparza compared to placebo, reducing the risk of disease progression or death by 70% in patients with newly-diagnosed, *BRCA*-mutated advanced ovarian cancer who were in complete or partial response to platinum-based chemotherapy.

In December 2018, Merck and AstraZeneca announced positive results from the randomized, open-label, controlled, Phase 3 SOLO-3 trial of Lynparza tablets in patients with relapsed ovarian cancer after two or more lines of treatment. The trial was conducted as a post-approval commitment in agreement with the FDA. Results from the trial showed *BRCA*-mutated advanced ovarian cancer patients treated with Lynparza following two or more prior lines of chemotherapy demonstrated a statistically significant and clinically meaningful improvement in the primary endpoint of ORR and the key secondary endpoint of PFS compared to chemotherapy. Merck and AstraZeneca plan to discuss these results with the FDA.

MK-7655A is a combination of relebactam, an investigational beta-lactamase inhibitor, and imipenem/cilastatin (an approved carbapenem antibiotic). In February 2019, Merck announced that the FDA accepted for Priority Review an NDA for MK-7655A for the treatment of complicated urinary tract infections and complicated intra-abdominal infections caused by certain susceptible Gram-negative bacteria in adults with limited or no alternative therapies available. The PDUFA date is July 16, 2019. In April 2018, Merck announced that a pivotal Phase 3 study of MK-7655A demonstrated a favorable overall response in the treatment of certain imipenem-non-susceptible bacterial infections, the primary endpoint, with lower treatment-emergent nephrotoxicity (kidney toxicity), a secondary endpoint, compared to a colistin (colistimethate sodium) plus imipenem/cilastatin regimen. The FDA had previously designated this combination a Qualified Infectious Disease Product with designated Fast Track status for the treatment of hospital-

acquired bacterial pneumonia, ventilator-associated bacterial pneumonia, complicated intra-abdominal infections and complicated urinary tract infections.

V920 (rVSVΔG-ZEBOV-GP, live attenuated), is an investigational Ebola Zaire disease vaccine candidate being studied in large scale Phase 2/3 clinical trials. In December 2015, Merck announced that the application for Emergency Use Assessment and Listing (EUAL) for V920 was accepted for review by the World Health Organization (WHO). According to the WHO, the EUAL process is designed to expedite the availability of vaccines needed for public health emergencies such as another outbreak of Ebola. The WHO decision to grant V920 EUAL status will be based on data regarding quality, safety, and efficacy/effectiveness; as well as a risk/benefit analysis for emergency use. While EUAL designation allows for emergency use, the vaccine remains investigational and has not yet been licensed for commercial distribution. In July 2016, Merck announced that the FDA granted V920 Breakthrough Therapy designation, and that the EMA granted the vaccine candidate PRIME (PRIority MEdicines) status. In November 2018, Merck announced that it has started the submission of a rolling BLA to the FDA for V920. This rolling submission was made pursuant to the FDA's Breakthrough Therapy designation. Merck expects the rolling submission of the BLA to be completed in 2019. The Company also intends to file V920 with the EMA in 2019.

In February 2019, Merck announced that the FDA accepted for Priority Review a supplemental NDA for *Zerbaxa* to treat adult patients with nosocomial pneumonia, including ventilator-associated pneumonia, caused by certain susceptible Gram-negative microorganisms. The PDUFA date is June 3, 2019. *Zerbaxa* is also under review for this indication by the EMA. *Zerbaxa* is currently approved in the United States for the treatment of adult patients with complicated urinary tract infections caused by certain susceptible Gram-negative microorganisms, and is also indicated, in combination with metronidazole, for the treatment of adult patients with complicated intra-abdominal infections caused by certain susceptible Gram-negative and Gram-positive microorganisms.

In addition to the candidates under regulatory review, the Company has several drug candidates in Phase 3 clinical development in addition to the *Keytruda* programs discussed above.

MK-7264, gefapixant, is a selective, non-narcotic, orally-administered P2X3-receptor agonist being investigated in Phase 3 trials for the treatment of refractory, chronic cough and in a Phase 2 trial for the treatment of women with endometriosis-related pain.

Lenvima, is an orally available tyrosine kinase inhibitor currently approved for certain types of thyroid cancer, hepatocellular carcinoma, and in combination for certain patients with renal cell carcinoma. In March 2018, Merck and Eisai entered into a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima. Under the agreement, Merck and Eisai will develop and commercialize Lenvima jointly, both as monotherapy and in combination with *Keytruda*. Per the agreement, the companies will jointly initiate clinical studies evaluating the *Keytruda*/Lenvima combination to support 11 potential indications in six types of cancer (endometrial cancer, NSCLC, hepatocellular carcinoma, head and neck cancer, bladder cancer and melanoma), as well as a basket trial targeting multiple cancer types. The FDA granted Breakthrough Therapy designation for *Keytruda* in combination with Lenvima for the potential treatment of patients with advanced and/or metastatic renal cell carcinoma and for the potential treatment of certain patients with advanced and/or metastatic non-microsatellite instability high/proficient mismatch repair endometrial carcinoma.

MK-1242, vericiguat, is an investigational treatment for heart failure being studied in patients suffering from chronic heart failure with reduced ejection fracture (Phase 3 clinical trial) and from chronic heart failure with preserved ejection fracture (Phase 2 clinical trial). The development of vericiguat is part of a worldwide strategic collaboration between Merck and Bayer.

V114 is an investigational polyvalent conjugate vaccine for the prevention of pneumococcal disease. In June 2018, Merck initiated the first Phase 3 study in the adult population for the prevention of invasive pneumococcal disease. Currently five Phase 3 adult studies are ongoing, including studies in healthy adults 50 years of age or older, adults with risk factors for pneumococcal disease, those infected with HIV, and those who are recipients of allogeneic hematopoietic stem cell transplant. In October 2018, Merck began the first Phase 3 study in the pediatric population. Currently, three studies are ongoing, including studies in healthy infants and in children afflicted with sickle cell disease. In January 2019, Merck announced that V114 received Breakthrough Therapy designation from the FDA for the prevention of invasive pneumococcal disease caused by the vaccine serotypes in pediatric patients 6 weeks to 18 years of age.

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As a result of changes in the herpes zoster vaccine environment, Merck is ending development of V212, its investigational vaccine for the prevention of shingles in immunocompromised patients.

The chart below reflects the Company's research pipeline as of February 22, 2019. Candidates shown in Phase 3 include specific products and the date such candidate entered into Phase 3 development. Candidates shown in Phase 2 include the most advanced compound with a specific mechanism or, if listed compounds have the same mechanism, they are each currently intended for commercialization in a given therapeutic area. Small molecules and biologics are given MK-number designations and vaccine candidates are given V-number designations. Except as otherwise noted, candidates in Phase 1, additional indications in the same therapeutic area (other than with respect to cancer and certain other indications) and additional claims, line extensions or formulations for in-line products are not shown.

Phase 2	Phase 3 (Phase 3 Entry Date)	Under Review
Cancer	**Cancer**	**New Molecular Entities/Vaccines**
MK-3475 *Keytruda*	MK-3475 *Keytruda*	**Bacterial Infection**
Advanced Solid Tumors	Breast (October 2015)	MK-7655A relebactam+imipenem/cilastatin (U.S.)
Cutaneous Squamous Cell Carcinoma	Cervical (October 2018) (EU)	**Ebola Vaccine**
Prostate	Colorectal (November 2015)	V920*(4)* (U.S.)
MK-7902 Lenvima*(1)*	Esophageal (December 2015)	
Biliary Tract	Gastric (May 2015) (EU)	
Non-Small-Cell Lung	Hepatocellular (May 2016) (EU)	**Certain Supplemental Filings**
V937 *Cavatak*	Mesothelioma (May 2018)	**Cancer**
Melanoma	Nasopharyngeal (April 2016)	MK-3475 *Keytruda*
MK-7690	Ovarian (December 2018)	• First-Line Advanced Renal Cell Carcinoma (KEYNOTE-426) (U.S.)
Colorectal*(2)*	Renal (October 2016) (EU)	• First-Line Metastatic Squamous Non-Small-Cell Lung Cancer (KEYNOTE-407) (EU)
MK-7339 Lynparza*(1)*	Small-Cell Lung (May 2017) (EU)	• First-Line Metastatic Non-Small-Cell Lung Cancer (KEYNOTE-042) (U.S.) (EU)
Advanced Solid Tumors	MK-7902 Lenvima*(1,2)*	• Third-Line Advanced Small-Cell Lung Cancer (KEYNOTE-158) (U.S.)
Cytomegalovirus Vaccine	Endometrial (June 2018)	• First-Line Head and Neck Cancer (KEYNOTE-048) (U.S.)
V160	MK-7339 Lynparza*(1)*	• Alternative Dosing Regimen (Q6W) (EU)
Diabetes Mellitus	Pancreatic (December 2014)	MK-7339 Lynparza*(1)*
MK-8521*(3)*	Prostate (April 2017)	• Second-Line Metastatic Breast Cancer (EU)
HIV-1 Infection	**Cough**	• First-Line Advanced Ovarian Cancer (EU)
MK-8591	MK-7264 (gefapixant) (March 2018)	**HABP/VABP***(5)*
Pediatric Neurofibromatosis Type-1	**Heart Failure**	MK-7625A *Zerbaxa* (U.S.)
MK-5618 (selumetinib)*(1)*	MK-1242 (vericiguat) (September 2016)*(1)*	
Respiratory Syncytial Virus	**Pneumoconjugate Vaccine**	**Footnotes:**
MK-1654	V114 (June 2018)	*(1)* Being developed in a collaboration.
Schizophrenia		*(2)* Being developed in combination with *Keytruda.*
MK-8189		*(3)* Development is currently on hold.
		(4) Rolling submission.
		(5) HABP - Hospital-Acquired Bacterial Pneumonia / VABP - Ventilator-Associated Bacterial Pneumonia

Employees

As of December 31, 2018, the Company had approximately 69,000 employees worldwide, with approximately 25,400 employed in the United States, including Puerto Rico. Approximately 30% of worldwide employees of the Company are represented by various collective bargaining groups.

Restructuring Activities

In 2010 and 2013, the Company commenced actions under global restructuring programs designed to streamline its cost structure. The actions under these programs include the elimination of positions in sales, administrative and headquarters organizations, as well as the sale or closure of certain manufacturing and research and

development sites and the consolidation of office facilities. The Company also continues to reduce its global real estate footprint and improve the efficiency of its manufacturing and supply network. Since inception of the programs through December 31, 2018, Merck has eliminated approximately 45,510 positions comprised of employee separations, as well as the elimination of contractors and vacant positions. The Company has substantially completed the actions under these programs.

Environmental Matters

The Company believes that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on the Company. The Company is also remediating environmental contamination resulting from past industrial activity at certain of its sites. Expenditures for remediation and environmental liabilities were $16 million in 2018, and are estimated at $57 million in the aggregate for the years 2019 through 2023. These amounts do not consider potential recoveries from other parties. The Company has taken an active role in identifying and accruing for these costs and, in management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $71 million and $82 million at December 31, 2018 and 2017, respectively. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed $60 million in the aggregate. Management also does not believe that these expenditures should have a material adverse effect on the Company's financial position, results of operations, liquidity or capital resources for any year.

Merck believes that climate change could present risks to its business. Some of the potential impacts of climate change to its business include increased operating costs due to additional regulatory requirements, physical risks to the Company's facilities, water limitations and disruptions to its supply chain. These potential risks are integrated into the Company's business planning including investment in reducing energy, water use and greenhouse gas emissions. The Company does not believe these risks are material to its business at this time.

Geographic Area Information

The Company's operations outside the United States are conducted primarily through subsidiaries. Sales worldwide by subsidiaries outside the United States as a percentage of total Company sales were 57% of sales in 2018, 57% of sales in 2017 and 54% of sales in 2016.

The Company's worldwide business is subject to risks of currency fluctuations, governmental actions and other governmental proceedings abroad. The Company does not regard these risks as a deterrent to further expansion of its operations abroad. However, the Company closely reviews its methods of operations and adopts strategies responsive to changing economic and political conditions.

Merck has operations in countries located in Latin America, the Middle East, Africa, Eastern Europe and Asia Pacific. Business in these developing areas, while sometimes less stable, offers important opportunities for growth over time.

Available Information

The Company's Internet website address is *www.merck.com*. The Company will make available, free of charge at the "Investors" portion of its website, its Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after such reports are electronically filed with, or furnished to, the U.S. Securities and Exchange Commission (SEC). The address of that website is http://www.sec.gov. In addition, the Company will provide without charge a copy of its Annual Report on Form 10-K, including financial statements and schedules, upon the written request of any shareholder to the Office of the Secretary, Merck & Co., Inc., 2000 Galloping Hill Road, K1-4157, Kenilworth, NJ 07033 U.S.A.

The Company's corporate governance guidelines and the charters of the Board of Directors' four standing committees are available on the Company's website at *www.merck.com/about/leadership* and all such information is available in print to any shareholder who requests it from the Company.

Item 1A. Risk Factors.

Investors should carefully consider all of the information set forth in this Form 10-K, including the following risk factors, before deciding to invest in any of the Company's securities. The risks below are not the only ones the Company faces. Additional risks not currently known to the Company or that the Company presently deems immaterial may also impair its business operations. The Company's business, financial condition, results of operations or prospects could be materially adversely affected by any of these risks. This Form 10-K also contains forward-looking statements that involve risks and uncertainties. The Company's results could materially differ from those anticipated in these forward-looking statements as a result of certain factors, including the risks it faces described below and elsewhere. See "Cautionary Factors that May Affect Future Results" below.

The Company is dependent on its patent rights, and if its patent rights are invalidated or circumvented, its business would be adversely affected.

Patent protection is considered, in the aggregate, to be of material importance to the Company's marketing of human health and animal health products in the United States and in most major foreign markets. Patents covering products that it has introduced normally provide market exclusivity, which is important for the successful marketing and sale of its products. The Company seeks patents covering each of its products in each of the markets where it intends to sell the products and where meaningful patent protection is available.

Even if the Company succeeds in obtaining patents covering its products, third parties or government authorities may challenge or seek to invalidate or circumvent its patents and patent applications. It is important for the Company's business to defend successfully the patent rights that provide market exclusivity for its products. The Company is often involved in patent disputes relating to challenges to its patents or claims by third parties of infringement against the Company. The Company defends its patents both within and outside the United States, including by filing claims of infringement against other parties. See Item 8. "Financial Statements and Supplementary Data," Note 11. "Contingencies and Environmental Liabilities" below. In particular, manufacturers of generic pharmaceutical products from time to time file abbreviated NDAs with the FDA seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned or licensed by the Company. The Company normally responds by defending its patent, including by filing lawsuits alleging patent infringement. Patent litigation and other challenges to the Company's patents are costly and unpredictable and may deprive the Company of market exclusivity for a patented product or, in some cases, third-party patents may prevent the Company from marketing and selling a product in a particular geographic area.

Additionally, certain foreign governments have indicated that compulsory licenses to patents may be granted in the case of national emergencies or in other circumstances, which could diminish or eliminate sales and profits from those regions and negatively affect the Company's results of operations. Further, court decisions relating to other companies' patents, potential legislation relating to patents, as well as regulatory initiatives may result in a more general weakening of intellectual property protection.

If one or more important products lose patent protection in profitable markets, sales of those products are likely to decline significantly as a result of generic versions of those products becoming available. The Company's results of operations may be adversely affected by the lost sales unless and until the Company has successfully launched commercially successful replacement products. In addition, if products that were measured at fair value and capitalized in connection with acquisitions experience difficulties in the market that negatively affect product cash flows, the Company may recognize material non-cash impairment charges with respect to the value of those products.

A chart listing the patent protection for certain of the Company's marketed products, and U.S. patent protection for candidates under review and in Phase 3 clinical development is set forth above in Item 1. "Business — Patents, Trademarks and Licenses."

As the Company's products lose market exclusivity, the Company generally experiences a significant and rapid loss of sales from those products.

The Company depends upon patents to provide it with exclusive marketing rights for its products for some period of time. Loss of patent protection for one of the Company's products typically leads to a significant and rapid loss of sales for that product as lower priced generic versions of that drug become available. In the case of products that contribute significantly to the Company's sales, the loss of market exclusivity can have a material adverse effect

on the Company's business, cash flow, results of operations, financial position and prospects. For example, pursuant to an agreement with a generic manufacturer, that manufacturer launched in the United States a generic version of *Zetia* in December 2016. In addition, the Company lost U.S. patent protection for *Vytorin* in April 2017. As a result, the Company experienced a significant and rapid loss of sales of *Zetia* and *Vytorin* in the United States in 2017, which continued in 2018. Furthermore, the patents that provide U.S. and EU market exclusivity for *Noxafil* will expire in July 2019 and December 2019, respectively, and the Company anticipates a significant decline in U.S. and EU *Noxafil* sales thereafter.

Key products generate a significant amount of the Company's profits and cash flows, and any events that adversely affect the markets for its leading products could have a material and negative impact on results of operations and cash flows.

The Company's ability to generate profits and operating cash flow depends largely upon the continued profitability of the Company's key products, such as *Keytruda, Januvia*, *Janumet*, *Gardasil/Gardasil* 9 and *Bridion*. As a result of the Company's dependence on key products, any event that adversely affects any of these products or the markets for any of these products could have a significant adverse impact on results of operations and cash flows. These events could include loss of patent protection, increased costs associated with manufacturing, generic or over-the-counter availability of the Company's product or a competitive product, the discovery of previously unknown side effects, results of post-approval trials, increased competition from the introduction of new, more effective treatments and discontinuation or removal from the market of the product for any reason. Such events could have a material adverse effect on the sales of any such products.

For example, in 2018, sales of *Zepatier* were materially unfavorably affected by increasing competition and declining patient volumes. Sales of *Zostavax* were also materially unfavorably affected due to competition. The Company expects that competition will continue to adversely affect the sales of these products.

The Company's research and development efforts may not succeed in developing commercially successful products and the Company may not be able to acquire commercially successful products in other ways; in consequence, the Company may not be able to replace sales of successful products that have lost patent protection.

Like other major pharmaceutical companies, in order to remain competitive, the Company must continue to launch new products. Expected declines in sales of products after the loss of market exclusivity mean that the Company's future success is dependent on its pipeline of new products, including new products that it may develop through collaborations and joint ventures and products that it is able to obtain through license or acquisition. To accomplish this, the Company commits substantial effort, funds and other resources to research and development, both through its own dedicated resources and through various collaborations with third parties. There is a high rate of failure inherent in the research and development process for new drugs. As a result, there is a high risk that funds invested by the Company in research programs will not generate financial returns. This risk profile is compounded by the fact that this research has a long investment cycle. To bring a pharmaceutical compound from the discovery phase to market may take a decade or more and failure can occur at any point in the process, including later in the process after significant funds have been invested.

For a description of the research and development process, see Item 1. "Business — Research and Development" above. Each phase of testing is highly regulated and during each phase there is a substantial risk that the Company will encounter serious obstacles or will not achieve its goals, therefore, the Company may abandon a product in which it has invested substantial amounts of time and resources. Some of the risks encountered in the research and development process include the following: pre-clinical testing of a new compound may yield disappointing results; competing products from other manufacturers may reach the market first; clinical trials of a new drug may not be successful; a new drug may not be effective or may have harmful side effects; a new drug may not be approved by the regulators for its intended use; it may not be possible to obtain a patent for a new drug; payers may refuse to cover or reimburse the new product; or sales of a new product may be disappointing.

The Company cannot state with certainty when or whether any of its products now under development will be approved or launched; whether it will be able to develop, license or otherwise acquire compounds, product candidates or products; or whether any products, once launched, will be commercially successful. The Company must maintain a continuous flow of successful new products and successful new indications or brand extensions for existing products

sufficient both to cover its substantial research and development costs and to replace sales that are lost as profitable products lose market exclusivity or are displaced by competing products or therapies. Failure to do so in the short term or long term would have a material adverse effect on the Company's business, results of operations, cash flow, financial position and prospects.

The Company's success is dependent on the successful development and marketing of new products, which are subject to substantial risks.

Products that appear promising in development may fail to reach the market or fail to succeed for numerous reasons, including the following:

- findings of ineffectiveness, superior safety or efficacy of competing products, or harmful side effects in clinical or pre-clinical testing;
- failure to receive the necessary regulatory approvals, including delays in the approval of new products and new indications, or the anticipated labeling, and uncertainties about the time required to obtain regulatory approvals and the benefit/risk standards applied by regulatory agencies in determining whether to grant approvals;
- failure in certain markets to obtain reimbursement commensurate with the level of innovation and clinical benefit presented by the product;
- lack of economic feasibility due to manufacturing costs or other factors; and
- preclusion from commercialization by the proprietary rights of others.

In the future, if certain pipeline programs are cancelled or if the Company believes that their commercial prospects have been reduced, the Company may recognize material non-cash impairment charges for those programs that were measured at fair value and capitalized in connection with acquisitions or certain collaborations.

Failure to successfully develop and market new products in the short term or long term would have a material adverse effect on the Company's business, results of operations, cash flow, financial position and prospects.

The Company's products, including products in development, cannot be marketed unless the Company obtains and maintains regulatory approval.

The Company's activities, including research, preclinical testing, clinical trials and the manufacturing and marketing of its products, are subject to extensive regulation by numerous federal, state and local governmental authorities in the United States, including the FDA, and by foreign regulatory authorities, including in the EU, Japan and China. In the United States, the FDA administers requirements covering the testing, approval, safety, effectiveness, manufacturing, labeling and marketing of prescription pharmaceuticals. In many cases, the FDA requirements have increased the amount of time and money necessary to develop new products and bring them to market in the United States. Regulation outside the United States also is primarily focused on drug safety and effectiveness and, in many cases, reduction in the cost of drugs. The FDA and foreign regulatory authorities have substantial discretion to require additional testing, to delay or withhold registration and marketing approval and to otherwise preclude distribution and sale of a product.

Even if the Company is successful in developing new products, it will not be able to market any of those products unless and until it has obtained all required regulatory approvals in each jurisdiction where it proposes to market the new products. Once obtained, the Company must maintain approval as long as it plans to market its new products in each jurisdiction where approval is required. The Company's failure to obtain approval, significant delays in the approval process, or its failure to maintain approval in any jurisdiction will prevent it from selling the products in that jurisdiction. The Company would not be able to realize revenues for those new products in any jurisdiction where it does not have approval.

Developments following regulatory approval may adversely affect sales of the Company's products.

Even after a product reaches the market, certain developments following regulatory approval may decrease demand for the Company's products, including the following:

- results in post-approval Phase 4 trials or other studies;

- the re-review of products that are already marketed;
- the recall or loss of marketing approval of products that are already marketed;
- changing government standards or public expectations regarding safety, efficacy or labeling changes; and
- greater scrutiny in advertising and promotion.

In the past several years, clinical trials and post-marketing surveillance of certain marketed drugs of the Company and of competitors within the industry have raised concerns that have led to recalls, withdrawals or adverse labeling of marketed products. Clinical trials and post-marketing surveillance of certain marketed drugs also have raised concerns among some prescribers and patients relating to the safety or efficacy of pharmaceutical products in general that have negatively affected the sales of such products. In addition, increased scrutiny of the outcomes of clinical trials has led to increased volatility in market reaction. Further, these matters often attract litigation and, even where the basis for the litigation is groundless, considerable resources may be needed to respond.

In addition, following in the wake of product withdrawals and other significant safety issues, health authorities such as the FDA, the EMA and Japan's Pharmaceutical and Medical Device Agency have increased their focus on safety when assessing the benefit/risk balance of drugs. Some health authorities appear to have become more cautious when making decisions about approvability of new products or indications and are re-reviewing select products that are already marketed, adding further to the uncertainties in the regulatory processes. There is also greater regulatory scrutiny, especially in the United States, on advertising and promotion and, in particular, direct-to-consumer advertising.

If previously unknown side effects are discovered or if there is an increase in negative publicity regarding known side effects of any of the Company's products, it could significantly reduce demand for the product or require the Company to take actions that could negatively affect sales, including removing the product from the market, restricting its distribution or applying for labeling changes. Further, in the current environment in which all pharmaceutical companies operate, the Company is at risk for product liability and consumer protection claims and civil and criminal governmental actions related to its products, research and/or marketing activities.

The Company faces intense competition from lower cost generic products.

In general, the Company faces increasing competition from lower-cost generic products. The patent rights that protect its products are of varying strengths and durations. In addition, in some countries, patent protection is significantly weaker than in the United States or in the EU. In the United States and the EU, political pressure to reduce spending on prescription drugs has led to legislation and other measures that encourage the use of generic and biosimilar products. Although it is the Company's policy to actively protect its patent rights, generic challenges to the Company's products can arise at any time, and the Company's patents may not prevent the emergence of generic competition for its products.

Loss of patent protection for a product typically is followed promptly by generic substitutes, reducing the Company's sales of that product. Availability of generic substitutes for the Company's drugs may adversely affect its results of operations and cash flow. In addition, proposals emerge from time to time in the United States and other countries for legislation to further encourage the early and rapid approval of generic drugs. Any such proposal that is enacted into law could worsen this substantial negative effect on the Company's sales and, potentially, its business, cash flow, results of operations, financial position and prospects.

The Company faces intense competition from competitors' products.

The Company's products face intense competition from competitors' products. This competition may increase as new products enter the market. In such an event, the competitors' products may be safer or more effective, more convenient to use, have better insurance coverage or reimbursement levels or be more effectively marketed and sold than the Company's products. Alternatively, in the case of generic competition, including the generic availability of competitors' branded products, they may be equally safe and effective products that are sold at a substantially lower price than the Company's products. As a result, if the Company fails to maintain its competitive position, this could have a material adverse effect on its business, cash flow, results of operations, financial position and prospects. In addition, if products that were measured at fair value and capitalized in connection with acquisitions experience

difficulties in the market that negatively impact product cash flows, the Company may recognize material non-cash impairment charges with respect to the value of those products.

The Company faces continued pricing pressure with respect to its products.

The Company faces continued pricing pressure globally and, particularly in mature markets, from managed care organizations, government agencies and programs that could negatively affect the Company's sales and profit margins. In the United States, these include (i) practices of managed care groups and institutional and governmental purchasers, (ii) U.S. federal laws and regulations related to Medicare and Medicaid, including the Medicare Prescription Drug Improvement and Modernization Act of 2003 and the ACA, and (iii) state activities aimed at increasing price transparency, including new laws as noted above in Item 1. "Competition and the Health Care Environment — Health Care Environment and Government Regulations." Changes to the health care system enacted as part of health care reform in the United States, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, could result in further pricing pressures. In addition, in the U.S., larger customers may, in the future, ask for and receive higher rebates on drugs in certain highly competitive categories. The Company must also compete to be placed on formularies of managed care organizations. Exclusion of a product from a formulary can lead to reduced usage in the managed care organization.

In order to provide information about the Company's pricing practices, the Company annually posts on its website its Pricing Transparency Report for the United States. The report provides the Company's average annual list price and net price increases across the Company's U.S. portfolio dating back to 2010.

Outside the United States, numerous major markets, including the EU, Japan and China have pervasive government involvement in funding health care and, in that regard, fix the pricing and reimbursement of pharmaceutical and vaccine products. Consequently, in those markets, the Company is subject to government decision making and budgetary actions with respect to its products.

The Company expects pricing pressures to continue in the future.

The health care industry in the United States will continue to be subject to increasing regulation and political action.

The Company believes that the health care industry will continue to be subject to increasing regulation as well as political and legal action, as future proposals to reform the health care system are considered by the Executive branch, Congress and state legislatures.

In 2010, the United States enacted major health care reform legislation in the form of the ACA. Various insurance market reforms have advanced and state and federal insurance exchanges were launched in 2014. With respect to the effect of the law on the pharmaceutical industry, the law increased the mandated Medicaid rebate from 15.1% to 23.1%, expanded the rebate to Medicaid managed care utilization, and increased the types of entities eligible for the federal 340B drug discount program.

The law also requires pharmaceutical manufacturers to pay a 50% point of service discount to Medicare Part D beneficiaries when they are in the Medicare Part D coverage gap (i.e., the so-called "donut hole"). In 2018, the Company's revenue was reduced by $365 million due to this requirement. Beginning in 2019, the 50% point of service discount will increase to a 70% point of service discount in the coverage gap, as a result of the Balanced Budget Act of 2018. In addition, the 70% point of service discount will be extended to biosimilar products. Also, pharmaceutical manufacturers are now required to pay an annual non-tax deductible health care reform fee. The total annual industry fee was $4.1 billion in 2018 and will be $2.8 billion in 2019. The fee is assessed on each company in proportion to its share of prior year branded pharmaceutical sales to certain government programs, such as Medicare and Medicaid. In 2018, the Company recorded $124 million of costs for this annual fee.

In 2016, the Centers for Medicare & Medicaid Services (CMS) issued the Medicaid rebate final rule that implements provisions of the ACA effective April 1, 2016. The rule provides comprehensive guidance on the calculation of Average Manufacturer Price and Best Price; two metrics utilized to determine the rebates drug manufacturers are required to pay to state Medicaid programs. The impact of changes resulting from the issuance of the rule is not material to Merck, at this time. However, the Company is still awaiting guidance from CMS on two aspects of the rule that were deferred for later implementation. These include a definition of what constitutes a product 'line extension' and a delay

in the participation of the U.S. Territories in the Medicaid Drug Rebate Program until April 1, 2020. The Company will evaluate the financial impact of these two elements when they become effective.

The Company cannot predict the likelihood of future changes in the health care industry in general, or the pharmaceutical industry in particular, or what impact they may have on the Company's business, cash flow, results of operations, financial position and prospects.

The Company is increasingly dependent on sophisticated software applications and computing infrastructure. In 2017, the Company experienced a network cyber-attack that led to a disruption of its worldwide operations, including manufacturing, research and sales operations. The Company could be a target of future cyber-attacks.

The Company is increasingly dependent on sophisticated software applications and complex information technology systems and computing infrastructure (collectively, "IT systems") to conduct critical operations. Disruption, degradation, or manipulation of these IT systems through intentional or accidental means could impact key business processes. Cyber-attacks against the Company's IT systems could result in exposure of confidential information, the modification of critical data, and/or the failure of critical operations. Misuse of these IT systems could result in the disclosure of sensitive personal information or the theft of trade secrets, intellectual property, or other confidential business information. The Company continues to leverage new and innovative technologies across the enterprise to improve the efficacy and efficiency of its business processes; the use of which can create new risks.

In 2017, the Company experienced a network cyber-attack that led to a disruption of its worldwide operations, including manufacturing, research and sales operations. Due to the cyber-attack, the Company was unable to fulfill orders for certain products in certain markets, which had an unfavorable effect on sales in 2017 of approximately $260 million. In addition, the Company recorded manufacturing-related expenses, primarily unfavorable manufacturing variances, in *Cost of sales*, as well as expenses related to remediation efforts in *Selling, general and administrative* expenses and *Research and development* expenses, which aggregated $285 million in 2017, net of insurance recoveries of approximately $45 million. Due to a residual backlog of orders, 2018 sales were unfavorably affected in certain markets by approximately $150 million from the cyber-attack.

The Company has insurance coverage insuring against costs resulting from cyber-attacks and has received proceeds. However, there are disputes with certain of the insurers about the availability of some of the insurance coverage for claims related to the 2017 cyber-attack.

The Company has implemented a variety of measures to further enhance and modernize its systems to guard against similar attacks in the future, and also is pursuing an enterprise-wide effort to enhance the Company's resiliency against future cyber-attacks, including incidents similar to the 2017 attack. The objective of these efforts is not only to protect against future cyber-attacks, but also to improve the speed of the Company's recovery from such attacks and enable continued business operations to the greatest extent possible during any recovery period.

Although the aggregate impact of cyber-attacks and network disruptions, including the 2017 cyber-attack, on the Company's operations and financial condition has not been material to date, the Company continues to be a target of events of this nature and expects them to continue. The Company monitors its data, information technology and personnel usage of Company IT systems to reduce these risks and continues to do so on an ongoing basis for any current or potential threats. There can be no assurance that the Company's efforts to protect its data and IT systems will be successful in preventing disruptions to its operations, including its manufacturing, research and sales operations. Any such disruption could result in loss of revenue, or the loss of critical or sensitive information from the Company's or the Company's third party providers' databases or IT systems and could also result in financial, legal, business or reputational harm to the Company and potentially substantial remediation costs.

The Company is subject to a variety of U.S. and international laws and regulations.

The Company is currently subject to a number of government laws and regulations and, in the future, could become subject to new government laws and regulations. The costs of compliance with such laws and regulations, or the negative results of non-compliance, could adversely affect the business, cash flow, results of operations, financial position and prospects of the Company; these laws and regulations include (i) additional healthcare reform initiatives in the United States or in other countries, including additional mandatory discounts or fees; (ii) the U.S. Foreign Corrupt Practices Act or other anti-bribery and corruption laws; (iii) new laws, regulations and judicial or other governmental

decisions affecting pricing, drug reimbursement, and access or marketing within or across jurisdictions; (iv) changes in intellectual property laws; (v) changes in accounting standards; (vi) new and increasing data privacy regulations and enforcement, particularly in the EU and the United States; (vii) legislative mandates or preferences for local manufacturing of pharmaceutical or vaccine products; (viii) emerging and new global regulatory requirements for reporting payments and other value transfers to healthcare professionals; (ix) environmental regulations; and (x) the potential impact of importation restrictions, embargoes, trade sanctions and legislative and/or other regulatory changes.

The uncertainty in global economic conditions together with cost-reduction measures being taken by certain governments could negatively affect the Company's operating results.

Uncertainty in global economic and geopolitical conditions may result in a slowdown to the global economy that could affect the Company's business by reducing the prices that drug wholesalers and retailers, hospitals, government agencies and managed health care providers may be able or willing to pay for the Company's products or by reducing the demand for the Company's products, which could in turn negatively impact the Company's sales and result in a material adverse effect on the Company's business, cash flow, results of operations, financial position and prospects.

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access. In the United States, pricing pressures continue on many of the Company's products and, in several international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. The Company anticipates these pricing actions will continue to negatively affect revenue performance in 2019.

If credit and economic conditions worsen, the resulting economic and currency impacts in the affected markets and globally could have a material adverse effect on the Company's results.

The Company has significant global operations, which expose it to additional risks, and any adverse event could have a material negative impact on the Company's results of operations.

The extent of the Company's operations outside the United States is significant. Risks inherent in conducting a global business include:

- changes in medical reimbursement policies and programs and pricing restrictions in key markets;
- multiple regulatory requirements that could restrict the Company's ability to manufacture and sell its products in key markets;
- trade protection measures and import or export licensing requirements, including the imposition of trade sanctions or similar restrictions by the United States or other governments;
- foreign exchange fluctuations;
- diminished protection of intellectual property in some countries; and
- possible nationalization and expropriation.

In addition, there may be changes to the Company's business and political position if there is instability, disruption or destruction in a significant geographic region, regardless of cause, including war, terrorism, riot, civil insurrection or social unrest; and natural or man-made disasters, including famine, flood, fire, earthquake, storm or disease. For example, in 2017, the Company's lone manufacturing plant in Puerto Rico was negatively affected by Hurricane Maria.

In 2016, the United Kingdom (UK) held a referendum in which voters approved an exit from the EU, commonly referred to as "Brexit". As a result of that referendum, the British government has been in the process of negotiating the terms of the UK's future relationship with the EU. While the Company has taken actions and made certain contingency plans for scenarios in which the UK and the EU do not reach a mutually satisfactory understanding as to that relationship, it is not possible at this time to predict whether there will be any such understanding, or if such an understanding is reached, whether its terms will vary in ways that result in greater restrictions on imports and exports between the UK and EU countries, increased regulatory complexities, and/or cross border labor issues that could materially adversely impact the Company's business operations in the UK.

Failure to attract and retain highly qualified personnel could affect the Company's ability to successfully develop and commercialize products.

The Company's success is largely dependent on its continued ability to attract and retain highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical research and development, governmental regulation and commercialization. Competition for qualified personnel in the pharmaceutical industry is intense. The Company cannot be sure that it will be able to attract and retain quality personnel or that the costs of doing so will not materially increase.

In the past, the Company has experienced difficulties and delays in manufacturing certain of its products, including vaccines.

Merck has, in the past, experienced difficulties in manufacturing certain of its products, including vaccines. In addition, the network cyber-attack experienced by the Company in June 2017 led to a disruption of the Company's operations, including its manufacturing operations. The Company may, in the future, experience difficulties and delays inherent in manufacturing its products, such as (i) failure of the Company or any of its vendors or suppliers to comply with Current Good Manufacturing Practices and other applicable regulations and quality assurance guidelines that could lead to manufacturing shutdowns, product shortages and delays in product manufacturing; (ii) construction delays related to the construction of new facilities or the expansion of existing facilities, including those intended to support future demand for the Company's products; and (iii) other manufacturing or distribution problems including changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, changes in types of products produced, or physical limitations that could impact continuous supply. In addition, the Company could experience difficulties or delays in manufacturing its products caused by natural disasters, such as hurricanes. Manufacturing difficulties can result in product shortages, leading to lost sales and reputational harm to the Company.

The Company may not be able to realize the expected benefits of its investments in emerging markets.

The Company has been taking steps to increase its sales in emerging markets. However, there is no guarantee that the Company's efforts to expand sales in these markets will succeed. Some countries within emerging markets may be especially vulnerable to periods of global financial instability or may have very limited resources to spend on health care. In order for the Company to successfully implement its emerging markets strategy, it must attract and retain qualified personnel. The Company may also be required to increase its reliance on third-party agents within less developed markets. In addition, many of these countries have currencies that fluctuate substantially and, if such currencies devalue and the Company cannot offset the devaluations, the Company's financial performance within such countries could be adversely affected.

The Company's business in China has grown rapidly in the past few years, and the importance of China to the Company's overall pharmaceutical and vaccines business outside the United States has increased accordingly. Continued growth of the Company's business in China is dependent upon ongoing development of a favorable environment for innovative pharmaceutical products and vaccines, sustained access for the Company's currently marketed products, and the absence of trade impediments or adverse pricing controls. As noted above in *Healthcare Environment*, pricing pressure in China has increased as the Chinese government has been taking steps to reduce costs, including implementing healthcare reform that has led to the acceleration of generic substitution, where available. In addition, the Company anticipates that the reported inquiries made by various governmental authorities involving multinational pharmaceutical companies in China may continue.

For all these reasons, sales within emerging markets carry significant risks. However, a failure to maintain the Company's presence in emerging markets could have a material adverse effect on the Company's business, cash flow, results of operations, financial position and prospects.

The Company is exposed to market risk from fluctuations in currency exchange rates and interest rates.

The Company operates in multiple jurisdictions and virtually all sales are denominated in currencies of the local jurisdiction. Additionally, the Company has entered and will enter into business development transactions, borrowings or other financial transactions that may give rise to currency and interest rate exposure.

Since the Company cannot, with certainty, foresee and mitigate against such adverse fluctuations, fluctuations in currency exchange rates, interest rates and inflation could negatively affect the Company's business, cash flow, results of operations, financial position and prospects.

In order to mitigate against the adverse impact of these market fluctuations, the Company will from time to time enter into hedging agreements. While hedging agreements, such as currency options and forwards and interest rate swaps, may limit some of the exposure to exchange rate and interest rate fluctuations, such attempts to mitigate these risks may be costly and not always successful.

The Company is subject to evolving and complex tax laws, which may result in additional liabilities that may affect results of operations.

The Company is subject to evolving and complex tax laws in the jurisdictions in which it operates. Significant judgment is required for determining the Company's tax liabilities, and the Company's tax returns are periodically examined by various tax authorities. The Company believes that its accrual for tax contingencies is adequate for all open years based on past experience, interpretations of tax law, and judgments about potential actions by tax authorities; however, due to the complexity of tax contingencies, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued. In addition, the Company may be affected by changes in tax laws, or new tax laws, affecting, for example, tax rates, and/or revised tax law interpretations in domestic or foreign jurisdictions.

Pharmaceutical products can develop unexpected safety or efficacy concerns.

Unexpected safety or efficacy concerns can arise with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals, or declining sales, as well as product liability, consumer fraud and/or other claims, including potential civil or criminal governmental actions.

Reliance on third-party relationships and outsourcing arrangements could adversely affect the Company's business.

The Company depends on third parties, including suppliers, alliances with other pharmaceutical and biotechnology companies, and third-party service providers, for key aspects of its business including development, manufacture and commercialization of its products and support for its information technology systems. Failure of these third parties to meet their contractual, regulatory and other obligations to the Company or the development of factors that materially disrupt the relationships between the Company and these third parties could have a material adverse effect on the Company's business.

Negative events in the animal health industry could have a negative impact on future results of operations.

Future sales of key animal health products could be adversely affected by a number of risk factors including certain risks that are specific to the animal health business. For example, the outbreak of disease carried by animals, such as Bovine Spongiform Encephalopathy or mad cow disease, could lead to their widespread death and precautionary destruction as well as the reduced consumption and demand for animals, which could adversely impact the Company's results of operations. Also, the outbreak of any highly contagious diseases near the Company's main production sites could require the Company to immediately halt production of vaccines at such sites or force the Company to incur substantial expenses in procuring raw materials or vaccines elsewhere. Other risks specific to animal health include epidemics and pandemics, government procurement and pricing practices, weather and global agribusiness economic events. As the Animal Health segment of the Company's business becomes more significant, the impact of any such events on future results of operations would also become more significant.

Biologics and vaccines carry unique risks and uncertainties, which could have a negative impact on future results of operations.

The successful development, testing, manufacturing and commercialization of biologics and vaccines, particularly human and animal health vaccines, is a long, complex, expensive and uncertain process. There are unique risks and uncertainties with biologics and vaccines, including:

- There may be limited access to, and supply of, normal and diseased tissue samples, cell lines, pathogens, bacteria, viral strains and other biological materials. In addition, government regulations in multiple

jurisdictions, such as the United States and the EU, could result in restricted access to, or transport or use of, such materials. If the Company loses access to sufficient sources of such materials, or if tighter restrictions are imposed on the use of such materials, the Company may not be able to conduct research activities as planned and may incur additional development costs.

- The development, manufacturing and marketing of biologics and vaccines are subject to regulation by the FDA, the EMA and other regulatory bodies. These regulations are often more complex and extensive than the regulations applicable to other pharmaceutical products. For example, in the United States, a BLA, including both preclinical and clinical trial data and extensive data regarding the manufacturing procedures, is required for human vaccine candidates, and FDA approval is generally required for the release of each manufactured commercial lot.

- Manufacturing biologics and vaccines, especially in large quantities, is often complex and may require the use of innovative technologies to handle living micro-organisms. Each lot of an approved biologic and vaccine must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, the Company may be required to provide pre-clinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes.

- Biologics and vaccines are frequently costly to manufacture because production ingredients are derived from living animal or plant material, and most biologics and vaccines cannot be made synthetically. In particular, keeping up with the demand for vaccines may be difficult due to the complexity of producing vaccines.

- The use of biologically derived ingredients can lead to variability in the manufacturing process and could lead to allegations of harm, including infections or allergic reactions, which allegations would be reviewed through a standard investigation process that could lead to closure of product facilities due to possible contamination. Any of these events could result in substantial costs.

Product liability insurance for products may be limited, cost prohibitive or unavailable.

As a result of a number of factors, product liability insurance has become less available while the cost has increased significantly. The Company is subject to a substantial number of product liability claims. See Item 8. “Financial Statements and Supplementary Data,” Note 11. “Contingencies and Environmental Liabilities” below for more information on the Company’s current product liability litigation. With respect to product liability, the Company self-insures substantially all of its risk, as the availability of commercial insurance has become more restrictive. The Company has evaluated its risks and has determined that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and, as such, has no insurance for certain product liabilities effective August 1, 2004, including liability for legacy Merck products first sold after that date. The Company will continually assess the most efficient means to address its risk; however, there can be no guarantee that insurance coverage will be obtained or, if obtained, will be sufficient to fully cover product liabilities that may arise.

Social media platforms present risks and challenges.

The inappropriate and/or unauthorized use of certain media vehicles could cause brand damage or information leakage or could lead to legal implications, including from the improper collection and/or dissemination of personally identifiable information. In addition, negative or inaccurate posts or comments about the Company or its products on any social networking platforms could damage the Company’s reputation, brand image and goodwill. Further, the disclosure of non-public Company-sensitive information by the Company’s workforce or others through external media channels could lead to information loss. Although there is an internal Company Social Media Policy that guides employees on appropriate personal and professional use of social media about the Company, the processes in place may not completely secure and protect information. Identifying new points of entry as social media continues to expand also presents new challenges.

Cautionary Factors that May Affect Future Results

(Cautionary Statements Under the Private Securities Litigation Reform Act of 1995)

This report and other written reports and oral statements made from time to time by the Company may contain so-called "forward-looking statements," all of which are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially from those set forth in the statements. One can identify these forward-looking statements by their use of words such as "anticipates," "expects," "plans," "will," "estimates," "forecasts," "projects" and other words of similar meaning, or negative variations of any of the foregoing. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address the Company's growth strategy, financial results, product development, product approvals, product potential, and development programs. One must carefully consider any such statement and should understand that many factors could cause actual results to differ materially from the Company's forward-looking statements. These factors include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. No forward-looking statement can be guaranteed and actual future results may vary materially. The Company does not assume the obligation to update any forward-looking statement. The Company cautions you not to place undue reliance on these forward-looking statements. Although it is not possible to predict or identify all such factors, they may include the following:

- Competition from generic and/or biosimilar products as the Company's products lose patent protection.

- Increased "brand" competition in therapeutic areas important to the Company's long-term business performance.

- The difficulties and uncertainties inherent in new product development. The outcome of the lengthy and complex process of new product development is inherently uncertain. A drug candidate can fail at any stage of the process and one or more late-stage product candidates could fail to receive regulatory approval. New product candidates may appear promising in development but fail to reach the market because of efficacy or safety concerns, the inability to obtain necessary regulatory approvals, the difficulty or excessive cost to manufacture and/or the infringement of patents or intellectual property rights of others. Furthermore, the sales of new products may prove to be disappointing and fail to reach anticipated levels.

- Pricing pressures, both in the United States and abroad, including rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and health care reform, pharmaceutical reimbursement and pricing in general.

- Changes in government laws and regulations, including laws governing intellectual property, and the enforcement thereof affecting the Company's business.

- Efficacy or safety concerns with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales.

- Significant changes in customer relationships or changes in the behavior and spending patterns of purchasers of health care products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing health care insurance coverage.

- Legal factors, including product liability claims, antitrust litigation and governmental investigations, including tax disputes, environmental concerns and patent disputes with branded and generic competitors, any of which could preclude commercialization of products or negatively affect the profitability of existing products.

- Cyber-attacks on the Company's information technology systems, which could disrupt the Company's operations.

- Lost market opportunity resulting from delays and uncertainties in the approval process of the FDA and foreign regulatory authorities.

- Increased focus on privacy issues in countries around the world, including the United States and the EU. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been

an increasing amount of focus on privacy and data protection issues with the potential to affect directly the Company's business, including recently enacted laws in a majority of states in the United States requiring security breach notification.

- Changes in tax laws including changes related to the taxation of foreign earnings.
- Changes in accounting pronouncements promulgated by standard-setting or regulatory bodies, including the Financial Accounting Standards Board and the SEC, that are adverse to the Company.
- Economic factors over which the Company has no control, including changes in inflation, interest rates and foreign currency exchange rates.

This list should not be considered an exhaustive statement of all potential risks and uncertainties. See "Risk Factors" above.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

The Company's corporate headquarters is located in Kenilworth, New Jersey. The Company's U.S. commercial operations are headquartered in Upper Gwynedd, Pennsylvania. The Company's U.S. pharmaceutical business is conducted through divisional headquarters located in Upper Gwynedd, Pennsylvania and Kenilworth, New Jersey. The Company's vaccines business is conducted through divisional headquarters located in Upper Gwynedd, Pennsylvania. Merck's Animal Health headquarters is located in Madison, New Jersey. Principal U.S. research facilities are located in Rahway and Kenilworth, New Jersey, West Point, Pennsylvania, Palo Alto, California, Boston, Massachusetts, South San Francisco, California and Elkhorn, Nebraska (Animal Health). Principal research facilities outside the United States are located in Switzerland and China. Merck's manufacturing operations are headquartered in Whitehouse Station, New Jersey. The Company also has production facilities for human health products at nine locations in the United States and Puerto Rico. Outside the United States, through subsidiaries, the Company owns or has an interest in manufacturing plants or other properties in Japan, Singapore, South Africa, and other countries in Western Europe, Central and South America, and Asia.

Capital expenditures were $2.6 billion in 2018, $1.9 billion in 2017 and $1.6 billion in 2016. In the United States, these amounted to $1.5 billion in 2018, $1.2 billion in 2017 and $1.0 billion in 2016. Abroad, such expenditures amounted to $1.1 billion in 2018, $728 million in 2017 and $594 million in 2016.

The Company and its subsidiaries own their principal facilities and manufacturing plants under titles that they consider to be satisfactory. The Company believes that its properties are in good operating condition and that its machinery and equipment have been well maintained. Plants for the manufacture of products are suitable for their intended purposes and have capacities and projected capacities adequate for current and projected needs for existing Company products. Some capacity of the plants is being converted, with any needed modification, to the requirements of newly introduced and future products. In addition, in October 2018, the Company announced it plans to invest approximately $16 billion on new capital projects from 2018-2022. The focus of this investment will primarily be on increasing manufacturing capacity across Merck's key businesses.

Item 3. Legal Proceedings.

The information called for by this Item is incorporated herein by reference to Item 8. "Financial Statements and Supplementary Data," Note 11. "Contingencies and Environmental Liabilities".

Item 4. Mine Safety Disclosures.

Not Applicable.

Executive Officers of the Registrant (ages as of February 1, 2019)

All officers listed below serve at the pleasure of the Board of Directors. None of these officers was elected pursuant to any arrangement or understanding between the officer and any other person(s).

Name	Age	Offices and Business Experience
Kenneth C. Frazier	64	Chairman, President and Chief Executive Officer (since December 2011)
Sanat Chattopadhyay	59	Executive Vice President and President, Merck Manufacturing Division (since March 2016); Senior Vice President, Operations, Merck Manufacturing Division (November 2009-March 2016)
Frank Clyburn	54	Executive Vice President, Chief Commercial Officer (since January 2019); President, Global Oncology Business Unit (October 2013-December 2018); President, Primary Care and Women's Health Business Line (September 2011-October 2013)
Robert M. Davis	52	Executive Vice President, Global Services, and Chief Financial Officer (since April 2016); Executive Vice President and Chief Financial Officer (April 2014-April 2016); Corporate Vice President and President, Medical Products, Baxter International, Inc. (October 2010-March 2014)
Richard R. DeLuca, Jr.	56	Executive Vice President and President, Merck Animal Health (since September 2011)
Julie L. Gerberding	62	Executive Vice President and Chief Patient Officer, Strategic Communications, Global Public Policy and Population Health (since July 2016); Executive Vice President for Strategic Communications, Global Public Policy and Population Health (January 2015-July 2016); President, Merck Vaccines (January 2010-January 2015)
Rita A. Karachun	55	Senior Vice President Finance - Global Controller (since March 2014); Assistant Controller (November 2009-March 2014)
Steven C. Mizell	58	Executive Vice President, Chief Human Resources Officer, Human Resources (since October 2018); Executive Vice President, Chief Human Resources Officer (December 2016-October 2018) and Executive Vice President, Human Resources, Monsanto Company (August 2011-December 2016)
Michael T. Nally	43	Executive Vice President, Chief Marketing Officer (since January 2019); President, Global Vaccines, Global Human Health (September 2016-January 2019); Managing Director, United Kingdom and Ireland, Global Human Health (January 2014-September 2016); Managing Director, Sweden, Global Human Health (November 2011-January 2014)
Roger M. Perlmutter, M.D., Ph.D.	66	Executive Vice President and President, Merck Research Laboratories (since April 2013)
Jim Scholefield	56	Executive Vice President, Chief Information and Digital Officer (since October 2018); Chief Information Officer, Nike, Inc (July 2015-October 2018); Chief Technology Officer, The Coca-Cola Company, (November 2010-June 2015)
Jennifer Zachary	41	Executive Vice President and General Counsel (since April 2018); Partner, Covington & Burling LLP (January 2013-March 2018)

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

The principal market for trading of the Company's Common Stock is the New York Stock Exchange (NYSE) under the symbol MRK.

As of January 31, 2019, there were approximately 115,320 shareholders of record of the Company's Common Stock.

Issuer purchases of equity securities for the three months ended December 31, 2018 were as follows:

Issuer Purchases of Equity Securities

			($ in millions)
Period	Total Number of Shares Purchased[1]	Average Price Paid Per Share	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs[1]
October 1 — October 31	59,154,075	$70.56	$12,709[2]
November 1 — November 30	5,279,715	$74.64	$12,315
December 1 — December 31	4,788,526	$76.30	$11,949
Total	69,222,316	$71.27	$11,949

(1) *All shares purchased during the period were made as part of a plan approved by the Board of Directors in November 2017 to purchase up to $10 billion in Merck shares. In October 2018, the Board of Directors authorized additional purchases of up to $10 billion of Merck's common stock for its treasury. Shares are approximated.*

(2) *Amount includes $1.0 billion being held back pending final settlement under the accelerated share repurchase agreements discussed below.*

Performance Graph

The following graph assumes a $100 investment on December 31, 2013, and reinvestment of all dividends, in each of the Company's Common Shares, the S&P 500 Index, and a composite peer group of major pharmaceutical companies, which are: AbbVie Inc., Amgen Inc., AstraZeneca plc, Bristol-Myers Squibb Company, Johnson & Johnson, Eli Lilly and Company, GlaxoSmithKline plc, Novartis AG, Pfizer Inc., Roche Holding AG, and Sanofi SA.

Comparison of Five-Year Cumulative Total Return*

Merck & Co., Inc., Composite Peer Group and S&P 500 Index

	End of Period Value	2018/2013 CAGR**
MERCK	$179	12%
PEER GRP.**	142	7%
S&P 500	150	8%

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	2013	2014	2015	2016	2017	2018
MERCK	100.00	117.10	112.40	129.40	127.40	178.70
PEER GRP.	100.00	111.40	114.80	111.20	133.00	142.20
S&P 500	100.00	113.70	115.20	129.00	157.20	150.30

* *Compound Annual Growth Rate*

** *Peer group average was calculated on a market cap weighted basis.*

This Performance Graph will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that the Company specifically incorporates it by reference. In addition, the Performance Graph will not be deemed to be "soliciting material" or to be "filed" with the SEC or subject to Regulation 14A or 14C, other than as provided in Regulation S-K, or to the liabilities of section 18 of the Securities Exchange Act of 1934, except to the extent that the Company specifically requests that such information be treated as soliciting material or specifically incorporates it by reference into a filing under the Securities Act or the Exchange Act.

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Item 6. Selected Financial Data.

The following selected financial data should be read in conjunction with Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and consolidated financial statements and notes thereto contained in Item 8. "Financial Statements and Supplementary Data" of this report.

Merck & Co., Inc. and Subsidiaries
($ in millions except per share amounts)

	2018 [1]	2017 [2][3]	2016 [2][4]	2015 [2][5]	2014 [2][6]
Results for Year:					
Sales	**$ 42,294**	$ 40,122	$ 39,807	$ 39,498	$ 42,237
Cost of sales	**13,509**	12,912	14,030	15,043	16,903
Selling, general and administrative	**10,102**	10,074	10,017	10,508	11,816
Research and development	**9,752**	10,339	10,261	6,796	7,290
Restructuring costs	**632**	776	651	619	1,013
Other (income) expense, net	**(402)**	(500)	189	1,131	(12,068)
Income before taxes	**8,701**	6,521	4,659	5,401	17,283
Taxes on income	**2,508**	4,103	718	942	5,349
Net income	**6,193**	2,418	3,941	4,459	11,934
Less: Net (loss) income attributable to noncontrolling interests	**(27)**	24	21	17	14
Net income attributable to Merck & Co., Inc.	**6,220**	2,394	3,920	4,442	11,920
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	**$ 2.34**	$ 0.88	$ 1.42	$ 1.58	$ 4.12
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	**$ 2.32**	$ 0.87	$ 1.41	$ 1.56	$ 4.07
Cash dividends declared	**5,313**	5,177	5,135	5,115	5,156
Cash dividends declared per common share	**$ 1.99**	$ 1.89	$ 1.85	$ 1.81	$ 1.77
Capital expenditures	**2,615**	1,888	1,614	1,283	1,317
Depreciation	**1,416**	1,455	1,611	1,593	2,471
Average common shares outstanding (millions)	**2,664**	2,730	2,766	2,816	2,894
Average common shares outstanding assuming dilution (millions)	**2,679**	2,748	2,787	2,841	2,928
Year-End Position:					
Working capital	**$ 3,669**	$ 6,152	$ 13,410	$ 10,550	$ 14,198
Property, plant and equipment, net	**13,291**	12,439	12,026	12,507	13,136
Total assets	**82,637**	87,872	95,377	101,677	98,096
Long-term debt	**19,806**	21,353	24,274	23,829	18,629
Total equity	**26,882**	34,569	40,308	44,767	48,791
Year-End Statistics:					
Number of stockholders of record	**115,800**	121,700	129,500	135,500	142,000
Number of employees	**69,000**	69,000	68,000	68,000	70,000

[1] *Amounts for 2018 include a charge related to the formation of a collaboration with Eisai Co., Ltd.*

[2] *Amounts have been recast as a result of the adoption, on January 1, 2018, of a new accounting standard related to the classification of certain defined benefit plan costs. There was no impact to net income as a result of adopting the new accounting standard.*

[3] *Amounts for 2017 include a provisional net tax charge related to the enactment of U.S. tax legislation and a charge related to the formation of a collaboration with AstraZeneca.*

[4] *Amounts for 2016 include a charge related to the settlement of worldwide patent litigation related to* Keytruda.

[5] *Amounts for 2015 include a net charge related to the settlement of* Vioxx *shareholder class action litigation, foreign exchange losses related to Venezuela, gains on the dispositions of businesses and other assets, and the favorable benefit of certain tax items.*

[6] *Amounts for 2014 reflect the divestiture of Merck's Consumer Care business on October 1, 2014, including a gain on the sale, as well as a gain recognized on an option exercise by AstraZeneca, gains on the dispositions of other businesses and assets, and a loss on extinguishment of debt.*

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Description of Merck's Business

Merck & Co., Inc. (Merck or the Company) is a global health care company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies and animal health products. The Company's operations are principally managed on a products basis and include four operating segments, which are the Pharmaceutical, Animal Health, Healthcare Services and Alliances segments. The Pharmaceutical and Animal Health segments are the only reportable segments.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. On December 31, 2016, Merck and Sanofi Pasteur S.A. (Sanofi) terminated their equally-owned joint venture, Sanofi Pasteur MSD (SPMSD), which developed and marketed vaccines in Europe. In 2017, Merck began recording vaccine sales and incurring costs as a result of operating its vaccines business in the European markets that were previously part of the SPMSD joint venture, which was accounted for as an equity method affiliate.

The Animal Health segment discovers, develops, manufactures and markets animal health products, including pharmaceutical and vaccine products, for the prevention, treatment and control of disease in all major livestock and companion animal species, which the Company sells to veterinarians, distributors and animal producers.

The Healthcare Services segment provides services and solutions that focus on engagement, health analytics and clinical services to improve the value of care delivered to patients.

The Alliances segment primarily includes activity from the Company's relationship with AstraZeneca LP related to sales of Nexium and Prilosec, which concluded in 2018 (see Note 9 to the consolidated financial statements).

Overview

The Company's performance during 2018 demonstrates execution of its innovation strategy, with revenue growth in oncology, vaccines, hospital acute care and animal health, focused investment in the research and development pipeline, and disciplined allocation of resources. Additionally, Merck completed several business development transactions, expanded its capital expenditures program primarily to increase future manufacturing capacity, and returned capital to shareholders.

Worldwide sales were $42.3 billion in 2018, an increase of 5% compared with 2017. Strong growth in the oncology franchise reflects the performance of *Keytruda*, as well as alliance revenue related to Lynparza and Lenvima resulting from Merck's business development activities. Also contributing to revenue growth were higher sales of vaccines, driven primarily by *Gardasil/Gardasil* 9, and growth in the hospital acute care franchise, largely attributable to *Bridion* and *Noxafil*. Higher sales of animal health products, reflecting increases in companion animal and livestock products both from in-line and recently launched products, also contributed to revenue growth. Growth in these areas was partially offset by competitive pressures on *Zepatier* and *Zostavax*, as well as the ongoing effects of generic and biosimilar competition that resulted in sales declines for products including *Zetia*, *Vytorin*, and *Remicade*.

Augmenting Merck's portfolio and pipeline with external innovation remains an important component of the Company's overall strategy. In 2018, Merck continued executing on this strategy by entering into a strategic collaboration with Eisai Co., Ltd. (Eisai) for the worldwide co-development and co-commercialization of Lenvima. Lenvima is an orally available tyrosine kinase inhibitor discovered by Eisai, which is approved for certain types of thyroid cancer, hepatocellular carcinoma, and in combination for certain patients with renal cell carcinoma. Under the agreement, Merck and Eisai will develop and commercialize Lenvima jointly, both as monotherapy and in combination with *Keytruda*. In addition, Merck acquired Viralytics Limited (Viralytics), a company focused on oncolytic immunotherapy treatments for a range of cancers. Also, the Company announced an agreement to acquire Antelliq Group (Antelliq), a leader in digital animal identification, traceability and monitoring solutions.

During 2018, the Company advanced its leadership in oncology through focused commercial execution, the achievement of important regulatory milestones and the presentation of clinical data. *Keytruda* continues its global launch with multiple new indications across several tumor types, including approval from the U.S. Food and Drug Administration (FDA) for the treatment of certain patients with cervical cancer, primary mediastinal large B-cell lymphoma (PMBCL), a type of non-Hodgkin lymphoma, hepatocellular carcinoma, Merkel cell carcinoma, and in combination with chemotherapy for the treatment of certain patients with squamous non-small-cell lung cancer (NSCLC). Also during 2018, the European Commission (EC) approved *Keytruda* for the treatment of certain patients with head and neck squamous cell carcinoma (HNSCC), for the adjuvant treatment of melanoma, and in combination with chemotherapy for the first-line treatment of certain patients with nonsquamous NSCLC. This was the first approval in Europe for an anti-PD-1 therapy in combination with chemotherapy. Also in 2018, *Keytruda* was approved in China for the treatment of certain patients with melanoma. Additionally, Merck recently announced the receipt of five new approvals for *Keytruda* in Japan, including three expanded uses in advanced NSCLC, one in adjuvant melanoma, as well as a new indication in advanced microsatellite instability-high (MSI-H) tumors. *Keytruda* also continues to launch in many other international markets.

In 2018, Lynparza, which is being developed in a collaboration with AstraZeneca PLC (AstraZeneca), received FDA approval for use in certain patients with metastatic breast cancer who have been previously treated with chemotherapy, and for use as maintenance treatment of adult patients with certain types of advanced ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to chemotherapy. Additionally, Lenvima was approved in the United States, European Union (EU), Japan and China for the treatment of certain patients with hepatocellular carcinoma. The FDA and EC also approved two new HIV-1 medicines: *Delstrigo*, a once-daily fixed-dose combination tablet of doravirine, lamivudine and tenofovir disoproxil fumarate; and *Pifeltro* (doravirine), a new non-nucleoside reverse transcriptase inhibitor to be administered in combination with other antiretroviral medicines.

Merck continues to invest in its pipeline, with an emphasis on being a leader in immuno-oncology and expanding in other areas such as vaccines and hospital acute care. In addition to the recent regulatory approvals discussed above, the Company has continued to advance its late-stage pipeline with several regulatory submissions. *Keytruda* is under review in the United States in combination with axitinib, a tyrosine kinase inhibitor, for the first-line treatment of patients with advanced renal cell carcinoma for which it has been granted Priority Review by the FDA; in the EU for the first-line treatment of certain patients with metastatic squamous NSCLC; in the United States and in the EU as monotherapy for the first-line treatment of certain patients with locally advanced or metastatic NSCLC; in the United States as monotherapy for the treatment of certain patients with advanced small-cell lung cancer (SCLC); and in the United States as monotherapy or in combination with chemotherapy for the first-line treatment of certain patients with recurrent or metastatic HNSCC for which it has been granted Priority Review by the FDA. Additionally, MK-7655A, the combination of relebactam and imipenem/cilastatin, has been accepted for Priority Review by the FDA for the treatment of complicated urinary tract infections and complicated intra-abdominal infections caused by certain susceptible Gram-negative bacteria in adults with limited or no alternative therapies available. Merck has also started the submission of a rolling Biologics License Application (BLA) to the FDA for V920, an investigational Ebola Zaire disease vaccine candidate.

The Company's Phase 3 oncology programs include *Keytruda* in the therapeutic areas of breast, cervical, colorectal, esophageal, gastric, hepatocellular, mesothelioma, nasopharyngeal, ovarian, renal and small-cell lung cancers; Lynparza for pancreatic and prostate cancer; and Lenvima in combination with *Keytruda* for endometrial cancer. Additionally, the Company has candidates in Phase 3 clinical development in several other therapeutic areas, including V114, an investigational polyvalent conjugate vaccine for the prevention of pneumococcal disease that received Breakthrough Therapy designation from the FDA for the prevention of invasive pneumococcal disease caused by the vaccine serotypes in pediatric patients 6 weeks to 18 years of age; MK-7264, gefapixant, a selective, non-narcotic, orally-administered P2X3-receptor agonist being developed for the treatment of refractory, chronic cough; and MK-1242, vericiguat, an investigational treatment for heart failure being developed in a collaboration (see "Research and Development" below).

The Company is allocating resources to effectively support its commercial opportunities in the near term while making the necessary investments to support long-term growth. *Research and development* expenses in 2018 reflect higher clinical development spending and investment in discovery and early drug development.

In October 2018, Merck's Board of Directors approved a 15% increase to the Company's quarterly dividend, raising it to $0.55 per share from $0.48 per share on the Company's outstanding common stock. Also in October 2018, Merck's Board of Directors approved a $10 billion share repurchase program and the Company entered into $5 billion of accelerated share repurchase (ASR) agreements. During 2018, the Company returned $14.3 billion to shareholders through dividends and share repurchases.

Earnings per common share assuming dilution attributable to common shareholders (EPS) for 2018 were $2.32 compared with $0.87 in 2017. EPS in both years reflect the impact of acquisition and divestiture-related costs, as well as restructuring costs and certain other items. Certain other items in 2018 include a charge related to the formation of the collaboration with Eisai and in 2017 include a provisional net tax charge related to the enactment of U.S. tax legislation and a charge related to the formation of a collaboration with AstraZeneca. Non-GAAP EPS, which exclude these items, were $4.34 in 2018 and $3.98 in 2017 (see "Non-GAAP Income and Non-GAAP EPS" below).

Pricing

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. In the United States, pricing pressure continues on many of the Company's products. Changes to the U.S. health care system as part of health care reform, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, have contributed to pricing pressure. In several international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. In addition, the Company's revenue performance in 2018 was negatively affected by other cost-reduction measures taken by governments and other third-parties to lower health care costs. The Company anticipates all of these actions will continue to negatively affect revenue performance in 2019.

Cyber-attack

On June 27, 2017, the Company experienced a network cyber-attack that led to a disruption of its worldwide operations, including manufacturing, research and sales operations. Due to a backlog of orders for certain products as a result of the cyber-attack, the Company was unable to fulfill orders for certain products in certain markets, which had an unfavorable effect on sales in 2018 and 2017 of approximately $150 million and $260 million, respectively. In addition, the Company recorded manufacturing-related expenses, primarily unfavorable manufacturing variances, in *Cost of sales*, as well as expenses related to remediation efforts in *Selling, general and administrative* expenses and *Research and development* expenses, which aggregated approximately $285 million in 2017, net of insurance recoveries of approximately $45 million. Costs in 2018 were immaterial.

As referenced above, the Company has insurance coverage insuring against costs resulting from cyber-attacks and has received insurance proceeds. However, there are disputes with certain of the insurers about the availability of some of the insurance coverage for claims related to this incident.

Operating Results

Sales

Worldwide sales were $42.3 billion in 2018, an increase of 5% compared with 2017. Sales growth was driven primarily by higher sales in the oncology franchise reflecting strong growth of *Keytruda*, as well as alliance revenue related to Lynparza and Lenvima. Also contributing to revenue growth were higher sales of vaccines, driven primarily by human papillomavirus (HPV) vaccine *Gardasil/Gardasil* 9, as well as higher sales in the hospital acute care franchise, largely attributable to *Bridion* and *Noxafil*. Higher sales of animal health products also drove revenue growth in 2018.

Sales growth in 2018 was partially offset by declines in the virology franchise driven primarily by lower sales of hepatitis C virus (HCV) treatment *Zepatier*, as well as lower sales of shingles (herpes zoster) vaccine *Zostavax*. The ongoing effects of generic and biosimilar competition for cardiovascular products *Zetia* and *Vytorin*, and immunology product *Remicade*, as well as lower sales of products within the diversified brands franchise also partially offset revenue growth in 2018. The diversified brands franchise includes certain products that are approaching the expiration of their marketing exclusivity or that are no longer protected by patents in developed markets.

Sales in the United States were $18.2 billion in 2018, growth of 5% compared with 2017. The increase was driven primarily by higher sales of *Keytruda*, *Gardasil/Gardasil* 9, *NuvaRing*, and *Bridion*, as well as alliance revenue

from Lynparza and Lenvima, and higher sales of animal health products. Growth was partially offset by lower sales of *Zepatier*, *Zetia*, *Vytorin*, *Zostavax*, *Januvia*, *Janumet*, *Invanz*, and products within the diversified brands franchise.

International sales were $24.1 billion in 2018, an increase of 6% compared with 2017. The increase primarily reflects growth in *Keytruda*, *Gardasil/Gardasil* 9, *Januvia, Janumet* and *Atozet*, as well as higher sales of animal health products. Sales growth was partially offset by lower sales of *Zepatier*, *Remicade*, *Zetia*, *Vytorin*, and products within the diversified brands franchise. International sales represented 57% of total sales in both 2018 and 2017.

Worldwide sales were $40.1 billion in 2017, an increase of 1% compared with 2016. Sales growth in 2017 was driven primarily by higher sales of *Keytruda*, *Zepatier* and *Bridion*. Additionally, sales in 2017 benefited from the December 31, 2016 termination of SPMSD, which marketed vaccines in most major European markets. In 2017, Merck began recording vaccine sales in the markets that were previously part of the SPMSD joint venture resulting in incremental vaccine sales of approximately $400 million during 2017. Higher sales of *Pneumovax* 23, Adempas, and animal health products also contributed to revenue growth in 2017. These increases were largely offset by the effects of generic competition for certain products including *Zetia*, which lost U.S. market exclusivity in December 2016, *Vytorin*, which lost U.S. market exclusivity in April 2017, *Cubicin* due to U.S. patent expiration in June 2016, and *Cancidas*, which lost EU patent protection in April 2017. Revenue growth was also offset by continued biosimilar competition for *Remicade* and ongoing generic erosion for products including *Singulair* and *Nasonex*. Collectively, the sales decline attributable to the above products affected by generic and biosimilar competition was $3.3 billion in 2017. Lower sales of other products within the diversified brands franchise, as well as lower combined sales of the diabetes franchise of *Januvia* and *Janumet*, and declines in sales of *Isentress/Isentress HD* also partially offset revenue growth. Additionally, sales in 2017 were reduced by $125 million due to a borrowing the Company made from the U.S. Centers for Disease Control and Prevention (CDC) Pediatric Vaccine Stockpile of doses of *Gardasil* 9 as discussed below. Also, the Company was unable to fulfill orders for certain products in certain markets due to the cyber-attack, which had an unfavorable effect on sales in 2017 of approximately $260 million.

See Note 19 to the consolidated financial statements for details on sales of the Company's products.

Pharmaceutical Segment

Oncology

Keytruda is approved in the United States and in the EU as monotherapy for the treatment of certain patients with NSCLC, melanoma, classical Hodgkin lymphoma (cHL), HNSCC and urothelial carcinoma, a type of bladder cancer, and in combination with chemotherapy for certain patients with nonsquamous NSCLC. *Keytruda* is also approved in the United States as monotherapy for the treatment of certain patients with gastric or gastroesophageal junction adenocarcinoma and MSI-H or mismatch repair deficient cancer. In addition, the FDA recently approved *Keytruda* for the treatment of certain patients with cervical cancer, PMBCL, hepatocellular carcinoma, Merkel cell carcinoma, and in combination with chemotherapy for patients with squamous NSCLC (see below). *Keytruda* is approved in Japan for the treatment of certain patients with NSCLC, both as monotherapy and in combination with chemotherapy, melanoma, cHL, MSI-H tumors, and urothelial carcinoma. Additionally, *Keytruda* has been approved in China for the treatment of certain patients with melanoma. *Keytruda* is also approved in many other international markets. The *Keytruda* clinical development program includes studies across a broad range of cancer types (see "Research and Development" below).

In August 2018, the FDA approved an expanded label for *Keytruda* in combination with pemetrexed and platinum chemotherapy for the first-line treatment of patients with metastatic nonsquamous NSCLC, with no EGFR or ALK genomic tumor aberrations, based on results of the KEYNOTE-189 trial. *Keytruda* in combination with pemetrexed and carboplatin was first approved in 2017 under the FDA's accelerated approval process for the first-line treatment of patients with metastatic nonsquamous NSCLC, based on tumor response rates and progression-free survival (PFS) data from a Phase 2 study (KEYNOTE-021, Cohort G1). In accordance with the accelerated approval process, continued approval was contingent upon verification and description of clinical benefit, which was demonstrated in KEYNOTE-189 and resulted in the FDA converting the accelerated approval to full (regular) approval. Also, in September 2018, the EC approved *Keytruda* in combination with pemetrexed and platinum chemotherapy for the first-line treatment of metastatic nonsquamous NSCLC in adults whose tumors have no EGFR or ALK positive mutations.

In June 2018, the FDA approved *Keytruda* for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 as determined by an FDA-

approved test. Also in June 2018, the FDA approved *Keytruda* for the treatment of adult and pediatric patients with refractory PMBCL, or who have relapsed after two or more prior lines of therapy.

In September 2018, the EC approved *Keytruda* as monotherapy for the treatment of recurrent or metastatic HNSCC in adults whose tumors express PD-L1 with a tumor proportion score (TPS) of ≥50%, and who progressed on or after platinum-containing chemotherapy, based on data from the Phase 3 KEYNOTE-040 trial.

In October 2018, the FDA approved *Keytruda*, in combination with carboplatin and either paclitaxel or nab-paclitaxel, for the first-line treatment of patients with metastatic squamous NSCLC based on results from the KEYNOTE-407 trial. This approval marks the first time an anti-PD-1 regimen has been approved for the first-line treatment of squamous NSCLC regardless of tumor PD-L1 expression status.

In November 2018, the FDA approved *Keytruda* for the treatment of patients with hepatocellular carcinoma who have been previously treated with sorafenib based on data from the KEYNOTE-224 trial.

In December 2018, the FDA approved *Keytruda* for the treatment of adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma, based on the results of the Cancer Immunotherapy Trials Network's CITN-09/KEYNOTE-017 trial.

Also in December 2018, the EC approved *Keytruda* for the adjuvant treatment of adults with stage III melanoma and lymph node involvement who have undergone complete resection. *Keytruda* was approved for this indication by the FDA in February 2019. These approvals were based on data from the pivotal Phase 3 EORTC1325/ KEYNOTE-054 trial, conducted in collaboration with the European Organisation for Research and Treatment of Cancer.

Global sales of *Keytruda* were $7.2 billion in 2018, $3.8 billion in 2017 and $1.4 billion in 2016. The year-over-year increases were driven by volume growth as the Company continues to launch *Keytruda* with multiple new indications globally. Sales in the United States continue to build across the multiple approved indications, in particular for the treatment of NSCLC reflecting both the continued adoption of *Keytruda* in the first-line setting as monotherapy for patients with metastatic NSCLC whose tumors have high PD-L1 expression, as well as the uptake of *Keytruda* in combination with pemetrexed and carboplatin, a commonly used chemotherapy regimen, for the first-line treatment of metastatic nonsquamous NSCLC with or without PD-L1 expression. Other indications contributing to sales growth include HNSCC, bladder, and melanoma. Recently approved indications, including squamous NSCLC and MSI-H cancer, also contributed to growth in 2018. Sales growth in international markets reflects continued uptake for the treatment of NSCLC as the Company has secured reimbursement in most major markets. Sales growth in international markets in 2018 also includes contributions from the more recently approved indications as described above, including for the treatment of HNSCC, bladder cancer and in combination with chemotherapy for the treatment of NSCLC in the EU, multiple new indications in Japan, and for the treatment of melanoma in China.

In January 2017, Merck entered into a settlement and license agreement to resolve worldwide patent infringement litigation related to *Keytruda*. Pursuant to the settlement, the Company will pay royalties of 6.5% on net sales of *Keytruda* in 2017 through 2023; and 2.5% on net sales of *Keytruda* in 2024 through 2026.

Global sales of *Emend*, for the prevention of chemotherapy-induced and post-operative nausea and vomiting, were $522 million in 2018, a decline of 6% compared with 2017 including a 1% favorable effect from foreign exchange. The decline primarily reflects lower demand in the United States due to competition. Worldwide sales of *Emend* were $556 million in 2017, an increase of 1% compared with 2016. The patent that provided U.S. market exclusivity for *Emend* expired in 2015 and the patent that provides market exclusivity in most major European markets will expire in May 2019. The patent that provides U.S. market exclusivity for *Emend* for Injection expires in September 2019 and the patent that provides market exclusivity in major European markets expires in February 2020 (although six-month pediatric exclusivity may extend this date). The Company anticipates that sales of *Emend* in these markets will decline significantly after these patent expiries.

Lynparza, an oral poly (ADP-ribose) polymerase (PARP) inhibitor being developed as part of a collaboration with AstraZeneca entered into in July 2017 (see Note 4 to the consolidated financial statements), is currently approved for certain types of ovarian and breast cancer. Merck recorded alliance revenue of $187 million in 2018 and $20 million in 2017 related to Lynparza. The revenue increase reflects the approval of new indications, as well as a full year of activity in 2018. In January 2018, the FDA approved Lynparza for use in patients with *BRCA*-mutated, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have been previously treated with chemotherapy,

triggering a $70 million capitalized milestone payment from Merck to AstraZeneca. Lynparza was also approved in Japan in July 2018 for use in patients with unresectable or recurrent *BRCA*-mutated, HER2-negative breast cancer who have received prior chemotherapy. Additionally, Lynparza was approved for use as a maintenance therapy in patients with platinum-sensitive relapsed ovarian cancer, regardless of *BRCA* mutation status in Japan in January 2018 and in the EU in May 2018. In December 2018, the FDA approved Lynparza for use as maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic *BRCA*-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy based on the results of the SOLO-1 clinical trial, triggering a $70 million capitalized milestone payment from Merck to AstraZeneca.

Lenvima, an oral receptor tyrosine kinase inhibitor being developed as part of a collaboration with Eisai entered into in March 2018 (see Note 4 to the consolidated financial statements), is approved for certain types of thyroid cancer, hepatocellular carcinoma, and in combination for certain patients with renal cell carcinoma. Merck recorded alliance revenue of $149 million in 2018 related to Lenvima. In 2018, Lenvima was approved for the treatment of certain patients with hepatocellular carcinoma in the United States, the EU, Japan and China, triggering capitalized milestone payments of $250 million in the aggregate from Merck to Eisai.

Vaccines

On December 31, 2016, Merck and Sanofi terminated their equally-owned joint venture, SPMSD, which developed and marketed vaccines in Europe. Accordingly, vaccine sales in 2018 and 2017 include sales of Merck vaccines in the European markets that were previously part of the SPMSD joint venture, whereas sales in periods prior to 2017 do not. Prior to 2017, vaccine sales in these European markets were sold through the SPMSD joint venture, the results of which were reflected in equity income from affiliates included in *Other (income) expense, net*. Supply sales to SPMSD, however, are included in vaccine sales in periods prior to 2017. Incremental vaccine sales resulting from the termination of the SPMSD joint venture were approximately $400 million in 2017, of which approximately $215 million relate to *Gardasil/Gardasil* 9.

Worldwide sales of *Gardasil/Gardasil* 9, vaccines to help prevent certain cancers and other diseases caused by certain types of HPV, were $3.2 billion in 2018, growth of 37% compared with 2017 including a 1% favorable effect from foreign exchange. Sales growth was driven primarily by higher sales in the Asia Pacific region, particularly in China reflecting continued uptake since launch, as well as higher demand in certain European markets. The sales increase was also attributable to the replenishment in 2018 of doses borrowed from the CDC Pediatric Vaccine Stockpile in 2017 as discussed below. In April 2018, China's Food and Drug Administration approved *Gardasil* 9 for use in girls and women ages 16 to 26. In October 2018, the FDA approved an expanded age indication for use in women and men ages 27 to 45 for the prevention of certain cancers and diseases caused by the nine HPV types covered by the vaccine.

During 2017, the Company made a request to borrow doses of *Gardasil* 9 from the CDC Pediatric Vaccine Stockpile, which the CDC granted. The Company's decision to borrow the doses from the CDC was driven in part by the temporary shutdown resulting from the cyber-attack that occurred in June 2017, as well as by overall higher demand than expected. As a result of the borrowing, the Company reversed the sales related to the borrowed doses and recognized a corresponding liability. The Company subsequently replenished a portion of the doses borrowed from the stockpile. The net effect of the borrowing and subsequent partial replenishment was a reduction in sales of $125 million in 2017. The Company replenished the remaining borrowed doses in 2018 resulting in the recognition of sales of $125 million in 2018 and a reversal of the related liability.

Global sales of *Gardasil/Gardasil* 9 were $2.3 billion in 2017, growth of 6% compared with 2016. Sales growth was driven primarily by higher sales in Europe resulting from the termination of the SPMSD joint venture noted above, as well as higher demand in the Asia Pacific region due in part to the launch in China, partially offset by lower sales in the United States. Lower sales in the United States reflect the timing of public sector purchases and the CDC stockpile borrowing as described above.

The Company is a party to certain third-party license agreements with respect to *Gardasil/Gardasil* 9 pursuant to which the Company pays royalties on worldwide *Gardasil/Gardasil* 9 sales. The royalties, which vary by country and range from 7% to 13%, are included in *Cost of sales*.

Global sales of *ProQuad*, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, were $593 million in 2018, an increase of 12% compared with 2017, driven primarily by higher volumes

and pricing in the United States and volume growth in certain European markets. Worldwide sales of *ProQuad* were $528 million in 2017, an increase of 7% compared with $495 million in 2016. Sales growth in 2017 was driven primarily by higher pricing and volumes in the United States, as well as volume growth in international markets, particularly in Europe. Foreign exchange favorably affected global sales performance by 1% in 2017.

Worldwide sales of *M-M-R* II, a vaccine to help protect against measles, mumps and rubella, were $430 million in 2018, an increase of 13% compared with 2017, driven primarily by volume growth in Latin America. Global sales of *M-M-R* II were $382 million in 2017, an increase of 8% compared with $353 million in 2016. Sales growth in 2017 was largely attributable to higher sales in Europe resulting from the termination of the SPMSD joint venture. Foreign exchange favorably affected global sales performance by 1% in 2018 and unfavorably affected global sales performance by 1% in 2017.

Global sales of *Varivax,* a vaccine to help prevent chickenpox (varicella), were $774 million in 2018, an increase of 1% compared with 2017, reflecting volume growth in Latin America and the Asia Pacific region, along with higher pricing in the United States, largely offset by volume declines in Turkey from the loss of a government tender due to competition. Worldwide sales of *Varivax* were $767 million in 2017, a decline of 3% compared with $792 million in 2016. The sales decline in 2017 was driven primarily by lower volumes in Brazil due to the loss of a government tender, as well as lower sales in the United States reflecting lower demand that was partially offset by higher pricing. Higher sales in Europe resulting from the termination of the SPMSD joint venture partially offset the sales decline in 2017.

Worldwide sales of *Pneumovax* 23, a vaccine to help prevent pneumococcal disease, were $907 million in 2018, an increase of 10% compared with 2017. Sales growth was driven primarily by higher pricing in the United States and volume growth in Europe. Global sales of *Pneumovax* 23 were $821 million in 2017, an increase of 28% compared with 2016, driven primarily by higher demand and pricing in the United States, as well as higher sales in Europe resulting from the termination of the SPMSD joint venture. Foreign exchange unfavorably affected sales performance by 1% in 2017.

Global sales of *RotaTeq,* a vaccine to help protect against rotavirus gastroenteritis in infants and children, were $728 million in 2018, an increase of 6% compared with 2017, driven primarily by the launch in China. Worldwide sales of *RotaTeq* were $686 million in 2017, an increase of 5% compared with 2016, driven primarily by higher sales in Europe resulting from the termination of the SPMSD joint venture.

Worldwide sales of *Zostavax,* a vaccine to help prevent shingles (herpes zoster) in adults 50 years of age and older, were $217 million in 2018, a decline of 68% compared with 2017, driven by lower volumes in most markets, particularly in the United States. Lower demand in the United States reflects the launch of a competing vaccine that received a preferential recommendation from the CDC's Advisory Committee on Immunization Practices in October 2017 for the prevention of shingles over *Zostavax*. The declines were partially offset by higher demand in certain European markets. The Company anticipates competition will continue to have an adverse effect on sales of *Zostavax* in future periods. Global sales of *Zostavax* were $668 million in 2017, a decline of 2% compared with 2016 including a 1% favorable effect from foreign exchange. The sales decline was driven primarily by lower demand in the United States reflecting the approval of a competing vaccine as noted above, partially offset by growth in Europe resulting from the termination of the SPMSD joint venture and volume growth in the Asia Pacific region.

In 2018, the FDA approved *Vaxelis* (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus, Haemophilus b Conjugate [Meningococcal Protein Conjugate] and Hepatitis B [Recombinant] Vaccine) for use in children from 6 weeks through 4 years of age (prior to the 5th birthday). *Vaxelis*, which is currently being marketed in Europe, was developed as part of a joint-partnership between Merck and Sanofi. Merck and Sanofi are working to maximize production of *Vaxelis* to allow for a sustainable supply to meet anticipated U.S. demand. Commercial supply will not be available prior to 2020.

Hospital Acute Care

Global sales of *Bridion*, for the reversal of two types of neuromuscular blocking agents used during surgery, were $917 million in 2018, growth of 30% compared with 2017, driven primarily by volume growth in the United States and certain European markets. Worldwide sales of *Bridion* were $704 million in 2017, growth of 46% compared with 2016, driven by strong global demand, particularly in the United States.

Worldwide sales of *Noxafil*, for the prevention of invasive fungal infections, were $742 million in 2018, an increase of 17% compared with 2017 including a 2% favorable effect from foreign exchange. Sales growth primarily reflects higher demand in the United States, certain European markets and China. Global sales of *Noxafil* were $636 million in 2017, an increase of 7% compared with 2016, primarily reflecting higher demand and pricing in the United States, as well as volume growth in Europe. The patent that provides U.S. market exclusivity for *Noxafil* expires in July 2019. Additionally, the patent for *Noxafil* will expire in a number of major European markets in December 2019. The Company anticipates sales of *Noxafil* in these markets will decline significantly thereafter.

Global sales of *Invanz*, for the treatment of certain infections, were $496 million in 2018, a decline of 18% compared with 2017 including a 1% unfavorable effect from foreign exchange. The sales decline was driven by lower volumes in the United States. The patent that provided U.S. market exclusivity for *Invanz* expired in November 2017 and generic competition began in the second half of 2018. The Company is experiencing a significant decline in U.S. *Invanz* sales as a result of this generic competition and expects the decline to continue. Worldwide sales of *Invanz* were $602 million in 2017, an increase of 7% compared with 2016, driven primarily by higher sales in the United States, reflecting higher pricing that was partially offset by lower demand, as well as higher demand in Brazil.

Global sales of *Cubicin*, an I.V. antibiotic for complicated skin and skin structure infections or bacteremia when caused by designated susceptible organisms, were $367 million in 2018, a decline of 4% compared with 2017 including a 1% favorable effect from foreign exchange. Worldwide sales of *Cubicin* were $382 million in 2017, a decline of 65% compared with 2016, resulting from generic competition in the United States following expiration of the U.S. composition patent for *Cubicin* in June 2016.

Global sales of *Cancidas*, an anti-fungal product sold primarily outside of the United States, were $326 million in 2018, a decline of 23% compared with 2017, and were $422 million in 2017, a decline of 24% compared with 2016. Foreign exchange favorably affected global sales performance by 2% in 2018. The sales declines were driven primarily by generic competition in certain European markets. The EU compound patent for *Cancidas* expired in April 2017. Accordingly, the Company is experiencing a significant decline in *Cancidas* sales in these European markets and expects the decline to continue.

Immunology

Sales of *Simponi*, a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were $893 million in 2018, growth of 9% compared with 2017 including a 4% favorable effect from foreign exchange. Sales of *Simponi* were $819 million in 2017, growth of 7% compared with 2016 including a 1% favorable effect from foreign exchange. Sales growth in both years was driven by higher demand in Europe. The Company anticipates sales of *Simponi* will be unfavorably affected in future periods by the recent launch of biosimilars for a competing product.

Sales of *Remicade,* a treatment for inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were $582 million in 2018, a decline of 31% compared with 2017, and were $837 million in 2017, a decline of 34% compared with 2016. Foreign exchange favorably affected sales performance by 2% in 2018. The Company lost market exclusivity for *Remicade* in major European markets in 2015 and no longer has market exclusivity in any of its marketing territories. The Company is experiencing pricing and volume declines in these markets as a result of biosimilar competition and expects the declines to continue.

Virology

Worldwide sales of *Isentress/Isentress HD,* an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, were $1.1 billion in 2018, a decline of 5% compared with 2017, and were $1.2 billion in 2017, a decline of 13% compared with 2016. Foreign exchange favorably affected global sales performance by 1% in 2017. The sales declines primarily reflect competitive pressure in the United States and Europe.

In August 2018, the FDA approved two new HIV-1 medicines: *Delstrigo*, a once-daily fixed-dose combination tablet of doravirine, lamivudine and tenofovir disoproxil fumarate; and *Pifeltro* (doravirine), a new non-nucleoside reverse transcriptase inhibitor to be administered in combination with other antiretroviral medicines. Both *Delstrigo* and *Pifeltro* are indicated for the treatment of HIV-1 infection in adult patients with no prior antiretroviral treatment experience. *Delstrigo* and *Pifeltro* were also approved by the EC in November 2018. In January 2019, the FDA accepted for review supplemental New Drug Applications (NDA) for *Pifeltro* and *Delstrigo* seeking approval for

use in patients living with HIV-1 who are switching from a stable antiretroviral regimen and whose virus is suppressed. The Prescription Drug User Fee Act (PDUFA) date for the supplemental NDAs is September 20, 2019.

Global sales of *Zepatier*, a treatment for adult patients with certain types of chronic hepatitis C virus (HCV) infection, were $455 million in 2018, a decline of 73% compared with 2017. The sales decline was driven primarily by the unfavorable effects of increasing competition and declining patient volumes, particularly in the United States, Europe and Japan. The Company anticipates that sales of *Zepatier* in the future will continue to be adversely affected by competition and lower patient volumes. Worldwide sales of *Zepatier* were $1.7 billion in 2017 compared with $555 million in 2016. Sales growth in 2017 was driven primarily by higher sales in Europe, the United States and Japan following product launch in 2016.

Cardiovascular

Combined global sales of *Zetia* (marketed in most countries outside the United States as *Ezetrol*), *Vytorin* (marketed outside the United States as *Inegy*), as well as *Atozet* and *Rosuzet* (both marketed in certain countries outside of the United States), medicines for lowering LDL cholesterol, were $1.8 billion in 2018, a decline of 26% compared with 2017 including a 3% favorable effect from foreign exchange. The sales decline was driven primarily by lower demand in the United States and Europe. *Zetia* and *Vytorin* lost market exclusivity in the United States in December 2016 and April 2017, respectively. Accordingly, the Company experienced a rapid and substantial decline in U.S. *Zetia* and *Vytorin* sales as a result of generic competition and has lost nearly all U.S. sales of these products. In addition, the Company lost market exclusivity in major European markets for *Ezetrol* in April 2018 and has also lost market exclusivity in certain European markets for *Inegy* (see Note 11 to the consolidated financial statements). Accordingly, the Company is experiencing significant sales declines in these markets as a result of generic competition and expects the declines to continue. These declines were partially offset by higher sales in Japan due in part to the launch of *Atozet*. Combined worldwide sales of the ezetimibe family were $2.4 billion in 2017, a decline of 39% compared with 2016. The sales decline was driven by lower volumes and pricing of *Zetia* and *Vytorin* in the United States as a result of generic competition due to the loss of U.S. market exclusivity as described above.

Pursuant to a collaboration with Bayer AG (Bayer) (see Note 4 to the consolidated financial statements), Merck has lead commercial rights for Adempas, a cardiovascular drug for the treatment of pulmonary arterial hypertension, in countries outside the Americas while Bayer has lead rights in the Americas, including the United States. The companies share profits equally under the collaboration. In 2016, Merck began promoting and distributing Adempas in Europe. Transition from Bayer in other Merck territories, including Japan, continued in 2017. Revenue from Adempas includes sales in Merck's marketing territories, as well as Merck's share of profits from the sale of Adempas in Bayer's marketing territories. Merck recorded revenue related to Adempas of $329 million in 2018, an increase of 10% compared with 2017, reflecting higher sales in Merck's marketing territories, partially offset by lower profit sharing from Bayer due in part to lower pricing in the United States. Revenue related to Adempas was $300 million in 2017, an increase of 78% compared with 2016, reflecting both higher sales in Merck's marketing territories, as well as the recognition of higher profit sharing from Bayer. Foreign exchange favorably affected global sales performance by 3% in 2018 and by 1% in 2017.

Diabetes

Worldwide combined sales of *Januvia* and *Janumet*, medicines that help lower blood sugar levels in adults with type 2 diabetes, were $5.9 billion in 2018, essentially flat compared with 2017. Global combined sales of *Januvia* and *Janumet* were $5.9 billion in 2017, a decline of 3% compared with 2016. Foreign exchange favorably affected sales performance by 1% in both 2018 and 2017. Sales performance in both periods was driven primarily by ongoing pricing pressure, particularly in the United States, partially offset by higher demand in most international markets. The Company expects pricing pressure to continue.

Women's Health

Worldwide sales of *NuvaRing*, a vaginal contraceptive product, were $902 million in 2018, an increase of 19% compared with 2017 including a 1% favorable effect from foreign exchange. Sales growth was driven primarily by higher pricing in the United States. The patent that provided U.S. market exclusivity for *NuvaRing* expired in April 2018 and the Company anticipates a significant decline in U.S. *NuvaRing* sales in future periods as a result of generic competition. Global sales of *NuvaRing* were $761 million in 2017, a decline of 2% compared with 2016 including a 1% favorable effect from foreign exchange. The sales decline was driven primarily by lower sales in the United States reflecting lower volumes that were partially offset by higher pricing, and lower demand in Europe.

Animal Health Segment

Global sales of Animal Health products were $4.2 billion in 2018, an increase of 9% compared with 2017, reflecting growth from both in-line and recently launched companion animal and livestock products. Higher sales of companion animal products reflect growth in the *Bravecto* line of products that kill fleas and ticks in dogs and cats for up to 12 weeks, as well as higher sales of companion animal vaccines. Growth in livestock products reflects higher sales of ruminant, poultry and swine products. Worldwide sales of Animal Health products were $3.9 billion in 2017, an increase of 11% compared with 2016, primarily reflecting higher sales of companion animal products, largely driven by growth in *Bravecto*, reflecting both growth in the oral formulation and continued uptake in the topical formulation, which was launched in 2016. Animal Health sales growth in 2017 was also driven by higher sales of ruminant, poultry and swine products.

In December 2018, the Company signed an agreement to acquire Antelliq, a leader in digital animal identification, traceability and monitoring solutions (see Note 3 to the consolidated financial statements).

Costs, Expenses and Other

($ in millions)		**2018**	**Change**	2017	Change	2016
Cost of sales	**$**	**13,509**	**5 %**	$ 12,912	-8 %	$ 14,030
Selling, general and administrative		**10,102**	**— %**	10,074	1 %	10,017
Research and development		**9,752**	**-6 %**	10,339	1 %	10,261
Restructuring costs		**632**	**-19 %**	776	19 %	651
Other (income) expense, net		**(402)**	**-20 %**	(500)	*	189
	$	**33,593**	**— %**	$ 33,601	-4 %	$ 35,148

** Greater than 100%.*

Cost of Sales

Cost of sales was $13.5 billion in 2018, $12.9 billion in 2017 and $14.0 billion in 2016. Costs in 2018 include a $423 million charge related to the termination of a collaboration agreement with Samsung Bioepis Co., Ltd. (Samsung) for insulin glargine (see Note 3 to the consolidated financial statements). Also in 2018, the Company recorded $188 million of cumulative amortization expense for amounts capitalized in connection with the recognition of liabilities for potential future milestone payments related to collaborations (see Note 4 to the consolidated financial statements). Cost of sales includes expenses for the amortization of intangible assets recorded in connection with business acquisitions which totaled $2.7 billion in 2018, $3.1 billion in 2017 and $3.7 billion in 2016. Costs in 2017 and 2016 also include intangible asset impairment charges of $58 million and $347 million, respectively, related to marketed products and other intangibles recorded in connection with business acquisitions (see Note 8 to the consolidated financial statements). Costs in 2017 also include a $76 million intangible asset impairment charge related to a licensing agreement. The Company may recognize additional non-cash impairment charges in the future related to intangible assets that were measured at fair value and capitalized in connection with business acquisitions and such charges could be material. Also included in cost of sales are expenses associated with restructuring activities which amounted to $21 million, $138 million and $181 million in 2018, 2017 and 2016, respectively, primarily reflecting accelerated depreciation and asset write-offs related to the planned sale or closure of manufacturing facilities. Separation costs associated with manufacturing-related headcount reductions have been incurred and are reflected in *Restructuring costs* as discussed below.

Gross margin was 68.1% in 2018 compared with 67.8% in 2017 and 64.5% in 2016. The year-over-year improvements in gross margin reflect a lower net impact from the amortization of intangible assets and intangible asset impairment charges related to business acquisitions, as well as restructuring costs as noted above, which reduced gross margin by 6.3 percentage points in 2018, 8.3 percentage points in 2017 and 10.6 percentage points in 2016. The gross margin improvement in 2018 compared with 2017 also reflects the favorable effects of product mix and amortization of unfavorable manufacturing variances recorded in 2017, resulting in part from the June 2017 cyber-attack. The gross margin improvement in 2018 was partially offset by a charge associated with the termination of a collaboration agreement

with Samsung, as well as the unfavorable effects of pricing pressure and cumulative amortization expense for potential future milestone payments related to collaborations as noted above. The gross margin improvement in 2017 compared with 2016 also reflects the favorable effects of product mix. Manufacturing-related costs associated with the cyber-attack partially offset the gross margin improvement in 2017.

Selling, General and Administrative

Selling, general and administrative (SG&A) expenses were $10.1 billion in 2018, essentially flat compared with 2017, reflecting higher administrative costs and the unfavorable effect of foreign exchange, offset by lower selling and promotional expenses. SG&A expenses were $10.1 billion in 2017, an increase of 1% compared with 2016. Higher administrative costs, including costs associated with the Company operating its vaccines business in the European markets that were previously part of the SPMSD joint venture, remediation costs related to the cyber-attack, and higher promotional expenses related to product launches, were partially offset by lower restructuring and acquisition and divestiture-related costs, lower selling expenses and the favorable effect of foreign exchange. SG&A expenses in 2016 include restructuring costs of $95 million related primarily to accelerated depreciation for facilities to be closed or divested. Separation costs associated with sales force reductions have been incurred and are reflected in *Restructuring costs* as discussed below. SG&A expenses also include acquisition and divestiture-related costs of $32 million, $44 million and $78 million in 2018, 2017 and 2016, respectively, consisting of integration, transaction, and certain other costs related to business acquisitions and divestitures.

Research and Development

Research and development (R&D) expenses were $9.8 billion in 2018, a decline of 6% compared with 2017. The decrease primarily reflects lower expenses in 2018 for upfront and license option payments related to the formation of oncology collaborations, lower in-process research and development (IPR&D) impairment charges, and a reduction in expenses associated with a decrease in the estimated fair value measurement of liabilities for contingent consideration, partially offset by higher clinical development spending and investment in discovery and early drug development, as well as higher expenses related to other business development activities, including a charge in 2018 for the acquisition of Viralytics. R&D expenses were $10.3 billion in 2017, an increase of 1% compared with 2016. The increase was driven primarily by a charge in 2017 related to the formation of a collaboration with AstraZeneca, an unfavorable effect from changes in the estimated fair value measurement of liabilities for contingent consideration, and higher clinical development spending, largely offset by lower IPR&D impairment charges and lower restructuring costs.

R&D expenses are comprised of the costs directly incurred by Merck Research Laboratories (MRL), the Company's research and development division that focuses on human health-related activities, which were $5.1 billion in 2018, $4.6 billion in 2017 and $4.4 billion in 2016. Also included in R&D expenses are costs incurred by other divisions in support of R&D activities, including depreciation, production and general and administrative, as well as licensing activity, and certain costs from operating segments, including the Pharmaceutical and Animal Health segments, which in the aggregate were $2.8 billion, $2.9 billion and $2.6 billion for 2018, 2017 and 2016, respectively. Additionally, R&D expenses in 2018 include a $1.4 billion charge related to the formation of a collaboration with Eisai (see Note 4 to the consolidated financial statements), as well as a $344 million charge for the acquisition of Viralytics (see Note 3 to the consolidated financial statements). R&D expenses in 2017 include a $2.35 billion charge related to the formation of a collaboration with AstraZeneca (see Note 4 to the consolidated financial statements). R&D expenses also include IPR&D impairment charges of $152 million, $483 million and $3.6 billion in 2018, 2017 and 2016, respectively (see Note 8 to the consolidated financial statements). The Company may recognize additional non-cash impairment charges in the future related to the cancellation or delay of other pipeline programs that were measured at fair value and capitalized in connection with business acquisitions and such charges could be material. In addition, R&D expenses include expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration recorded in connection with acquisitions. During 2018 and 2016, the Company recorded a net reduction in expenses of $54 million and $402 million, respectively, to decrease the estimated fair value of liabilities for contingent consideration related to the discontinuation or delay of certain programs (see Note 6 to the consolidated financial statements). During 2017, the Company recorded charges of $27 million to increase the estimated fair value of liabilities for contingent consideration. R&D expenses in 2016 also reflect $142 million of accelerated depreciation and asset abandonment costs associated with restructuring activities.

Restructuring Costs

In 2010 and 2013, the Company commenced actions under global restructuring programs designed to streamline its cost structure. The actions under these programs include the elimination of positions in sales, administrative and headquarters organizations, as well as the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities. The Company also continues to reduce its global real estate footprint and improve the efficiency of its manufacturing and supply network.

Restructuring costs, primarily representing separation and other related costs associated with these restructuring activities, were $632 million, $776 million and $651 million in 2018, 2017 and 2016, respectively. In 2018, 2017 and 2016, separation costs of $473 million, $552 million and $216 million, respectively, were incurred associated with actual headcount reductions, as well as estimated expenses under existing severance programs for headcount reductions that were probable and could be reasonably estimated. Merck eliminated approximately 2,160 positions in 2018, 2,450 positions in 2017 and 2,625 positions in 2016 related to these restructuring activities. Also included in restructuring costs are asset abandonment, shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation plan costs. For segment reporting, restructuring costs are unallocated expenses.

Additional costs associated with the Company's restructuring activities are included in *Cost of sales*, *Selling, general and administrative* and *Research and development* as discussed above. The Company recorded aggregate pretax costs of $658 million in 2018, $927 million in 2017 and $1.1 billion in 2016 related to restructuring program activities (see Note 5 to the consolidated financial statements). The Company has substantially completed the actions under these programs.

Other (Income) Expense, Net

Other (income) expense, net, was $402 million of income in 2018, $500 million of income in 2017 and $189 million of expense in 2016. For details on the components of Other (income) expense, net, see Note 15 to the consolidated financial statements.

Segment Profits

($ in millions)	**2018**	2017	2016
Pharmaceutical segment profits	**$ 24,292**	$ 22,495	$ 22,141
Animal Health segment profits	**1,659**	1,552	1,357
Other non-reportable segment profits	**103**	275	146
Other	**(17,353)**	(17,801)	(18,985)
Income before taxes	**$ 8,701**	$ 6,521	$ 4,659

Pharmaceutical segment profits are comprised of segment sales less standard costs, as well as SG&A and R&D expenses directly incurred by the segment. Animal Health segment profits are comprised of segment sales, less all cost of sales, as well as SG&A and R&D expenses directly incurred by the segment. For internal management reporting presented to the chief operating decision maker, Merck does not allocate the remaining cost of sales not included in segment profits as described above, research and development expenses incurred in MRL, or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. Also excluded from the determination of segment profits are acquisition and divestiture-related costs (amortization of purchase accounting adjustments, intangible asset impairment charges and expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration), restructuring costs, and a portion of equity income. Additionally, segment profits do not reflect other expenses from corporate and manufacturing cost centers and other miscellaneous income or expense. These unallocated items, including a charge related to the termination of a collaboration agreement with Samsung for insulin glargine in 2018, a loss on the extinguishment of debt in 2017, and a charge related to the settlement of worldwide *Keytruda* patent litigation and gains on divestitures in 2016, are reflected in "Other" in the above table. Also included in "Other" are miscellaneous corporate profits (losses), as well as operating profits (losses) related to third-party manufacturing sales. In the first quarter of 2018, the Company adopted a new accounting standard related to the classification of certain defined benefit plan costs, which resulted in a change to the measurement of segment profits (see Note 19 to the consolidated financial statements). Prior period amounts have been recast to conform to the new presentation.

Pharmaceutical segment profits grew 8% in 2018 compared with 2017 primarily reflecting higher sales and lower selling and promotional costs. Pharmaceutical segment profits grew 2% in 2017 compared with 2016 primarily reflecting higher sales and the favorable effects of product mix. Animal Health segment profits grew 7% in 2018 and 14% in 2017 driven primarily by higher sales, partially offset by increased selling and promotional costs.

Taxes on Income

The effective income tax rates of 28.8% in 2018, 62.9% in 2017 and 15.4% in 2016 reflect the impacts of acquisition and divestiture-related costs, restructuring costs and the beneficial impact of foreign earnings. The effective income tax rate in 2018 includes measurement-period adjustments to the provisional amounts recorded in 2017 associated with the enactment of U.S. tax legislation known as the Tax Cuts and Jobs Act (TCJA), including $124 million related to the transition tax (see Note 16 to the consolidated financial statements). In addition, the effective income tax rate for 2018 reflects the unfavorable impacts of a $1.4 billion pretax charge recorded in connection with the formation of a collaboration with Eisai and a $423 million pretax charge related to the termination of a collaboration agreement with Samsung for which no tax benefits were recognized. The effective income tax rate for 2017 includes a provisional net charge of $2.6 billion related to the enactment of the TCJA. The effective income tax rate for 2017 also reflects the unfavorable impact of a $2.35 billion pretax charge recorded in connection with the formation of a collaboration with AstraZeneca for which no tax benefit was recognized, partially offset by the favorable impact of a net tax benefit of $234 million related to the settlement of certain federal income tax issues (see Note 16 to the consolidated financial statements), and a benefit of $88 million related to the settlement of a state income tax issue.

Net (Loss) Income Attributable to Noncontrolling Interests

Net (loss) income attributable to noncontrolling interests was $(27) million in 2018 compared with $24 million in 2017 and $21 million in 2016. The loss in 2018 primarily reflects the portion of goodwill impairment charges related to certain business in the Healthcare Services segment that are attributable to noncontrolling interests.

Net Income and Earnings per Common Share

Net income attributable to Merck & Co., Inc. was $6.2 billion in 2018, $2.4 billion in 2017 and $3.9 billion in 2016. EPS was $2.32 in 2018, $0.87 in 2017 and $1.41 in 2016.

Non-GAAP Income and Non-GAAP EPS

Non-GAAP income and non-GAAP EPS are alternative views of the Company's performance that Merck is providing because management believes this information enhances investors' understanding of the Company's results as it permits investors to understand how management assesses performance. Non-GAAP income and non-GAAP EPS exclude certain items because of the nature of these items and the impact that they have on the analysis of underlying business performance and trends. The excluded items (which should not be considered non-recurring) consist of acquisition and divestiture-related costs, restructuring costs and certain other items. These excluded items are significant components in understanding and assessing financial performance.

Non-GAAP income and non-GAAP EPS are important internal measures for the Company. Senior management receives a monthly analysis of operating results that includes non-GAAP EPS. Management uses these measures internally for planning and forecasting purposes and to measure the performance of the Company along with other metrics. Senior management's annual compensation is derived in part using non-GAAP income and non-GAAP EPS. Since non-GAAP income and non-GAAP EPS are not measures determined in accordance with GAAP, they have no standardized meaning prescribed by GAAP and, therefore, may not be comparable to the calculation of similar measures of other companies. The information on non-GAAP income and non-GAAP EPS should be considered in addition to, but not as a substitute for or superior to, net income and EPS prepared in accordance with generally accepted accounting principles in the United States (GAAP).

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A reconciliation between GAAP financial measures and non-GAAP financial measures is as follows:

($ in millions except per share amounts)	**2018**	2017	2016
Income before taxes as reported under GAAP	**$ 8,701**	$ 6,521	$ 4,659
Increase (decrease) for excluded items:			
Acquisition and divestiture-related costs	**3,066**	3,760	7,312
Restructuring costs	**658**	927	1,069
Other items:			
Charge related to the formation of an oncology collaboration with Eisai	**1,400**	—	—
Charge related to the termination of a collaboration with Samsung	**423**	—	—
Charge for the acquisition of Viralytics	**344**	—	—
Charge related to the formation of an oncology collaboration with AstraZeneca	**—**	2,350	—
Charge related to the settlement of worldwide *Keytruda* patent litigation	**—**	—	625
Other	**(57)**	(16)	(67)
Non-GAAP income before taxes	**14,535**	13,542	13,598
Taxes on income as reported under GAAP	**2,508**	4,103	718
Estimated tax benefit on excluded items [1]	**535**	785	2,321
Net tax charge related to the enactment of the TCJA [2]	**(160)**	(2,625)	—
Net tax benefit from the settlement of certain federal income tax issues	**—**	234	—
Tax benefit related to the settlement of a state income tax issue	**—**	88	—
Non-GAAP taxes on income	**2,883**	2,585	3,039
Non-GAAP net income	**11,652**	10,957	10,559
Less: Net (loss) income attributable to noncontrolling interests as reported under GAAP	**(27)**	24	21
Acquisition and divestiture-related costs attributable to noncontrolling interests	**(58)**	—	—
Non-GAAP net income attributable to noncontrolling interests	**31**	**24**	**21**
Non-GAAP net income attributable to Merck & Co., Inc.	**$ 11,621**	$ 10,933	$ 10,538
EPS assuming dilution as reported under GAAP	**$ 2.32**	$ 0.87	$ 1.41
EPS difference [3]	**2.02**	3.11	2.37
Non-GAAP EPS assuming dilution	**$ 4.34**	$ 3.98	$ 3.78

[1] *The estimated tax impact on the excluded items is determined by applying the statutory rate of the originating territory of the non-GAAP adjustments.*

[2] *Amount in 2017 was provisional (see Note 16 to the consolidated financial statements).*

[3] *Represents the difference between calculated GAAP EPS and calculated non-GAAP EPS, which may be different than the amount calculated by dividing the impact of the excluded items by the weighted-average shares for the applicable year.*

Acquisition and Divestiture-Related Costs

Non-GAAP income and non-GAAP EPS exclude the impact of certain amounts recorded in connection with business acquisitions and divestitures. These amounts include the amortization of intangible assets and amortization of purchase accounting adjustments to inventories, as well as intangible asset impairment charges and expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration. Also excluded are integration, transaction, and certain other costs associated with business acquisitions and divestitures.

Restructuring Costs

Non-GAAP income and non-GAAP EPS exclude costs related to restructuring actions (see Note 5 to the consolidated financial statements). These amounts include employee separation costs and accelerated depreciation associated with facilities to be closed or divested. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the asset, based upon the anticipated date the

site will be closed or divested or the equipment disposed of, and depreciation expense as determined utilizing the useful

life prior to the restructuring actions. Restructuring costs also include asset abandonment, shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation costs.

Certain Other Items

Non-GAAP income and non-GAAP EPS exclude certain other items. These items are adjusted for after evaluating them on an individual basis, considering their quantitative and qualitative aspects, and typically consist of items that are unusual in nature, significant to the results of a particular period or not indicative of future operating results. Excluded from non-GAAP income and non-GAAP EPS in 2018 is a charge related to the formation of a collaboration with Eisai (see Note 4 to the consolidated financial statements), a charge related to the termination of a collaboration agreement with Samsung for insulin glargine (see Note 3 to the consolidated financial statements), a charge for the acquisition of Viralytics (see Note 3 to the consolidated financial statements), and measurement-period adjustments related to the provisional amounts recorded for the TCJA (see Note 16 to the consolidated financial statements). Excluded from non-GAAP income and non-GAAP EPS in 2017 is a charge related to the formation of a collaboration with AstraZeneca (see Note 4 to the consolidated financial statements), as well as a provisional net tax charge related to the enactment of the TCJA, a net tax benefit related to the settlement of certain federal income tax issues and a tax benefit related to the settlement of a state income tax issue (see Note 16 to the consolidated financial statements). Excluded from non-GAAP income and non-GAAP EPS in 2016 is a charge to settle worldwide patent litigation related to *Keytruda*.

Research and Development

A chart reflecting the Company's current research pipeline as of February 22, 2019 is set forth in Item 1. "Business — Research and Development" above.

Research and Development Update

The Company currently has several candidates under regulatory review in the United States and internationally.

Keytruda is an approved anti-PD-1 therapy in clinical development for expanded indications in different cancer types.

In February 2019, the FDA accepted and granted Priority Review for a supplemental BLA for *Keytruda* in combination with Inlyta (axitinib), a tyrosine kinase inhibitor, for the first-line treatment of patients with advanced renal cell carcinoma. This supplemental BLA is based on findings from the Phase 3 KEYNOTE-426 trial, which demonstrated that *Keytruda* in combination with axitinib, as compared to sunitinib, significantly improved overall survival (OS) and PFS in the first-line treatment of advanced renal cell carcinoma. These data were presented at the American Society for Clinical Oncology (ASCO) Genitourinary Cancers Symposium in February 2019. The supplemental BLA also included supporting data from the Phase 1b KEYNOTE-035 trial. The FDA set a PDUFA date of June 20, 2019. Merck has filed data from KEYNOTE-426 with regulatory authorities worldwide.

In February 2019, the Committee for Medicinal Products for Human Use of the European Medicines Agency (EMA) adopted a positive opinion recommending *Keytruda*, in combination with carboplatin and either paclitaxel or nab-paclitaxel, for the first-line treatment of metastatic squamous NSCLC in adults. This recommendation is based on results from the pivotal Phase 3 KEYNOTE-407 trial, which enrolled patients regardless of PD-L1 tumor expression status. The trial showed a significant improvement in OS and PFS for patients taking *Keytruda* in combination with chemotherapy (carboplatin and either paclitaxel or nab-paclitaxel) compared with chemotherapy alone. If approved, this would mark the first approval in Europe for an anti-PD-1 therapy in combination with chemotherapy for adults with metastatic squamous NSCLC. In October 2018, the FDA approved *Keytruda* in combination with carboplatin-paclitaxel or nab-paclitaxel as a first-line treatment for metastatic squamous NSCLC, regardless of PD-L1 expression.

In December 2018, the FDA extended the action date for the supplemental BLA seeking approval for *Keytruda* as monotherapy for the first-line treatment of locally advanced or metastatic NSCLC in patients whose tumors express PD-L1 (TPS ≥1%) without EGFR or ALK genomic tumor aberrations. The supplemental BLA is based on results of the Phase 3 KEYNOTE-042 trial where *Keytruda* monotherapy demonstrated a significant improvement in OS compared with chemotherapy in this patient population. The Company submitted additional data and analyses to

the FDA, which constituted a major amendment and extended the PDUFA date by three months to April 11, 2019. Merck continues to work closely with the FDA during the review of this supplemental BLA.

In February 2019, the FDA accepted and granted Priority Review for a supplemental BLA for *Keytruda* as monotherapy for the treatment of patients with advanced SCLC whose disease has progressed after two or more lines of prior therapy. This supplemental BLA, which is seeking accelerated approval for this new indication, is based on data from the SCLC cohorts of the Phase 2 KEYNOTE-158 and Phase 1b KEYNOTE-028 trials. The FDA set a PDUFA date of June 17, 2019. *Keytruda* is also being studied in combination with chemotherapy in the ongoing Phase 3 KEYNOTE-604 study in patients with newly diagnosed extensive stage SCLC.

In February 2019, the FDA accepted a supplemental BLA for *Keytruda* as monotherapy or in combination with platinum and 5-fluorouracil chemotherapy for the first-line treatment of patients with recurrent or metastatic HNSCC. This supplemental BLA is based in part on data from the pivotal Phase 3 KEYNOTE-048 trial where *Keytruda* demonstrated a significant improvement in OS compared with the standard of care, as monotherapy in patients whose tumors expressed PD-L1 with Combined Positive Score (CPS)≥20 and CPS≥1 and in combination with chemotherapy in the total patient population. These data were presented at the European Society for Medical Oncology (ESMO) 2018 Congress. The FDA granted Priority Review to the supplemental BLA and set a PDUFA date of June 10, 2019. KEYNOTE-048 also serves as the confirmatory trial for KEYNOTE-012, a Phase 1b study which supported the previous accelerated approval for *Keytruda* as monotherapy for the treatment of patients with recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy.

In November 2018, Merck announced that the Phase 3 KEYNOTE-181 trial investigating *Keytruda* as monotherapy in the second-line treatment of advanced or metastatic esophageal or esophagogastric junction carcinoma met a primary endpoint of OS in patients whose tumors expressed PD-L1 (CPS ≥10). In this pivotal study, treatment with *Keytruda* resulted in a statistically significant improvement in OS compared to chemotherapy (paclitaxel, docetaxel or irinotecan) in patients with CPS ≥10, regardless of histology. The primary endpoint of OS was also evaluated in patients with squamous cell histology and in the entire intention-to-treat study population. While directionally favorable, statistical significance for OS was not met in these two patient groups. Per the statistical analysis plan, the key secondary endpoints of PFS and objective response rate (ORR) were not formally tested, as OS was not reached in the full intention-to-treat study population. These results were presented in January 2019 at the ASCO Gastrointestinal Cancers Symposium and have been submitted for regulatory review.

Additionally, *Keytruda* has received Breakthrough Therapy designation from the FDA for the treatment of high-risk early-stage triple-negative breast cancer in combination with neoadjuvant chemotherapy. The FDA's Breakthrough Therapy designation is intended to expedite the development and review of a candidate that is planned for use, alone or in combination, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

In October 2018, Merck announced the first presentation of results from an interim analysis of KEYNOTE-057, a Phase 2 trial evaluating *Keytruda* for previously treated patients with high-risk non-muscle invasive bladder cancer. An interim analysis of the study's primary endpoint showed a complete response rate of nearly 40% at three months with *Keytruda* in patients whose disease was unresponsive to Bacillus Calmette-Guérin therapy, the current standard of care for this disease, and who were ineligible for or who refused to undergo radical cystectomy. These results, as well as other study findings, were presented at the ESMO 2018 Congress.

In February 2019, Merck announced that the pivotal Phase 3 KEYNOTE-240 trial evaluating *Keytruda*, plus best supportive care, for the treatment of patients with advanced hepatocellular carcinoma who were previously treated with systemic therapy, did not meet its co-primary endpoints of OS and PFS compared with placebo plus best supportive care. In the final analysis of the study, there was an improvement in OS for patients treated with *Keytruda* compared to placebo, however these OS results did not meet statistical significance per the pre-specified statistical plan. Results for PFS were also directionally favorable in the *Keytruda* arm compared with placebo but did not reach statistical significance. The key secondary endpoint of ORR was not formally tested, since superiority was not reached for OS or PFS. Results will be presented at an upcoming medical meeting and have been shared with the FDA for discussion.

The *Keytruda* clinical development program consists of more than 900 clinical trials, including more than 600 trials that combine *Keytruda* with other cancer treatments. These studies encompass more than 30 cancer types including: bladder, cervical, colorectal, esophageal, gastric, head and neck, hepatocellular, Hodgkin lymphoma, non-Hodgkin lymphoma, melanoma, mesothelioma, nasopharyngeal, NSCLC, ovarian, PMBCL, prostate, renal, small-cell lung and triple-negative breast, many of which are currently in Phase 3 clinical development. Further trials are being planned for other cancers.

Lynparza, is an oral PARP inhibitor currently approved for certain types of ovarian and breast cancer. In July 2017, Merck and AstraZeneca entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza for multiple cancer types (see Note 4 to the consolidated financial statements).

In April 2018, Merck and AstraZeneca announced that the EMA validated for review the Marketing Authorization Application for Lynparza for use in patients with deleterious or suspected deleterious *BRCA*-mutated, HER2-negative metastatic breast cancer who have been previously treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. This was the first regulatory submission for a PARP inhibitor in breast cancer in Europe.

Lynparza tablets are also under review in the EU as a maintenance treatment in patients with newly-diagnosed, *BRCA*-mutated advanced ovarian cancer who were in complete or partial response following first-line standard platinum-based chemotherapy. This submission was based on positive results from the pivotal Phase 3 SOLO-1 trial. The trial showed a statistically-significant and clinically-meaningful improvement in PFS for Lynparza compared to placebo, reducing the risk of disease progression or death by 70% in patients with newly-diagnosed, *BRCA*-mutated advanced ovarian cancer who were in complete or partial response to platinum-based chemotherapy.

In December 2018, Merck and AstraZeneca announced positive results from the randomized, open-label, controlled, Phase 3 SOLO-3 trial of Lynparza tablets in patients with relapsed ovarian cancer after two or more lines of treatment. The trial was conducted as a post-approval commitment in agreement with the FDA. Results from the trial showed *BRCA*-mutated advanced ovarian cancer patients treated with Lynparza following two or more prior lines of chemotherapy demonstrated a statistically significant and clinically meaningful improvement in the primary endpoint of ORR and the key secondary endpoint of PFS compared to chemotherapy. Merck and AstraZeneca plan to discuss these results with the FDA.

MK-7655A is a combination of relebactam, an investigational beta-lactamase inhibitor, and imipenem/cilastatin (an approved carbapenem antibiotic). In February 2019, Merck announced that the FDA accepted for Priority Review an NDA for MK-7655A for the treatment of complicated urinary tract infections and complicated intra-abdominal infections caused by certain susceptible Gram-negative bacteria in adults with limited or no alternative therapies available. The PDUFA date is July 16, 2019. In April 2018, Merck announced that a pivotal Phase 3 study of MK-7655A demonstrated a favorable overall response in the treatment of certain imipenem-non-susceptible bacterial infections, the primary endpoint, with lower treatment-emergent nephrotoxicity (kidney toxicity), a secondary endpoint, compared to a colistin (colistimethate sodium) plus imipenem/cilastatin regimen. The FDA had previously designated this combination a Qualified Infectious Disease Product with designated Fast Track status for the treatment of hospital-acquired bacterial pneumonia, ventilator-associated bacterial pneumonia, complicated intra-abdominal infections and complicated urinary tract infections.

V920 (rVSVΔG-ZEBOV-GP, live attenuated), is an investigational Ebola Zaire disease vaccine candidate being studied in large scale Phase 2/3 clinical trials. In December 2015, Merck announced that the application for Emergency Use Assessment and Listing (EUAL) for V920 was accepted for review by the World Health Organization (WHO). According to the WHO, the EUAL process is designed to expedite the availability of vaccines needed for public health emergencies such as another outbreak of Ebola. The WHO decision to grant V920 EUAL status will be based on data regarding quality, safety, and efficacy/effectiveness; as well as a risk/benefit analysis for emergency use. While EUAL designation allows for emergency use, the vaccine remains investigational and has not yet been licensed for commercial distribution. In July 2016, Merck announced that the FDA granted V920 Breakthrough Therapy designation, and that the EMA granted the vaccine candidate PRIME (PRIority MEdicines) status. In November 2018, Merck announced that it has started the submission of a rolling BLA to the FDA for V920. This rolling submission was made pursuant to the FDA's Breakthrough Therapy designation. Merck expects the rolling submission of the BLA to be completed in 2019. The Company also intends to file V920 with the EMA in 2019.

In February 2019, Merck announced that the FDA accepted for Priority Review a supplemental NDA for *Zerbaxa* to treat adult patients with nosocomial pneumonia, including ventilator-associated pneumonia, caused by certain susceptible Gram-negative microorganisms. The PDUFA date is June 3, 2019. *Zerbaxa* is also under review for this indication by the EMA. *Zerbaxa* is currently approved in the United States for the treatment of adult patients with complicated urinary tract infections caused by certain susceptible Gram-negative microorganisms, and is also indicated, in combination with metronidazole, for the treatment of adult patients with complicated intra-abdominal infections caused by certain susceptible Gram-negative and Gram-positive microorganisms.

In addition to the candidates under regulatory review, the Company has several drug candidates in Phase 3 clinical development in addition to the *Keytruda* programs discussed above.

MK-7264, gefapixant, is a selective, non-narcotic, orally-administered P2X3-receptor agonist being investigated in Phase 3 trials for the treatment of refractory, chronic cough and in a Phase 2 trial for the treatment of women with endometriosis-related pain.

Lenvima, is an orally available tyrosine kinase inhibitor currently approved for certain types of thyroid cancer, hepatocellular carcinoma, and in combination for certain patients with renal cell carcinoma. In March 2018, Merck and Eisai entered into a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima (see Note 4 to the consolidated financial statements). Under the agreement, Merck and Eisai will develop and commercialize Lenvima jointly, both as monotherapy and in combination with *Keytruda*. Per the agreement, the companies will jointly initiate clinical studies evaluating the *Keytruda*/Lenvima combination to support 11 potential indications in six types of cancer (endometrial cancer, NSCLC, hepatocellular carcinoma, head and neck cancer, bladder cancer and melanoma), as well as a basket trial targeting multiple cancer types. The FDA granted Breakthrough Therapy designation for *Keytruda* in combination with Lenvima for the potential treatment of patients with advanced and/or metastatic renal cell carcinoma and for the potential treatment of certain patients with advanced and/or metastatic non-microsatellite instability high/proficient mismatch repair endometrial carcinoma.

MK-1242, vericiguat, is an investigational treatment for heart failure being studied in patients suffering from chronic heart failure with reduced ejection fracture (Phase 3 clinical trial) and from chronic heart failure with preserved ejection fracture (Phase 2 clinical trial). The development of vericiguat is part of a worldwide strategic collaboration between Merck and Bayer (see Note 4 to the consolidated financial statements).

V114 is an investigational polyvalent conjugate vaccine for the prevention of pneumococcal disease. In June 2018, Merck initiated the first Phase 3 study in the adult population for the prevention of invasive pneumococcal disease. Currently five Phase 3 adult studies are ongoing, including studies in healthy adults 50 years of age or older, adults with risk factors for pneumococcal disease, those infected with HIV, and those who are recipients of allogeneic hematopoietic stem cell transplant. In October 2018, Merck began the first Phase 3 study in the pediatric population. Currently, three studies are ongoing, including studies in healthy infants and in children afflicted with sickle cell disease. In January 2019, Merck announced that V114 received Breakthrough Therapy designation from the FDA for the prevention of invasive pneumococcal disease caused by the vaccine serotypes in pediatric patients 6 weeks to 18 years of age.

As a result of changes in the herpes zoster vaccine environment, Merck is ending development of V212, its investigational vaccine for the prevention of shingles in immunocompromised patients.

The Company maintains a number of long-term exploratory and fundamental research programs in biology and chemistry as well as research programs directed toward product development. The Company's research and development model is designed to increase productivity and improve the probability of success by prioritizing the Company's research and development resources on candidates the Company believes are capable of providing unambiguous, promotable advantages to patients and payers and delivering the maximum value of its approved medicines and vaccines through new indications and new formulations. Merck is pursuing emerging product opportunities independent of therapeutic area or modality (small molecule, biologics and vaccines) and is building its biologics capabilities. The Company is committed to ensuring that externally sourced programs remain an important component of its pipeline strategy, with a focus on supplementing its internal research with a licensing and external alliance strategy focused on the entire spectrum of collaborations from early research to late-stage compounds, as well as access to new technologies.

The Company also reviews its pipeline to examine candidates that may provide more value through out-licensing. The Company continues to evaluate certain late-stage clinical development and platform technology assets to determine their out-licensing or sale potential.

The Company's clinical pipeline includes candidates in multiple disease areas, including cancer, cardiovascular diseases, diabetes, infectious diseases, neurosciences, obesity, pain, respiratory diseases, and vaccines.

Acquired In-Process Research and Development

In connection with business acquisitions, the Company has recorded the fair value of in-process research projects which, at the time of acquisition, had not yet reached technological feasibility. At December 31, 2018, the balance of IPR&D was $1.1 billion.

The IPR&D projects that remain in development are subject to the inherent risks and uncertainties in drug development and it is possible that the Company will not be able to successfully develop and complete the IPR&D programs and profitably commercialize the underlying product candidates. The time periods to receive approvals from the FDA and other regulatory agencies are subject to uncertainty. Significant delays in the approval process, or the Company's failure to obtain approval at all, would delay or prevent the Company from realizing revenues from these products. Additionally, if certain of the IPR&D programs fail or are abandoned during development, then the Company will not realize the future cash flows it has estimated and recorded as IPR&D as of the acquisition date, and the Company may also not recover the research and development expenditures made since the acquisition to further develop such programs. If such circumstances were to occur, the Company's future operating results could be adversely affected and the Company may recognize impairment charges and such charges could be material.

In 2018, 2017, and 2016 the Company recorded IPR&D impairment charges within *Research and development* expenses of $152 million, $483 million and $3.6 billion, respectively (see Note 8 to the consolidated financial statements).

Additional research and development will be required before any of the remaining programs reach technological feasibility. The costs to complete the research projects will depend on whether the projects are brought to their final stages of development and are ultimately submitted to the FDA or other regulatory agencies for approval.

Acquisitions, Research Collaborations and License Agreements

Merck continues to remain focused on pursuing opportunities that have the potential to drive both near- and long-term growth. Certain of the more recent transactions are described below. Merck is actively monitoring the landscape for growth opportunities that meet the Company's strategic criteria.

In March 2018, Merck and Eisai announced a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima, an orally available tyrosine kinase inhibitor discovered by Eisai. Under the agreement, Merck and Eisai will develop and commercialize Lenvima jointly, both as monotherapy and in combination with Merck's anti-PD-1 therapy, *Keytruda*. Under the agreement, Merck made an upfront payment to Eisai of $750 million and will make payments of up to $650 million for certain option rights through 2021 (of which $325 million will be paid in March 2019, $200 million is expected to be paid in 2020 and $125 million is expected to be paid in 2021). The Company recorded a charge of $1.4 billion in *Research and development* expenses in 2018 related to the upfront payment and future option payments. In addition, the agreement provides for Eisai to receive up to $385 million associated with the achievement of certain clinical and regulatory milestones and up to $3.97 billion for the achievement of milestones associated with sales of Lenvima (see Note 4 to the consolidated financial statements).

In June 2018, Merck acquired Viralytics Limited (Viralytics), an Australian publicly traded company focused on oncolytic immunotherapy treatments for a range of cancers, for AUD 502 million ($378 million). The transaction provided Merck with full rights to *Cavatak* (V937, formerly CVA21), Viralytics's investigational oncolytic immunotherapy. *Cavatak* is based on Viralytics's proprietary formulation of an oncolytic virus (Coxsackievirus Type A21) that has been shown to preferentially infect and kill cancer cells. *Cavatak* is currently being evaluated in multiple Phase 1 and Phase 2 clinical trials, both as an intratumoral and intravenous agent, including in combination with *Keytruda*. Under a previous agreement between Merck and Viralytics, a study is investigating the use of the *Keytruda* and *Cavatak* combination in melanoma, prostate, lung and bladder cancers. The transaction was accounted for as an acquisition of an asset. Merck recorded net assets of $34 million (primarily cash) at the acquisition date and *Research*

and development expenses of $344 million in 2018 related to the transaction. There are no future contingent payments associated with the acquisition.

In February 2019, Merck and Immune Design entered into a definitive agreement under which Merck will acquire Immune Design for $5.85 per share in cash for an approximate value of $300 million. Immune Design is a late-stage immunotherapy company employing next-generation *in vivo* approaches to enable the body's immune system to fight disease. Immune Design's proprietary technologies, GLAAS and ZVex, are engineered to activate the immune system's natural ability to generate and/or expand antigen-specific cytotoxic immune cells to fight cancer and other chronic diseases. Under the terms of the acquisition agreement, Merck, through a subsidiary, will initiate a tender offer to acquire all outstanding shares of Immune Design. The closing of the tender offer will be subject to certain conditions, including the tender of shares representing at least a majority of the total number of Immune Design's outstanding shares, the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and other customary conditions. The transaction is expected to close early in the second quarter of 2019.

Capital Expenditures

Capital expenditures were $2.6 billion in 2018, $1.9 billion in 2017 and $1.6 billion in 2016. Expenditures in the United States were $1.5 billion in 2018, $1.2 billion in 2017 and $1.0 billion in 2016. In October 2018, the Company announced it plans to invest approximately $16 billion on new capital projects from 2018-2022. The focus of this investment will primarily be on increasing manufacturing capacity across Merck's key businesses.

Depreciation expense was $1.4 billion in 2018, $1.5 billion in 2017 and $1.6 billion in 2016. In each of these years, $1.0 billion of the depreciation expense applied to locations in the United States. Total depreciation expense in 2017 and 2016 included accelerated depreciation of $60 million and $227 million, respectively, associated with restructuring activities (see Note 5 to the consolidated financial statements).

Analysis of Liquidity and Capital Resources

Merck's strong financial profile enables it to fund research and development, focus on external alliances, support in-line products and maximize upcoming launches while providing significant cash returns to shareholders.

Selected Data

($ in millions)	**2018**	2017	2016
Working capital	**$ 3,669**	$ 6,152	$ 13,410
Total debt to total liabilities and equity	**30.4 %**	27.8 %	26.0 %
Cash provided by operations to total debt	**0.4:1**	0.3:1	0.4:1

The decline in working capital in 2018 compared with 2017 reflects the utilization of cash and short-term borrowings to fund $5.0 billion of ASR agreements, a $1.25 billion payment to redeem debt in connection with the exercise of a make-whole provision as discussed below, as well as a $750 million upfront payment related to the formation of a collaboration with Eisai discussed above. The decline in working capital in 2017 compared with 2016 primarily reflects the reclassification of $3.0 billion of notes due in the first half of 2018 from long-term debt to short-term debt, $1.85 billion of upfront and option payments related to the formation of the AstraZeneca collaboration discussed above, as well as $810 million paid to redeem debt in connection with tender offers discussed below.

Cash provided by operating activities was $10.9 billion in 2018, $6.5 billion in 2017 and $10.4 billion in 2016. The lower cash provided by operating activities in 2017 reflects a $2.8 billion payment related to the settlement of certain federal income tax issues (see Note 16 to the consolidated financial statements), payments of $1.85 billion related to the formation of a collaboration with AstraZeneca (see Note 4 to the consolidated financial statements), and a $625 million payment made by the Company related to the previously disclosed settlement of worldwide *Keytruda* patent litigation. Cash provided by operating activities continues to be the Company's primary source of funds to finance operating needs, capital expenditures, treasury stock purchases and dividends paid to shareholders.

Cash provided by investing activities was $4.3 billion in 2018 compared with $2.7 billion in 2017. The increase in cash provided by investing activities was driven primarily by lower purchases of securities and other investments, partially offset by higher capital expenditures, lower proceeds from the sales of securities and other investments, and a $350 million milestone payment in 2018 related to a collaboration with Bayer (see Note 4 to the

consolidated financial statements). Cash provided by investing activities was $2.7 billion in 2017 compared with a use

of cash in investing activities of $3.2 billion in 2016. The change was driven primarily by lower purchases of securities and other investments, higher proceeds from the sales of securities and other investments and a lower use of cash for the acquisitions of businesses.

Cash used in financing activities was $13.2 billion in 2018 compared with $10.0 billion in 2017. The increase in cash used in financing activities was driven primarily by higher purchases of treasury stock (largely under ASR agreements as discussed below), higher payments on debt and payment of contingent consideration related to a prior year business acquisition, partially offset by an increase in short-term borrowings. Cash used in financing activities was $10.0 billion in 2017 compared with $9.0 billion in 2016. The increase in cash used in financing activities was driven primarily by proceeds from the issuance of debt in 2016, as well as higher purchases of treasury stock and lower proceeds from the exercise of stock options in 2017, partially offset by lower payments on debt in 2017.

The Company's contractual obligations as of December 31, 2018 are as follows:

Payments Due by Period

($ in millions)	Total	2019	2020—2021	2022—2023	Thereafter
Purchase obligations [1]	$ 2,349	$ 886	$ 1,011	$ 407	$ 45
Loans payable and current portion of long-term debt	5,309	5,309	—	—	—
Long-term debt	19,882	—	4,237	4,000	11,645
Interest related to debt obligations	7,680	662	1,163	932	4,923
Unrecognized tax benefits [2]	44	44	—	—	—
Transition tax related to the enactment of the TCJA [3]	4,899	275	873	1,217	2,534
Leases	997	188	348	218	243
	$ 41,160	$ 7,364	$ 7,632	$ 6,774	$ 19,390

[1] *Includes future inventory purchases the Company has committed to in connection with certain divestitures.*

[2] *As of December 31, 2018, the Company's Consolidated Balance Sheet reflects liabilities for unrecognized tax benefits, interest and penalties of $2.3 billion, including $44 million reflected as a current liability. Due to the high degree of uncertainty regarding the timing of future cash outflows of liabilities for unrecognized tax benefits beyond one year, a reasonable estimate of the period of cash settlement for years beyond 2019 cannot be made.*

[3] *In connection with the enactment of the TCJA, the Company is required to pay a one-time transition tax, which the Company has elected to pay over a period of eight years as permitted under the TCJA (see Note 16 to the consolidated financial statements).*

Purchase obligations are enforceable and legally binding obligations for purchases of goods and services including minimum inventory contracts, research and development and advertising. Amounts reflected for research and development obligations do not include contingent milestone payments related to collaborative arrangements and acquisitions. Contingent milestone payments are not considered contractual obligations as they are contingent upon the successful achievement of developmental, regulatory approval and commercial milestones. At December 31, 2018, the Company has liabilities for milestone payments related to collaborations with AstraZeneca, Eisai and Bayer (see Note 4 to the consolidated financial statements). Also excluded from research and development obligations are potential future funding commitments of up to approximately $40 million for investments in research venture capital funds. Loans payable and current portion of long-term debt reflects $149 million of long-dated notes that are subject to repayment at the option of the holders. Required funding obligations for 2019 relating to the Company's pension and other postretirement benefit plans are not expected to be material. However, the Company currently anticipates contributing approximately $50 million to its U.S. pension plans, $150 million to its international pension plans and $15 million to its other postretirement benefit plans during 2019.

In December 2018, the Company exercised a make-whole provision on its $1.25 billion, 5.00% notes due 2019 and repaid this debt.

In November 2017, the Company launched tender offers for certain outstanding notes and debentures. The Company paid $810 million in aggregate consideration (applicable purchase price together with accrued interest) to redeem $585 million principal amount of debt that was validly tendered in connection with the tender offers.

In November 2016, the Company issued €1.0 billion principal amount of senior unsecured notes consisting of €500 million principal amount of 0.50% notes due 2024 and €500 million principal amount of 1.375% notes due 2036. The Company used the net proceeds of the offering of $1.1 billion for general corporate purposes.

The Company has a $6.0 billion credit facility that matures in June 2023. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

In March 2018, the Company filed a securities registration statement with the U.S. Securities and Exchange Commission (SEC) under the automatic shelf registration process available to "well-known seasoned issuers" which is effective for three years.

Effective as of November 3, 2009, the Company executed a full and unconditional guarantee of the then existing debt of its subsidiary Merck Sharp & Dohme Corp. (MSD) and MSD executed a full and unconditional guarantee of the then existing debt of the Company (excluding commercial paper), including for payments of principal and interest. These guarantees do not extend to debt issued subsequent to that date.

The Company continues to maintain a conservative financial profile. The Company places its cash and investments in instruments that meet high credit quality standards, as specified in its investment policy guidelines. These guidelines also limit the amount of credit exposure to any one issuer. The Company does not participate in any off-balance sheet arrangements involving unconsolidated subsidiaries that provide financing or potentially expose the Company to unrecorded financial obligations.

In October 2018, Merck announced that its Board of Directors approved a 15% increase to the Company's quarterly dividend, raising it to $0.55 per share from $0.48 per share on the Company's outstanding common stock. Payment was made in January 2019. In January 2019, the Board of Directors declared a quarterly dividend of $0.55 per share on the Company's common stock for the second quarter of 2019 payable in April 2019.

In November 2017, Merck's Board of Directors authorized purchases of up to $10 billion of Merck's common stock for its treasury. The treasury stock purchase authorization has no time limit and will be made over time in open-market transactions, block transactions, on or off an exchange, or in privately negotiated transactions. In October 2018, Merck's Board of Directors authorized an additional $10 billion of treasury stock purchases with no time limit for completion and the Company entered into ASR agreements of $5 billion as discussed below. The Company spent $9.1 billion to purchase shares of its common stock for its treasury during 2018. As of December 31, 2018, the Company's remaining share repurchase authorization was $11.9 billion. The Company purchased $4.0 billion and $3.4 billion of its common stock during 2017 and 2016, respectively, under authorized share repurchase programs.

On October 25, 2018, the Company entered into ASR agreements with two third-party financial institutions (Dealers). Under the ASR agreements, Merck agreed to purchase $5 billion of Merck's common stock, in total, with an initial delivery of 56.7 million shares of Merck's common stock, based on the then-current market price, made by the Dealers to Merck, and payments of $5 billion made by Merck to the Dealers on October 29, 2018, which were funded with existing cash and investments, as well as short-term borrowings. The number of shares of Merck's common stock that Merck may receive, or may be required to remit, upon final settlement under the ASR agreements will be based upon the average daily volume weighted-average price of Merck's common stock during the term of the ASR program, less a negotiated discount. Final settlement of the transaction under the ASR agreements is expected to occur in the first half of 2019, but may occur earlier at the option of the Dealers, or later under certain circumstances. If Merck is obligated to make adjustment payments to the Dealers under the ASR agreements, Merck may elect to satisfy such obligations in cash or in shares of Merck's common stock.

Financial Instruments Market Risk Disclosures

The Company manages the impact of foreign exchange rate movements and interest rate movements on its earnings, cash flows and fair values of assets and liabilities through operational means and through the use of various financial instruments, including derivative instruments.

A significant portion of the Company's revenues and earnings in foreign affiliates is exposed to changes in foreign exchange rates. The objectives and accounting related to the Company's foreign currency risk management program, as well as its interest rate risk management activities are discussed below.

Foreign Currency Risk Management

The Company has established revenue hedging, balance sheet risk management, and net investment hedging programs to protect against volatility of future foreign currency cash flows and changes in fair value caused by volatility in foreign exchange rates.

The objective of the revenue hedging program is to reduce the variability caused by changes in foreign exchange rates that would affect the U.S. dollar value of future cash flows derived from foreign currency denominated sales, primarily the euro and Japanese yen. To achieve this objective, the Company will hedge a portion of its forecasted foreign currency denominated third-party and intercompany distributor entity sales (forecasted sales) that are expected to occur over its planning cycle, typically no more than two years into the future. The Company will layer in hedges over time, increasing the portion of forecasted sales hedged as it gets closer to the expected date of the forecasted sales. The portion of forecasted sales hedged is based on assessments of cost-benefit profiles that consider natural offsetting exposures, revenue and exchange rate volatilities and correlations, and the cost of hedging instruments. The Company manages its anticipated transaction exposure principally with purchased local currency put options, forward contracts, and purchased collar options.

Because Merck principally sells foreign currency in its revenue hedging program, a uniform weakening of the U.S. dollar would yield the largest overall potential loss in the market value of these hedge instruments. The market value of Merck's hedges would have declined by an estimated $441 million and $400 million at December 31, 2018 and 2017, respectively, from a uniform 10% weakening of the U.S. dollar. The market value was determined using a foreign exchange option pricing model and holding all factors except exchange rates constant. Although not predictive in nature, the Company believes that a 10% threshold reflects reasonably possible near-term changes in Merck's major foreign currency exposures relative to the U.S. dollar. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

The Company manages operating activities and net asset positions at each local subsidiary in order to mitigate the effects of exchange on monetary assets and liabilities. The Company also uses a balance sheet risk management program to mitigate the exposure of net monetary assets that are denominated in a currency other than a subsidiary's functional currency from the effects of volatility in foreign exchange. In these instances, Merck principally utilizes forward exchange contracts to offset the effects of exchange on exposures denominated in developed country currencies, primarily the euro and Japanese yen. For exposures in developing country currencies, the Company will enter into forward contracts to partially offset the effects of exchange on exposures when it is deemed economical to do so based on a cost-benefit analysis that considers the magnitude of the exposure, the volatility of the exchange rate and the cost of the hedging instrument. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

A sensitivity analysis to changes in the value of the U.S. dollar on foreign currency denominated derivatives, investments and monetary assets and liabilities indicated that if the U.S. dollar uniformly weakened by 10% against all currency exposures of the Company at December 31, 2018 and 2017, *Income before taxes* would have declined by approximately $134 million and $92 million in 2018 and 2017, respectively. Because the Company was in a net short (payable) position relative to its major foreign currencies after consideration of forward contracts, a uniform weakening of the U.S. dollar will yield the largest overall potential net loss in earnings due to exchange. This measurement assumes that a change in one foreign currency relative to the U.S. dollar would not affect other foreign currencies relative to the U.S. dollar. Although not predictive in nature, the Company believes that a 10% threshold reflects reasonably possible near-term changes in Merck's major foreign currency exposures relative to the U.S. dollar. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

The economy of Argentina was determined to be hyperinflationary in 2018; consequently, in accordance with U.S. GAAP, the Company began remeasuring its monetary assets and liabilities for those operations in earnings. The impact to the Company's results was immaterial.

The Company also uses forward exchange contracts to hedge its net investment in foreign operations against movements in exchange rates. The forward contracts are designated as hedges of the net investment in a foreign operation. The Company hedges a portion of the net investment in certain of its foreign operations. The unrealized gains or losses on these contracts are recorded in foreign currency translation adjustment within *Other Comprehensive Income (Loss)* (*OCI*), and remain in *Accumulated Other Comprehensive Income (Loss)* (*AOCI)* until either the sale or complete or substantially complete liquidation of the subsidiary. The Company excludes certain portions of the change in fair value of its derivative instruments from the assessment of hedge effectiveness (excluded component). Changes in fair value of the excluded components are recognized in *OCI*. In accordance with the new guidance adopted on January 1, 2018 (see Note 2 to the consolidated financial statements), the Company has elected to recognize in earnings the initial value of the excluded component on a straight-line basis over the life of the derivative instrument, rather

than using the mark-to-market approach. The cash flows from these contracts are reported as investing activities in the Consolidated Statement of Cash Flows.

Foreign exchange risk is also managed through the use of foreign currency debt. The Company's senior unsecured euro-denominated notes have been designated as, and are effective as, economic hedges of the net investment in a foreign operation. Accordingly, foreign currency transaction gains or losses due to spot rate fluctuations on the euro-denominated debt instruments are included in foreign currency translation adjustment within *OCI*.

Interest Rate Risk Management

The Company may use interest rate swap contracts on certain investing and borrowing transactions to manage its net exposure to interest rate changes and to reduce its overall cost of borrowing. The Company does not use leveraged swaps and, in general, does not leverage any of its investment activities that would put principal capital at risk.

In May 2018, four interest rate swaps with notional amounts aggregating $1.0 billion matured. These swaps effectively converted the Company's $1.0 billion, 1.30% fixed-rate notes due 2018 to variable rate debt. In December 2018, in connection with the early repayment of debt, the Company settled three interest rate swaps with notional amounts aggregating $550 million. These swaps effectively converted a portion of the Company's $1.25 billion, 5.00% notes due 2019 to variable rate debt. At December 31, 2018, the Company was a party to 19 pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes as detailed in the table below.

($ in millions)	**2018**		
Debt Instrument	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
1.85% notes due 2020	$ 1,250	5	$ 1,250
3.875% notes due 2021	1,150	5	1,150
2.40% notes due 2022	1,000	4	1,000
2.35% notes due 2022	1,250	5	1,250

The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in the benchmark London Interbank Offered Rate (LIBOR) swap rate. The fair value changes in the notes attributable to changes in the LIBOR swap rate are recorded in interest expense along with the offsetting fair value changes in the swap contracts. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

The Company's investment portfolio includes cash equivalents and short-term investments, the market values of which are not significantly affected by changes in interest rates. The market value of the Company's medium- to long-term fixed-rate investments is modestly affected by changes in U.S. interest rates. Changes in medium- to long-term U.S. interest rates have a more significant impact on the market value of the Company's fixed-rate borrowings, which generally have longer maturities. A sensitivity analysis to measure potential changes in the market value of Merck's investments and debt from a change in interest rates indicated that a one percentage point increase in interest rates at December 31, 2018 and 2017 would have positively affected the net aggregate market value of these instruments by $1.2 billion and $1.3 billion, respectively. A one percentage point decrease at December 31, 2018 and 2017 would have negatively affected the net aggregate market value by $1.4 billion and $1.5 billion, respectively. The fair value of Merck's debt was determined using pricing models reflecting one percentage point shifts in the appropriate yield curves. The fair values of Merck's investments were determined using a combination of pricing and duration models.

Critical Accounting Policies

The Company's consolidated financial statements are prepared in conformity with GAAP and, accordingly, include certain amounts that are based on management's best estimates and judgments. Estimates are used when accounting for amounts recorded in connection with acquisitions, including initial fair value determinations of assets and liabilities, primarily IPR&D, other intangible assets and contingent consideration, as well as subsequent fair value measurements. Additionally, estimates are used in determining such items as provisions for sales discounts and returns, depreciable and amortizable lives, recoverability of inventories, including those produced in preparation for product launches, amounts recorded for contingencies, environmental liabilities, accruals for contingent sales-based milestone payments and other reserves, pension and other postretirement benefit plan assumptions, share-based compensation assumptions, restructuring costs, impairments of long-lived assets (including intangible assets and goodwill) and investments, and taxes on income. Because of the uncertainty inherent in such estimates, actual results may differ from these estimates. Application of the following accounting policies result in accounting estimates having the potential for the most significant impact on the financial statements.

Acquisitions and Dispositions

To determine whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses, the Company makes certain judgments, which include assessment of the inputs, processes, and outputs associated with the acquired set of activities. If the Company determines that substantially all of the fair value of gross assets included in a transaction is concentrated in a single asset (or a group of similar assets), the assets would not represent a business. To be considered a business, the assets in a transaction need to include an input and a substantive process that together significantly contribute to the ability to create outputs.

In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the acquisition at their respective fair values with limited exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are generally recognized at fair value. If fair value cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Accordingly, the Company may be required to value assets at fair value measures that do not reflect the Company's intended use of those assets. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in the Company's consolidated financial statements after the date of the acquisition. The fair values of intangible assets, including acquired IPR&D, are determined utilizing information available near the acquisition date based on expectations and assumptions that are deemed reasonable by management. Given the considerable judgment involved in determining fair values, the Company typically obtains assistance from third-party valuation specialists for significant items. Amounts allocated to acquired IPR&D are capitalized and accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, Merck will make a separate determination as to the then-useful life of the asset, generally determined by the period in which the substantial majority of the cash flows are expected to be generated, and begin amortization. Certain of the Company's business acquisitions involve the potential for future payment of consideration that is contingent upon the achievement of performance milestones, including product development milestones and royalty payments on future product sales. The fair value of contingent consideration liabilities is determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date, at each reporting period, the contingent consideration liability is remeasured at current fair value with changes (either expense or income) recorded in earnings. Changes in any of the inputs may result in a significantly different fair value adjustment.

The judgments made in determining estimated fair values assigned to assets acquired and liabilities assumed in a business combination, as well as asset lives, can materially affect the Company's results of operations.

The fair values of identifiable intangible assets related to currently marketed products and product rights are primarily determined by using an income approach through which fair value is estimated based on each asset's

discounted projected net cash flows. The Company's estimates of market participant net cash flows consider historical and projected pricing, margins and expense levels; the performance of competing products where applicable; relevant industry and therapeutic area growth drivers and factors; current and expected trends in technology and product life cycles; the time and investment that will be required to develop products and technologies; the ability to obtain marketing and regulatory approvals; the ability to manufacture and commercialize the products; the extent and timing of potential new product introductions by the Company's competitors; and the life of each asset's underlying patent, if any. The net cash flows are then probability-adjusted where appropriate to consider the uncertainties associated with the underlying assumptions, as well as the risk profile of the net cash flows utilized in the valuation. The probability-adjusted future net cash flows of each product are then discounted to present value utilizing an appropriate discount rate.

The fair values of identifiable intangible assets related to IPR&D are also determined using an income approach, through which fair value is estimated based on each asset's probability-adjusted future net cash flows, which reflect the different stages of development of each product and the associated probability of successful completion. The net cash flows are then discounted to present value using an appropriate discount rate.

If the Company determines the transaction will not be accounted for as an acquisition of a business, the transaction will be accounted for as an asset acquisition rather than a business combination and, therefore, no goodwill will be recorded. In an asset acquisition, acquired IPR&D with no alternative future use is charged to expense and contingent consideration is not recognized at the acquisition date.

Revenue Recognition

On January 1, 2018, the Company adopted a new standard on revenue recognition (see Note 2 to the consolidated financial statements). Changes to the Company's revenue recognition policy as a result of adopting the new guidance are described below.

Recognition of revenue requires evidence of a contract, probable collection of sales proceeds and completion of substantially all performance obligations. Merck acts as the principal in substantially all of its customer arrangements and therefore records revenue on a gross basis. The majority of the Company's contracts related to the Pharmaceutical and Animal Health segments have a single performance obligation - the promise to transfer goods. Shipping is considered immaterial in the context of the overall customer arrangement and damages or loss of goods in transit are rare. Therefore, shipping is not deemed a separately recognized performance obligation.

The vast majority of revenues from sales of products are recognized at a point in time when control of the goods is transferred to the customer, which the Company has determined is when title and risks and rewards of ownership transfer to the customer and the Company is entitled to payment. Certain Merck entities, including U.S. entities, have contract terms under which control of the goods passes to the customer upon shipment; however, either pursuant to the terms of the contract or as a business practice, Merck retains responsibility for goods lost or damaged in transit. Prior to the adoption of the new standard, Merck would recognize revenue for these entities upon delivery of the goods. Under the new guidance, the Company is now recognizing revenue at time of shipment for these entities.

For businesses within the Company's Healthcare Services segment and certain services in the Animal Health segment, revenue is recognized over time, generally ratably over the contract term as services are provided. These service revenues are not material.

The nature of the Company's business gives rise to several types of variable consideration including discounts and returns, which are estimated at the time of sale generally using the expected value method, although the most likely amount method is used for prompt pay discounts.

In the United States, sales discounts are issued to customers at the point-of-sale, through an intermediary wholesaler (known as chargebacks), or in the form of rebates. Additionally, sales are generally made with a limited right of return under certain conditions. Revenues are recorded net of provisions for sales discounts and returns, which are established at the time of sale. In addition, revenues are recorded net of time value of money discounts if collection of accounts receivable is expected to be in excess of one year.

The U.S. provision for aggregate customer discounts covers chargebacks and rebates. Chargebacks are discounts that occur when a contracted customer purchases through an intermediary wholesaler. The contracted customer generally purchases product from the wholesaler at its contracted price plus a mark-up. The wholesaler, in turn, charges

the Company back for the difference between the price initially paid by the wholesaler and the contract price paid to the wholesaler by the customer. The provision for chargebacks is based on expected sell-through levels by the Company's wholesale customers to contracted customers, as well as estimated wholesaler inventory levels. Rebates are amounts owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. The Company uses historical customer segment utilization mix, sales forecasts, changes to product mix and price, inventory levels in the distribution channel, government pricing calculations and prior payment history in order to estimate the expected provision. Amounts accrued for aggregate customer discounts are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal and state agencies, and other customers to the amounts accrued.

The Company continually monitors its provision for aggregate customer discounts. There were no material adjustments to estimates associated with the aggregate customer discount provision in 2018, 2017 or 2016.

Summarized information about changes in the aggregate customer discount accrual related to U.S. sales is as follows:

($ in millions)	**2018**	2017
Balance January 1	**$ 2,551**	$ 2,945
Current provision	**10,837**	11,001
Adjustments to prior years	**(117)**	(286)
Payments	**(10,641)**	(11,109)
Balance December 31	**$ 2,630**	$ 2,551

Accruals for chargebacks are reflected as a direct reduction to accounts receivable and accruals for rebates as current liabilities. The accrued balances relative to these provisions included in *Accounts receivable* and *Accrued and other current liabilities* were $245 million and $2.4 billion, respectively, at December 31, 2018 and were $198 million and $2.4 billion, respectively, at December 31, 2017.

Outside of the United States, variable consideration in the form of discounts and rebates are a combination of commercially-driven discounts in highly competitive product classes, discounts required to gain or maintain reimbursement, or legislatively mandated rebates. In certain European countries, legislatively mandated rebates are calculated based on an estimate of the government's total unbudgeted spending and the Company's specific payback obligation. Rebates may also be required based on specific product sales thresholds. The Company applies an estimated factor against its actual invoiced sales to represent the expected level of future discount or rebate obligations associated with the sale.

The Company maintains a returns policy that allows its U.S. pharmaceutical customers to return product within a specified period prior to and subsequent to the expiration date (generally, three to six months before and 12 months after product expiration). The estimate of the provision for returns is based upon historical experience with actual returns. Additionally, the Company considers factors such as levels of inventory in the distribution channel, product dating and expiration period, whether products have been discontinued, entrance in the market of generic competition, changes in formularies or launch of over-the-counter products, among others. The product returns provision for U.S. pharmaceutical sales as a percentage of U.S. net pharmaceutical sales was 1.6% in 2018, 2.1% in 2017 and 1.4% in 2016. Outside of the United States, returns are only allowed in certain countries on a limited basis.

Merck's payment terms for U.S. pharmaceutical customers are typically net 36 days from receipt of invoice and for U.S. animal health customers are typically net 30 days from receipt of invoice; however, certain products, including *Keytruda*, have longer payment terms up to 90 days. Outside of the United States, payment terms are typically 30 days to 90 days, although certain markets have longer payment terms.

Through its distribution programs with U.S. wholesalers, the Company encourages wholesalers to align purchases with underlying demand and maintain inventories below specified levels. The terms of the programs allow the wholesalers to earn fees upon providing visibility into their inventory levels, as well as by achieving certain performance parameters such as inventory management, customer service levels, reducing shortage claims and reducing

product returns. Information provided through the wholesaler distribution programs includes items such as sales trends, inventory on-hand, on-order quantity and product returns.

Wholesalers generally provide only the above-mentioned data to the Company, as there is no regulatory requirement to report lot level information to manufacturers, which is the level of information needed to determine the remaining shelf life and original sale date of inventory. Given current wholesaler inventory levels, which are generally less than a month, the Company believes that collection of order lot information across all wholesale customers would have limited use in estimating sales discounts and returns.

Inventories Produced in Preparation for Product Launches

The Company capitalizes inventories produced in preparation for product launches sufficient to support estimated initial market demand. Typically, capitalization of such inventory does not begin until the related product candidates are in Phase 3 clinical trials and are considered to have a high probability of regulatory approval. The Company monitors the status of each respective product within the regulatory approval process; however, the Company generally does not disclose specific timing for regulatory approval. If the Company is aware of any specific risks or contingencies other than the normal regulatory approval process or if there are any specific issues identified during the research process relating to safety, efficacy, manufacturing, marketing or labeling, the related inventory would generally not be capitalized. Expiry dates of the inventory are affected by the stage of completion. The Company manages the levels of inventory at each stage to optimize the shelf life of the inventory in relation to anticipated market demand in order to avoid product expiry issues. For inventories that are capitalized, anticipated future sales and shelf lives support the realization of the inventory value as the inventory shelf life is sufficient to meet initial product launch requirements. Inventories produced in preparation for product launches capitalized at December 31, 2018 and 2017 were $7 million and $80 million, respectively.

Contingencies and Environmental Liabilities

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property and commercial litigation, as well as certain additional matters (see Note 11 to the consolidated financial statements). The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. For product liability claims, a portion of the overall accrual is actuarially determined and considers such factors as past experience, number of claims reported and estimates of claims incurred but not yet reported. Individually significant contingent losses are accrued when probable and reasonably estimable.

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of December 31, 2018 and 2017 of approximately $245 million and $160 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

The Company and its subsidiaries are parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund, and other federal and state equivalents. When a legitimate claim for contribution is asserted, a liability is initially accrued based upon the estimated transaction costs to manage the site. Accruals are adjusted as site investigations, feasibility studies and related cost assessments of remedial techniques are completed, and as the extent to which other potentially responsible parties who may be jointly and severally liable can be expected to contribute is determined.

The Company is also remediating environmental contamination resulting from past industrial activity at certain of its sites and takes an active role in identifying and accruing for these costs. In the past, Merck performed a worldwide survey to assess all sites for potential contamination resulting from past industrial activities. Where

assessment indicated that physical investigation was warranted, such investigation was performed, providing a better evaluation of the need for remedial action. Where such need was identified, remedial action was then initiated. As definitive information became available during the course of investigations and/or remedial efforts at each site, estimates were refined and accruals were established or adjusted accordingly. These estimates and related accruals continue to be refined annually.

The Company believes that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on the Company. Expenditures for remediation and environmental liabilities were $16 million in 2018, and are estimated at $57 million in the aggregate for the years 2019 through 2023. In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $71 million and $82 million at December 31, 2018 and 2017, respectively. These liabilities are undiscounted, do not consider potential recoveries from other parties and will be paid out over the periods of remediation for the applicable sites, which are expected to occur primarily over the next 15 years. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed $60 million in the aggregate. Management also does not believe that these expenditures should result in a material adverse effect on the Company's financial position, results of operations, liquidity or capital resources for any year.

Share-Based Compensation

The Company expenses all share-based payment awards to employees, including grants of stock options, over the requisite service period based on the grant date fair value of the awards. The Company determines the fair value of certain share-based awards using the Black-Scholes option-pricing model which uses both historical and current market data to estimate the fair value. This method incorporates various assumptions such as the risk-free interest rate, expected volatility, expected dividend yield and expected life of the options. Total pretax share-based compensation expense was $348 million in 2018, $312 million in 2017 and $300 million in 2016. At December 31, 2018, there was $560 million of total pretax unrecognized compensation expense related to nonvested stock option, restricted stock unit and performance share unit awards which will be recognized over a weighted average period of 1.9 years. For segment reporting, share-based compensation costs are unallocated expenses.

Pensions and Other Postretirement Benefit Plans

Net periodic benefit cost for pension plans totaled $195 million in 2018, $201 million in 2017 and $144 million in 2016. Net periodic benefit (credit) for other postretirement benefit plans was $(45) million in 2018, $(60) million in 2017 and $(88) million in 2016. Pension and other postretirement benefit plan information for financial reporting purposes is calculated using actuarial assumptions including a discount rate for plan benefit obligations and an expected rate of return on plan assets. The changes in net periodic benefit cost year over year for pension plans are largely attributable to changes in the discount rate affecting net loss amortization.

The Company reassesses its benefit plan assumptions on a regular basis. For both the pension and other postretirement benefit plans, the discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due. The discount rates for the Company's U.S. pension and other postretirement benefit plans ranged from 4.00% to 4.40% at December 31, 2018, compared with a range of 3.20% to 3.80% at December 31, 2017.

The expected rate of return for both the pension and other postretirement benefit plans represents the average rate of return to be earned on plan assets over the period the benefits included in the benefit obligation are to be paid. In developing the expected rate of return, the Company considers long-term compound annualized returns of historical market data, current market conditions and actual returns on the Company's plan assets. Using this reference information, the Company develops forward-looking return expectations for each asset category and a weighted-average expected long-term rate of return for a target portfolio allocated across these investment categories. The expected portfolio performance reflects the contribution of active management as appropriate. For 2019, the expected rate of return for the Company's U.S. pension and other postretirement benefit plans will range from 7.70% to 8.10%, compared to a range of 7.70% to 8.30% in 2018. The decrease is primarily due to a modest shift in asset allocation.

The Company has established investment guidelines for its U.S. pension and other postretirement plans to create an asset allocation that is expected to deliver a rate of return sufficient to meet the long-term obligation of each

plan, given an acceptable level of risk. The target investment portfolio of the Company's U.S. pension and other postretirement benefit plans is allocated 30% to 50% in U.S. equities, 15% to 30% in international equities, 30% to 45% in fixed-income investments, and up to 5% in cash and other investments. The portfolio's equity weighting is consistent with the long-term nature of the plans' benefit obligations. The expected annual standard deviation of returns of the target portfolio, which approximates 11%, reflects both the equity allocation and the diversification benefits among the asset classes in which the portfolio invests. For non-U.S. pension plans, the targeted investment portfolio varies based on the duration of pension liabilities and local government rules and regulations. Although a significant percentage of plan assets are invested in U.S. equities, concentration risk is mitigated through the use of strategies that are diversified within management guidelines.

Actuarial assumptions are based upon management's best estimates and judgment. A reasonably possible change of plus (minus) 25 basis points in the discount rate assumption, with other assumptions held constant, would have had an estimated $80 million favorable (unfavorable) impact on the Company's net periodic benefit cost in 2018. A reasonably possible change of plus (minus) 25 basis points in the expected rate of return assumption, with other assumptions held constant, would have had an estimated $50 million favorable (unfavorable) impact on Merck's net periodic benefit cost in 2018. Required funding obligations for 2019 relating to the Company's pension and other postretirement benefit plans are not expected to be material. The preceding hypothetical changes in the discount rate and expected rate of return assumptions would not impact the Company's funding requirements.

Net loss amounts, which reflect experience differentials primarily relating to differences between expected and actual returns on plan assets as well as the effects of changes in actuarial assumptions, are recorded as a component of *AOCI*. Expected returns for pension plans are based on a calculated market-related value of assets. Under this methodology, asset gains/losses resulting from actual returns that differ from the Company's expected returns are recognized in the market-related value of assets ratably over a five-year period. Also, net loss amounts in *AOCI* in excess of certain thresholds are amortized into net periodic benefit cost over the average remaining service life of employees.

Restructuring Costs

Restructuring costs have been recorded in connection with restructuring programs designed to streamline the Company's cost structure. As a result, the Company has made estimates and judgments regarding its future plans, including future termination benefits and other exit costs to be incurred when the restructuring actions take place. When accruing termination costs, the Company will recognize the amount within a range of costs that is the best estimate within the range. When no amount within the range is a better estimate than any other amount, the Company recognizes the minimum amount within the range. In connection with these actions, management also assesses the recoverability of long-lived assets employed in the business. In certain instances, asset lives have been shortened based on changes in the expected useful lives of the affected assets. Severance and other related costs are reflected within *Restructuring costs*. Asset-related charges are reflected within *Cost of sales*, *Selling, general and administrative* expenses and *Research and development* expenses depending upon the nature of the asset.

Impairments of Long-Lived Assets

The Company assesses changes in economic, regulatory and legal conditions and makes assumptions regarding estimated future cash flows in evaluating the value of the Company's property, plant and equipment, goodwill and other intangible assets.

The Company periodically evaluates whether current facts or circumstances indicate that the carrying values of its long-lived assets to be held and used may not be recoverable. If such circumstances are determined to exist, an estimate of the undiscounted future cash flows of these assets, or appropriate asset groupings, is compared to the carrying value to determine whether an impairment exists. If the asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows approach.

Goodwill represents the excess of the consideration transferred over the fair value of net assets of businesses acquired. Goodwill is assigned to reporting units and evaluated for impairment on at least an annual basis, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. Some of the factors considered in the assessment include general macroeconomic conditions, conditions specific to the industry and market, cost factors which could have a significant effect on earnings or cash flows, the overall financial performance of the reporting unit,

and whether there have been sustained declines in the Company's share price. If the Company concludes it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a quantitative fair value test is performed. If the carrying value of a reporting unit is greater than its fair value, a goodwill impairment charge will be recorded for the difference (up to the carrying value of goodwill).

Other acquired intangible assets (excluding IPR&D) are initially recorded at fair value, assigned an estimated useful life, and amortized primarily on a straight-line basis over their estimated useful lives. When events or circumstances warrant a review, the Company will assess recoverability from future operations using pretax undiscounted cash flows derived from the lowest appropriate asset groupings. Impairments are recognized in operating results to the extent that the carrying value of the intangible asset exceeds its fair value, which is determined based on the net present value of estimated future cash flows.

IPR&D that the Company acquires through business combinations represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. The amounts are capitalized and accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the project. The Company tests IPR&D for impairment at least annually, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the IPR&D intangible asset is less than its carrying amount. If the Company concludes it is more likely than not that the fair value is less than the carrying amount, a quantitative test that compares the fair value of the IPR&D intangible asset with its carrying value is performed. For impairment testing purposes, the Company may combine separately recorded IPR&D intangible assets into one unit of account based on the relevant facts and circumstances. Generally, the Company will combine IPR&D intangible assets for testing purposes if they operate as a single asset and are essentially inseparable. If the fair value is less than the carrying amount, an impairment loss is recognized within the Company's operating results.

The judgments made in evaluating impairment of long-lived intangibles can materially affect the Company's results of operations.

Impairments of Investments

The Company reviews its investments in marketable debt securities for impairments based on the determination of whether the decline in market value of the investment below the carrying value is other-than-temporary. The Company considers available evidence in evaluating potential impairments of its investments in marketable debt securities, including the duration and extent to which fair value is less than cost. Changes in fair value that are considered temporary are reported net of tax in *OCI*. An other-than-temporary impairment has occurred if the Company does not expect to recover the entire amortized cost basis of the marketable debt security. If the Company does not intend to sell the impaired debt security, and it is not more likely than not it will be required to sell the debt security before the recovery of its amortized cost basis, the amount of the other-than-temporary impairment recognized in earnings, recorded in *Other (income) expense, net*, is limited to the portion attributed to credit loss. The remaining portion of the other-than-temporary impairment related to other factors is recognized in *OCI*.

Investments in publicly traded equity securities are reported at fair value determined using quoted market prices in active markets for identical assets or quoted prices for similar assets or other inputs that are observable or can be corroborated by observable market data. Changes in fair value are included in *Other (income) expense, net*. Investments in equity securities without readily determinable fair values are recorded at cost, plus or minus subsequent observable price changes in orderly transactions for identical or similar investments, minus impairments. Such adjustments are recognized in *Other (income) expense, net*. Realized gains and losses for equity securities are included in *Other (income) expense, net*.

Taxes on Income

The Company's effective tax rate is based on pretax income, statutory tax rates and tax planning opportunities available in the various jurisdictions in which the Company operates. An estimated effective tax rate for a year is applied to the Company's quarterly operating results. In the event that there is a significant unusual or one-time item recognized, or expected to be recognized, in the Company's quarterly operating results, the tax attributable to that item would be separately calculated and recorded at the same time as the unusual or one-time item. The Company considers the resolution of prior year tax matters to be such items. Significant judgment is required in determining the Company's tax provision and in evaluating its tax positions. The recognition and measurement of a tax position is based on

management's best judgment given the facts, circumstances and information available at the reporting date. The Company evaluates tax positions to determine whether the benefits of tax positions are more likely than not of being sustained upon audit based on the technical merits of the tax position. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely of being realized upon ultimate settlement in the financial statements. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit in the financial statements. If the more likely than not threshold is not met in the period for which a tax position is taken, the Company may subsequently recognize the benefit of that tax position if the tax matter is effectively settled, the statute of limitations expires, or if the more likely than not threshold is met in a subsequent period (see Note 16 to the consolidated financial statements).

Tax regulations require items to be included in the tax return at different times than the items are reflected in the financial statements. Timing differences create deferred tax assets and liabilities. Deferred tax assets generally represent items that can be used as a tax deduction or credit in the tax return in future years for which the Company has already recorded the tax benefit in the financial statements. The Company establishes valuation allowances for its deferred tax assets when the amount of expected future taxable income is not likely to support the use of the deduction or credit. Deferred tax liabilities generally represent tax expense recognized in the financial statements for which payment has been deferred or expense for which the Company has already taken a deduction on the tax return, but has not yet recognized as expense in the financial statements.

Recently Issued Accounting Standards

For a discussion of recently issued accounting standards, see Note 2 to the consolidated financial statements.

Cautionary Factors That May Affect Future Results

This report and other written reports and oral statements made from time to time by the Company may contain so-called "forward-looking statements," all of which are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially from those set forth in the statements. One can identify these forward-looking statements by their use of words such as "anticipates," "expects," "plans," "will," "estimates," "forecasts," "projects" and other words of similar meaning, or negative variations of any of the foregoing. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address the Company's growth strategy, financial results, product development, product approvals, product potential and development programs. One must carefully consider any such statement and should understand that many factors could cause actual results to differ materially from the Company's forward-looking statements. These factors include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. No forward-looking statement can be guaranteed and actual future results may vary materially.

The Company does not assume the obligation to update any forward-looking statement. One should carefully evaluate such statements in light of factors, including risk factors, described in the Company's filings with the Securities and Exchange Commission, especially on this Form 10-K and Forms 10-Q and 8-K. In Item 1A. "Risk Factors" of this annual report on Form 10-K the Company discusses in more detail various important risk factors that could cause actual results to differ from expected or historic results. The Company notes these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. One should understand that it is not possible to predict or identify all such factors. Consequently, the reader should not consider any such list to be a complete statement of all potential risks or uncertainties.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

The information required by this Item is incorporated by reference to the discussion under "Financial Instruments Market Risk Disclosures" in Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Item 8. Financial Statements and Supplementary Data.

(a) Financial Statements

The consolidated balance sheet of Merck & Co., Inc. and subsidiaries as of December 31, 2018 and 2017, and the related consolidated statements of income, of comprehensive income, of equity and of cash flows for each of the three years in the period ended December 31, 2018, the notes to consolidated financial statements, and the report dated February 27, 2019 of PricewaterhouseCoopers LLP, independent registered public accounting firm, are as follows:

Consolidated Statement of Income
Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions except per share amounts)

	2018	2017	2016
Sales	**$ 42,294**	$ 40,122	$ 39,807
Costs, Expenses and Other			
Cost of sales	**13,509**	12,912	14,030
Selling, general and administrative	**10,102**	10,074	10,017
Research and development	**9,752**	10,339	10,261
Restructuring costs	**632**	776	651
Other (income) expense, net	**(402)**	(500)	189
	33,593	33,601	35,148
Income Before Taxes	**8,701**	6,521	4,659
Taxes on Income	**2,508**	4,103	718
Net Income	**6,193**	2,418	3,941
Less: Net (Loss) Income Attributable to Noncontrolling Interests	**(27)**	24	21
Net Income Attributable to Merck & Co., Inc.	**$ 6,220**	$ 2,394	$ 3,920
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	**$ 2.34**	$ 0.88	$ 1.42
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	**$ 2.32**	$ 0.87	$ 1.41

Consolidated Statement of Comprehensive Income
Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions)

	2018	2017	2016
Net Income Attributable to Merck & Co., Inc.	**$ 6,220**	$ 2,394	$ 3,920
Other Comprehensive (Loss) Income Net of Taxes:			
Net unrealized gain (loss) on derivatives, net of reclassifications	**297**	(446)	(66)
Net unrealized loss on investments, net of reclassifications	**(10)**	(58)	(44)
Benefit plan net (loss) gain and prior service (cost) credit, net of amortization	**(425)**	419	(799)
Cumulative translation adjustment	**(223)**	401	(169)
	(361)	316	(1,078)
Comprehensive Income Attributable to Merck & Co., Inc.	**$ 5,859**	$ 2,710	$ 2,842

The accompanying notes are an integral part of these consolidated financial statements.

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Consolidated Balance Sheet
Merck & Co., Inc. and Subsidiaries
December 31
($ in millions except per share amounts)

	2018	2017
Assets		
Current Assets		
Cash and cash equivalents	**$ 7,965**	$ 6,092
Short-term investments	**899**	2,406
Accounts receivable (net of allowance for doubtful accounts of $119 in 2018 and $159 in 2017)	**7,071**	6,873
Inventories (excludes inventories of $1,417 in 2018 and $1,187 in 2017 classified in Other assets - see Note 7)	**5,440**	5,096
Other current assets	**4,500**	4,299
Total current assets	**25,875**	24,766
Investments	**6,233**	12,125
Property, Plant and Equipment (at cost)		
Land	**333**	365
Buildings	**11,486**	11,726
Machinery, equipment and office furnishings	**14,441**	14,649
Construction in progress	**3,355**	2,301
	29,615	29,041
Less: accumulated depreciation	**16,324**	16,602
	13,291	12,439
Goodwill	**18,253**	18,284
Other Intangibles, Net	**11,431**	14,183
Other Assets	**7,554**	6,075
	$ 82,637	$ 87,872
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	**$ 5,308**	$ 3,057
Trade accounts payable	**3,318**	3,102
Accrued and other current liabilities	**10,151**	10,427
Income taxes payable	**1,971**	708
Dividends payable	**1,458**	1,320
Total current liabilities	**22,206**	18,614
Long-Term Debt	**19,806**	21,353
Deferred Income Taxes	**1,702**	2,219
Other Noncurrent Liabilities	**12,041**	11,117
Merck & Co., Inc. Stockholders' Equity		
Common stock, $0.50 par value Authorized - 6,500,000,000 shares Issued - 3,577,103,522 shares in 2018 and 2017	**1,788**	1,788
Other paid-in capital	**38,808**	39,902
Retained earnings	**42,579**	41,350
Accumulated other comprehensive loss	**(5,545)**	(4,910)
	77,630	78,130
Less treasury stock, at cost: 984,543,979 shares in 2018 and 880,491,914 shares in 2017	**50,929**	43,794
Total Merck & Co., Inc. stockholders' equity	**26,701**	34,336

Noncontrolling Interests	**181**	233
Total equity	**26,882**	34,569
	$ 82,637	$ 87,872

The accompanying notes are an integral part of this consolidated financial statement.

Consolidated Statement of Equity
Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions except per share amounts)

	Common Stock	Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock	Non-controlling Interests	Total
Balance January 1, 2016	$1,788	$ 40,222	$ 45,348	$ (4,148)	$ (38,534)	$ 91	$ 44,767
Net income attributable to Merck & Co., Inc.	—	—	3,920	—	—	—	3,920
Other comprehensive loss, net of taxes	—	—	—	(1,078)	—	—	(1,078)
Cash dividends declared on common stock ($1.85 per share)	—	—	(5,135)	—	—	—	(5,135)
Treasury stock shares purchased	—	—	—	—	(3,434)	—	(3,434)
Acquisition of The StayWell Company LLC	—	—	—	—	—	124	124
Net income attributable to noncontrolling interests	—	—	—	—	—	21	21
Distributions attributable to noncontrolling interests	—	—	—	—	—	(16)	(16)
Share-based compensation plans and other	—	(283)	—	—	1,422	—	1,139
Balance December 31, 2016	1,788	39,939	44,133	(5,226)	(40,546)	220	40,308
Net income attributable to Merck & Co., Inc.	—	—	2,394	—	—	—	2,394
Other comprehensive income, net of taxes	—	—	—	316	—	—	316
Cash dividends declared on common stock ($1.89 per share)	—	—	(5,177)	—	—	—	(5,177)
Treasury stock shares purchased	—	—	—	—	(4,014)	—	(4,014)
Acquisition of Vallée S.A.	—	—	—	—	—	7	7
Net income attributable to noncontrolling interests	—	—	—	—	—	24	24
Distributions attributable to noncontrolling interests	—	—	—	—	—	(18)	(18)
Share-based compensation plans and other	—	(37)	—	—	766	—	729
Balance December 31, 2017	1,788	39,902	41,350	(4,910)	(43,794)	233	34,569
Net income attributable to Merck & Co., Inc.	**—**	**—**	**6,220**	**—**	**—**	**—**	**6,220**
Adoption of new accounting standards (see Note 2)	**—**	**—**	**322**	**(274)**	**—**	**—**	**48**
Other comprehensive loss, net of taxes	**—**	**—**	**—**	**(361)**	**—**	**—**	**(361)**
Cash dividends declared on common stock ($1.99 per share)	**—**	**—**	**(5,313)**	**—**	**—**	**—**	**(5,313)**
Treasury stock shares purchased	**—**	**(1,000)**	**—**	**—**	**(8,091)**	**—**	**(9,091)**
Net loss attributable to noncontrolling interests	**—**	**—**	**—**	**—**	**—**	**(27)**	**(27)**
Distributions attributable to noncontrolling interests	**—**	**—**	**—**	**—**	**—**	**(25)**	**(25)**
Share-based compensation plans and other	**—**	**(94)**	**—**	**—**	**956**	**—**	**862**
Balance December 31, 2018	**$ 1,788**	**$ 38,808**	**$ 42,579**	**$ (5,545)**	**$ (50,929)**	**$ 181**	**$ 26,882**

The accompanying notes are an integral part of this consolidated financial statement.

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Consolidated Statement of Cash Flows
Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions)

	2018	2017	2016
Cash Flows from Operating Activities			
Net income	**$ 6,193**	$ 2,418	$ 3,941
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	**4,519**	4,676	5,471
Intangible asset impairment charges	**296**	646	3,948
Charge for future payments related to collaboration license options	**650**	500	—
Provisional charge for one-time transition tax related to the enactment of U.S. tax legislation	**—**	5,347	—
Charge related to the settlement of worldwide *Keytruda* patent litigation	**—**	—	625
Deferred income taxes	**(509)**	(2,621)	(1,521)
Share-based compensation	**348**	312	300
Other	**978**	190	213
Net changes in assets and liabilities:			
Accounts receivable	**(418)**	297	(619)
Inventories	**(911)**	(145)	206
Trade accounts payable	**230**	254	278
Accrued and other current liabilities	**(341)**	(922)	(2,018)
Income taxes payable	**827**	(3,291)	124
Noncurrent liabilities	**(266)**	(123)	(809)
Other	**(674)**	(1,087)	237
Net Cash Provided by Operating Activities	**10,922**	6,451	10,376
Cash Flows from Investing Activities			
Capital expenditures	**(2,615)**	(1,888)	(1,614)
Purchases of securities and other investments	**(7,994)**	(10,739)	(15,651)
Proceeds from sales of securities and other investments	**15,252**	15,664	14,353
Acquisitions, net of cash acquired	**(431)**	(396)	(780)
Other	**102**	38	482
Net Cash Provided by (Used in) Investing Activities	**4,314**	2,679	(3,210)
Cash Flows from Financing Activities			
Net change in short-term borrowings	**5,124**	(26)	—
Payments on debt	**(4,287)**	(1,103)	(2,386)
Proceeds from issuance of debt	**—**	—	1,079
Purchases of treasury stock	**(9,091)**	(4,014)	(3,434)
Dividends paid to stockholders	**(5,172)**	(5,167)	(5,124)
Proceeds from exercise of stock options	**591**	499	939
Other	**(325)**	(195)	(118)
Net Cash Used in Financing Activities	**(13,160)**	(10,006)	(9,044)
Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash	**(205)**	457	(131)
Net Increase (Decrease) in Cash, Cash Equivalents and Restricted Cash	**1,871**	(419)	(2,009)
Cash, Cash Equivalents and Restricted Cash at Beginning of Year (includes $4 million of restricted cash at January 1, 2018 included in Other Assets)	**6,096**	6,515	8,524
Cash, Cash Equivalents and Restricted Cash at End of Year (includes $2 million of restricted cash at December 31, 2018 included in Other Assets)	**$ 7,967**	$ 6,096	$ 6,515

The accompanying notes are an integral part of this consolidated financial statement.

Notes to Consolidated Financial Statements
Merck & Co., Inc. and Subsidiaries
($ in millions except per share amounts)

1. Nature of Operations

Merck & Co., Inc. (Merck or the Company) is a global health care company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies and animal health products. The Company's operations are principally managed on a products basis and include four operating segments, which are the Pharmaceutical, Animal Health, Healthcare Services and Alliances segments. The Pharmaceutical and Animal Health segments are the only reportable segments.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. On December 31, 2016, Merck and Sanofi Pasteur S.A. (Sanofi) terminated their equally-owned joint venture, Sanofi Pasteur MSD (SPMSD), which developed and marketed vaccines in Europe. In 2017, Merck began recording vaccine sales and incurring costs as a result of operating its vaccines business in the European markets that were previously part of the SPMSD joint venture, which was accounted for as an equity method affiliate.

The Animal Health segment discovers, develops, manufactures and markets animal health products, including pharmaceutical and vaccine products, for the prevention, treatment and control of disease in all major livestock and companion animal species, which the Company sells to veterinarians, distributors and animal producers.

The Healthcare Services segment provides services and solutions that focus on engagement, health analytics and clinical services to improve the value of care delivered to patients.

The Alliances segment primarily includes activity from the Company's relationship with AstraZeneca LP related to sales of Nexium and Prilosec, which concluded in 2018 (see Note 9).

2. Summary of Accounting Policies

Principles of Consolidation — The consolidated financial statements include the accounts of the Company and all of its subsidiaries in which a controlling interest is maintained. Intercompany balances and transactions are eliminated. Controlling interest is determined by majority ownership interest and the absence of substantive third-party participating rights or, in the case of variable interest entities, by majority exposure to expected losses, residual returns or both. For those consolidated subsidiaries where Merck ownership is less than 100%, the outside shareholders' interests are shown as *Noncontrolling interests* in equity. Investments in affiliates over which the Company has significant influence but not a controlling interest, such as interests in entities owned equally by the Company and a third party that are under shared control, are carried on the equity basis.

Acquisitions — In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the acquisition at their respective fair values with limited exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are generally recognized at fair value. If fair value cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Accordingly, the Company may be required to value assets at fair value measures that do not reflect the Company's intended use of those assets. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in the Company's consolidated financial statements after the date of the acquisition. If the Company determines the assets acquired do not meet the

definition of a business under the acquisition method of accounting, the transaction will be accounted for as an acquisition of assets rather than a business combination and, therefore, no goodwill will be recorded. In an asset acquisition, acquired in-process research and development (IPR&D) with no alternative future use is charged to expense and contingent consideration is not recognized at the acquisition date.

Foreign Currency Translation — The net assets of international subsidiaries where the local currencies have been determined to be the functional currencies are translated into U.S. dollars using current exchange rates. The U.S. dollar effects that arise from translating the net assets of these subsidiaries at changing rates are recorded in the foreign currency translation account, which is included in *Accumulated other comprehensive income (loss)* (*AOCI*) and reflected as a separate component of equity. For those subsidiaries that operate in highly inflationary economies and for those subsidiaries where the U.S. dollar has been determined to be the functional currency, non-monetary foreign currency assets and liabilities are translated using historical rates, while monetary assets and liabilities are translated at current rates, with the U.S. dollar effects of rate changes included in *Other (income) expense, net*.

Cash Equivalents — Cash equivalents are comprised of certain highly liquid investments with original maturities of less than three months.

Inventories — Inventories are valued at the lower of cost or net realizable value. The cost of a substantial majority of U.S. pharmaceutical and vaccine inventories is determined using the last-in, first-out (LIFO) method for both financial reporting and tax purposes. The cost of all other inventories is determined using the first-in, first-out (FIFO) method. Inventories consist of currently marketed products, as well as certain inventories produced in preparation for product launches that are considered to have a high probability of regulatory approval. In evaluating the recoverability of inventories produced in preparation for product launches, the Company considers the likelihood that revenue will be obtained from the future sale of the related inventory together with the status of the product within the regulatory approval process.

Investments — Investments in marketable debt securities classified as available-for-sale are reported at fair value. Fair values of the Company's investments in marketable debt securities are determined using quoted market prices in active markets for identical assets or liabilities or quoted prices for similar assets or liabilities or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Changes in fair value that are considered temporary are reported net of tax in *Other Comprehensive Income* (*OCI*). The Company considers available evidence in evaluating potential impairments of its investments in marketable debt securities, including the duration and extent to which fair value is less than cost. An other-than-temporary impairment has occurred if the Company does not expect to recover the entire amortized cost basis of the marketable debt security. If the Company does not intend to sell the impaired debt security, and it is not more likely than not it will be required to sell the debt security before the recovery of its amortized cost basis, the amount of the other-than-temporary impairment recognized in earnings, recorded in *Other (income) expense, net*, is limited to the portion attributed to credit loss. The remaining portion of the other-than-temporary impairment related to other factors is recognized in *OCI*. Realized gains and losses for debt securities are included in *Other (income) expense, net*.

Investments in publicly traded equity securities are reported at fair value determined using quoted market prices in active markets for identical assets or quoted prices for similar assets or other inputs that are observable or can be corroborated by observable market data. Changes in fair value are included in *Other (income) expense, net*. Investments in equity securities without readily determinable fair values are recorded at cost, plus or minus subsequent observable price changes in orderly transactions for identical or similar investments, minus impairments. Such adjustments are recognized in *Other (income) expense, net*. Realized gains and losses for equity securities are included in *Other (income) expense, net*.

Revenue Recognition — On January 1, 2018, the Company adopted ASU 2014-09, *Revenue from Contracts with Customers*, and subsequent amendments (ASC 606 or new guidance), using the modified retrospective method. Merck applied the new guidance to all contracts with customers within the scope of the standard that were in effect on January 1, 2018 and recognized the cumulative effect of initially applying the new guidance as an adjustment to the opening balance of retained earnings (see "*Recently Adopted Accounting Standards*" below). Comparative information for prior periods has not been restated and continues to be reported under the accounting standards in effect for those periods.

The new guidance requires an entity to recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration that it expects to be entitled to in exchange for those goods or services. The new guidance introduces a 5-step model to recognize revenue when or as control is transferred: identify the contract with a customer, identify the performance obligations in the contract, determine the transaction price, allocate the transaction price to the performance obligations in the contract, and recognize revenue when or as the performance obligations are satisfied. Changes to the Company's revenue recognition policy as a result of adopting ASC 606 are described below. See Note 19 for disaggregated revenue disclosures.

Recognition of revenue requires evidence of a contract, probable collection of sales proceeds and completion of substantially all performance obligations. Merck acts as the principal in substantially all of its customer arrangements and therefore records revenue on a gross basis. The majority of the Company's contracts related to the Pharmaceutical and Animal Health segments have a single performance obligation - the promise to transfer goods. Shipping is considered immaterial in the context of the overall customer arrangement and damages or loss of goods in transit are rare. Therefore, shipping is not deemed a separately recognized performance obligation.

The vast majority of revenues from sales of products are recognized at a point in time when control of the goods is transferred to the customer, which the Company has determined is when title and risks and rewards of ownership transfer to the customer and the Company is entitled to payment. Certain Merck entities, including U.S. entities, have contract terms under which control of the goods passes to the customer upon shipment; however, either pursuant to the terms of the contract or as a business practice, Merck retains responsibility for goods lost or damaged in transit. Prior to the adoption of the new standard, Merck would recognize revenue for these entities upon delivery of the goods. Under the new guidance, the Company is now recognizing revenue at time of shipment for these entities.

The Company recognizes revenue from the sales of vaccines to the Federal government for placement into vaccine stockpiles in accordance with Securities and Exchange Commission (SEC) Interpretation*, Commission Guidance Regarding Accounting for Sales of Vaccines and BioTerror Countermeasures to the Federal Government for Placement into the Pediatric Vaccine Stockpile or the Strategic National Stockpile*. This interpretation allows companies to recognize revenue for sales of vaccines into U.S. government stockpiles even though these sales might not meet the criteria for revenue recognition under other accounting guidance.

For businesses within the Company's Healthcare Services segment and certain services in the Animal Health segment, revenue is recognized over time, generally ratably over the contract term as services are provided. These service revenues are not material.

The nature of the Company's business gives rise to several types of variable consideration including discounts and returns, which are estimated at the time of sale generally using the expected value method, although the most likely amount method is used for prompt pay discounts.

In the United States, sales discounts are issued to customers at the point-of-sale, through an intermediary wholesaler (known as chargebacks), or in the form of rebates. Additionally, sales are generally made with a limited right of return under certain conditions. Revenues are recorded net of provisions for sales discounts and returns, which are established at the time of sale. In addition, revenues are recorded net of time value of money discounts if collection of accounts receivable is expected to be in excess of one year.

The U.S. provision for aggregate customer discounts covering chargebacks and rebates was $10.7 billion in 2018, $10.7 billion in 2017 and $9.7 billion in 2016. Chargebacks are discounts that occur when a contracted customer purchases through an intermediary wholesaler. The contracted customer generally purchases product from the wholesaler at its contracted price plus a mark-up. The wholesaler, in turn, charges the Company back for the difference between the price initially paid by the wholesaler and the contract price paid to the wholesaler by the customer. The provision for chargebacks is based on expected sell-through levels by the Company's wholesale customers to contracted customers, as well as estimated wholesaler inventory levels. Rebates are amounts owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. The Company uses historical customer segment utilization mix, sales forecasts, changes to product mix and price, inventory levels in the distribution channel, government pricing calculations and prior payment history in order to estimate the expected provision. Amounts accrued for aggregate customer discounts

are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal and state agencies, and other customers to the amounts accrued. The accrued balances relative to the provisions for chargebacks and rebates included in *Accounts receivable* and *Accrued and other current liabilities* were $245 million and $2.4 billion, respectively, at December 31, 2018 and were $198 million and $2.4 billion, respectively, at December 31, 2017.

Outside of the United States, variable consideration in the form of discounts and rebates are a combination of commercially-driven discounts in highly competitive product classes, discounts required to gain or maintain reimbursement, or legislatively mandated rebates. In certain European countries, legislatively mandated rebates are calculated based on an estimate of the government's total unbudgeted spending and the Company's specific payback obligation. Rebates may also be required based on specific product sales thresholds. The Company applies an estimated factor against its actual invoiced sales to represent the expected level of future discount or rebate obligations associated with the sale.

The Company maintains a returns policy that allows its U.S. pharmaceutical customers to return product within a specified period prior to and subsequent to the expiration date (generally, three to six months before and 12 months after product expiration). The estimate of the provision for returns is based upon historical experience with actual returns. Additionally, the Company considers factors such as levels of inventory in the distribution channel, product dating and expiration period, whether products have been discontinued, entrance in the market of generic competition, changes in formularies or launch of over-the-counter products, among others. Outside of the United States, returns are only allowed in certain countries on a limited basis.

Merck's payment terms for U.S. pharmaceutical customers are typically net 36 days from receipt of invoice and for U.S. animal health customers are typically net 30 days from receipt of invoice; however, certain products, including *Keytruda*, have longer payment terms up to 90 days. Outside of the United States, payment terms are typically 30 days to 90 days, although certain markets have longer payment terms.

The following table provides the effects of adopting ASC 606 on the Consolidated Statement of Income:

Year Ended December 31, 2018	As Reported	Effects of Adopting ASC 606	Amounts Without Adoption of ASC 606
Sales	$ 42,294	$ (2)	$ 42,292
Cost of sales	13,509	(6)	13,503
Income before taxes	8,701	4	8,705
Taxes on income	2,508	1	2,509
Net income attributable to Merck & Co., Inc.	6,220	3	6,223

The following table provides the effects of adopting ASC 606 on the Consolidated Balance Sheet:

December 31, 2018	As Reported	Effects of Adopting ASC 606	Amounts Without Adoption of ASC 606
Assets			
Accounts receivable	$ 7,071	$ (13)	$ 7,058
Inventories	5,440	7	5,447
Liabilities			
Accrued and other current liabilities	10,151	(3)	10,148
Income taxes payable	1,971	(1)	1,970
Equity			
Retained earnings	42,579	(2)	42,577

Depreciation — Depreciation is provided over the estimated useful lives of the assets, principally using the straight-line method. For tax purposes, accelerated tax methods are used. The estimated useful lives primarily range from 25 to 45 years for *Buildings*, and from 3 to 15 years for *Machinery, equipment and office furnishings*. Depreciation expense was $1.4 billion in 2018, $1.5 billion in 2017 and $1.6 billion in 2016.

Advertising and Promotion Costs — Advertising and promotion costs are expensed as incurred. The Company recorded advertising and promotion expenses of $2.1 billion, $2.2 billion and $2.1 billion in 2018, 2017 and 2016, respectively.

Software Capitalization — The Company capitalizes certain costs incurred in connection with obtaining or developing internal-use software including external direct costs of material and services, and payroll costs for employees directly involved with the software development. Capitalized software costs are included in *Property, plant and equipment* and amortized beginning when the software project is substantially complete and the asset is ready for its intended use. Capitalized software costs associated with projects that are being amortized over 6 to 10 years (including the Company's on-going multi-year implementation of an enterprise-wide resource planning system) were $439 million and $449 million, net of accumulated amortization at December 31, 2018 and 2017, respectively. All other capitalized software costs are being amortized over periods ranging from 3 to 5 years. Costs incurred during the preliminary project stage and post-implementation stage, as well as maintenance and training costs, are expensed as incurred.

Goodwill — Goodwill represents the excess of the consideration transferred over the fair value of net assets of businesses acquired. Goodwill is assigned to reporting units and evaluated for impairment on at least an annual basis, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If the Company concludes it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a quantitative fair value test is performed. If the carrying value of a reporting unit is greater than its fair value, a goodwill impairment charge will be recorded for the difference (up to the carrying value of goodwill).

Acquired Intangibles — Acquired intangibles include products and product rights, tradenames and patents, which are initially recorded at fair value, assigned an estimated useful life, and amortized primarily on a straight-line basis over their estimated useful lives ranging from 2 to 20 years (see Note 8). The Company periodically evaluates whether current facts or circumstances indicate that the carrying values of its acquired intangibles may not be recoverable. If such circumstances are determined to exist, an estimate of the undiscounted future cash flows of these assets, or appropriate asset groupings, is compared to the carrying value to determine whether an impairment exists. If the asset is determined to be impaired, the loss is measured based on the difference between the carrying value of the intangible asset and its fair value, which is determined based on the net present value of estimated future cash flows.

Acquired In-Process Research and Development — Acquired IPR&D that the Company acquires through business combinations represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. The amounts are capitalized and are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, Merck will make a determination as to the then-useful life of the intangible asset, generally determined by the period in which the substantial majority of the cash flows are expected to be generated, and begin amortization. The Company tests IPR&D for impairment at least annually, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the IPR&D intangible asset is less than its carrying amount. If the Company concludes it is more likely than not that the fair value is less than the carrying amount, a quantitative test that compares the fair value of the IPR&D intangible asset with its carrying value is performed. If the fair value is less than the carrying amount, an impairment loss is recognized in operating results.

Contingent Consideration — Certain of the Company's business acquisitions involve the potential for future payment of consideration that is contingent upon the achievement of performance milestones, including product development milestones and royalty payments on future product sales. The fair value of contingent consideration liabilities is determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date, at each reporting period, the contingent consideration liability is remeasured at current fair value with changes (either expense or income) recorded in earnings.

Research and Development — Research and development is expensed as incurred. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the

activity has been performed or when the goods have been received rather than when the payment is made. Research and development expenses include restructuring costs and IPR&D impairment charges. In addition, research and development expenses include expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration. Research and development expenses also include upfront and milestone payments related to asset acquisitions and licensing transactions involving clinical development programs that have not yet received regulatory approval.

Collaborative Arrangements — Merck has entered into collaborative arrangements that provide the Company with varying rights to develop, produce and market products together with its collaborative partners. When Merck is the principal on sales transactions with third parties, the Company recognizes sales, cost of sales and selling, general and administrative expenses on a gross basis. Profit sharing amounts it pays to its collaborative partners are recorded within *Cost of sales*. When the collaborative partner is the principal on sales transactions with third parties, the Company records profit sharing amounts received from its collaborative partners as alliance revenue (within *Sales*). Alliance revenue is recorded net of cost of sales and includes an adjustment to share commercialization costs between the partners in accordance with the collaboration agreement. The adjustment is determined by comparing the commercialization costs Merck has incurred directly and reported within *Selling, general and administrative* expenses with the costs the collaborative partner has incurred. Research and development costs Merck incurs related to collaborations are recorded within *Research and development* expenses. Cost reimbursements to the collaborative partner or payments received from the collaborative partner to share these costs pursuant to the terms of the collaboration agreements are recorded as increases or decreases to *Research and development* expenses.

In addition, the terms of the collaboration agreements may require the Company to make payments based upon the achievement of certain developmental, regulatory approval or commercial milestones. Upfront and milestone payments payable by Merck to collaborative partners prior to regulatory approval are expensed as incurred and included in *Research and development* expenses. Payments due to collaborative partners upon or subsequent to regulatory approval are capitalized and amortized over the estimated useful life of the corresponding intangible asset to *Cost of sales* provided that future cash flows support the amounts capitalized. Sales-based milestones payable by Merck to collaborative partners are accrued when probable of being achieved and capitalized, subject to cumulative amortization catch-up. The amortization catch-up is calculated either from the time of the first regulatory approval for indications that were unapproved at the time the collaboration was formed, or from time of the formation of the collaboration for approved products. The related intangible asset that is recognized is amortized to *Cost of sales* over its remaining useful life, subject to impairment testing.

Share-Based Compensation — The Company expenses all share-based payments to employees over the requisite service period based on the grant-date fair value of the awards.

Restructuring Costs — The Company records liabilities for costs associated with exit or disposal activities in the period in which the liability is incurred. In accordance with existing benefit arrangements, employee termination costs are accrued when the restructuring actions are probable and estimable. When accruing these costs, the Company will recognize the amount within a range of costs that is the best estimate within the range. When no amount within the range is a better estimate than any other amount, the Company recognizes the minimum amount within the range. Costs for one-time termination benefits in which the employee is required to render service until termination in order to receive the benefits are recognized ratably over the future service period.

Contingencies and Legal Defense Costs — The Company records accruals for contingencies and legal defense costs expected to be incurred in connection with a loss contingency when it is probable that a liability has been incurred and the amount can be reasonably estimated.

Taxes on Income — Deferred taxes are recognized for the future tax effects of temporary differences between financial and income tax reporting based on enacted tax laws and rates. The Company evaluates tax positions to determine whether the benefits of tax positions are more likely than not of being sustained upon audit based on the technical merits of the tax position. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely of being realized upon ultimate settlement in the financial statements. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit in the financial statements. The Company recognizes interest

and penalties associated with uncertain tax positions as a component of *Taxes on income* in the Consolidated Statement of Income.

Use of Estimates — The consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States (GAAP) and, accordingly, include certain amounts that are based on management's best estimates and judgments. Estimates are used when accounting for amounts recorded in connection with acquisitions, including initial fair value determinations of assets and liabilities, primarily IPR&D, other intangible assets and contingent consideration, as well as subsequent fair value measurements. Additionally, estimates are used in determining such items as provisions for sales discounts and returns, depreciable and amortizable lives, recoverability of inventories, including those produced in preparation for product launches, amounts recorded for contingencies, environmental liabilities, accruals for contingent sales-based milestone payments and other reserves, pension and other postretirement benefit plan assumptions, share-based compensation assumptions, restructuring costs, impairments of long-lived assets (including intangible assets and goodwill) and investments, and taxes on income. Because of the uncertainty inherent in such estimates, actual results may differ from these estimates.

Reclassifications — Certain reclassifications have been made to prior year amounts to conform to the current year presentation.

Recently Adopted Accounting Standards — In May 2014, the Financial Accounting Standards Board (FASB) issued amended accounting guidance on revenue recognition (ASU 2014-09) that applies to all contracts with customers. The objective of the new guidance is to improve comparability of revenue recognition practices across entities and to provide more useful information to users of financial statements through improved disclosure requirements. The new standard permits two methods of adoption: retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of adopting the guidance being recognized at the date of initial application (modified retrospective method). The new standard was effective as of January 1, 2018 and was adopted using the modified retrospective method. The Company recorded a cumulative-effect adjustment upon adoption increasing *Retained earnings* by $5 million.

In January 2016, the FASB issued revised guidance for the accounting and reporting of financial instruments (ASU 2016-01) and in 2018 issued related technical corrections (ASU 2018-03). The new guidance requires that equity investments with readily determinable fair values currently classified as available for sale be measured at fair value with changes in fair value recognized in net income. The Company has elected to measure equity investments without readily determinable fair values at cost, adjusted for subsequent observable price changes and less impairments, which will be recognized in net income. The new guidance also changed certain disclosure requirements. ASU 2016-01 was effective as of January 1, 2018 and was adopted using a modified retrospective approach. The Company recorded a cumulative-effect adjustment upon adoption increasing *Retained earnings* by $8 million. ASU 2018-03 was also adopted as of January 1, 2018 on a prospective basis and did not result in any additional impacts upon adoption.

In October 2016, the FASB issued guidance on the accounting for the income tax consequences of intra-entity transfers of assets other than inventory (ASU 2016-16). The new guidance requires the recognition of the income tax consequences of an intra-entity transfer of an asset (with the exception of inventory) when the intra-entity transfer occurs, replacing the prohibition against doing so. The current exception to defer the recognition of any tax impact on the transfer of inventory within the consolidated entity until it is sold to a third party remains unaffected. The new standard was effective as of January 1, 2018 and was adopted using a modified retrospective approach. The Company recorded a cumulative-effect adjustment upon adoption increasing *Retained earnings* by $54 million with a corresponding decrease to *Deferred Income Taxes*.

In August 2017, the FASB issued new guidance on hedge accounting (ASU 2017-12) that is intended to more closely align hedge accounting with companies' risk management strategies, simplify the application of hedge accounting, and increase transparency as to the scope and results of hedging programs. The new guidance makes more financial and nonfinancial hedging strategies eligible for hedge accounting, amends the presentation and disclosure requirements, and changes how companies assess effectiveness. The Company elected to early adopt this guidance as of January 1, 2018 on a modified retrospective basis. The new guidance was applied to all existing hedges as of the adoption date. For fair value hedges of interest rate risk outstanding as of the date of adoption, the Company recorded a cumulative-effect adjustment upon adoption to the basis adjustment on the hedged item resulting from applying the benchmark component of the coupon guidance. This adjustment decreased *Retained earnings* by $11 million. Also, in

accordance with the transition provisions of ASU 2017-12, the Company was required to eliminate the separate measurement of ineffectiveness for its cash flow hedging instruments existing as of the adoption date through a cumulative-effect adjustment to retained earnings; however, all such amounts were *de minimis*.

In February 2018, the FASB issued new guidance to address a narrow-scope financial reporting issue that arose as a consequence of the Tax Cuts and Jobs Act of 2017 (TCJA) (ASU 2018-02). Existing guidance requires that deferred tax liabilities and assets be adjusted for a change in tax laws or rates with the effect included in income from continuing operations in the reporting period that includes the enactment date. That guidance is applicable even in situations in which the related income tax effects of items in accumulated other comprehensive income were originally recognized in other comprehensive income (rather than in net income), such as amounts related to benefit plans and hedging activity. As a result, the tax effects of items within accumulated other comprehensive income do not reflect the appropriate tax rate (the difference is referred to as stranded tax effects). The new guidance allows for a reclassification of the stranded tax effects resulting from the TCJA from accumulated other comprehensive income to retained earnings thereby eliminating these stranded tax effects. The Company elected to early adopt the new guidance in the first quarter of 2018 and reclassified the stranded income tax effects of the TCJA, increasing *Accumulated other comprehensive loss* in the amount of $266 million with a corresponding increase to *Retained earnings* (see Note 18). The Company's policy for releasing disproportionate income tax effects from *Accumulated other comprehensive loss* is to utilize the item-by-item approach.

The impact of adopting the above standards is as follows:

($ in millions)	ASU 2014-09 (Revenue)	ASU 2016-01 (Financial Instruments)	ASU 2016-16 (Intra-Entity Transfers of Assets Other than Inventory)	ASU 2017-12 (Derivatives and Hedging)	ASU 2018-02 (Reclassification of Certain Tax Effects)	Total
Assets - Increase (Decrease)						
Accounts receivable	$ 5					$ 5
Liabilities - Increase (Decrease)						
Income Taxes Payable				(3)		(3)
Debt				14		14
Deferred Income Taxes			(54)			(54)
Equity - Increase (Decrease)						
Retained earnings	5	8	54	(11)	266	322
Accumulated other comprehensive loss		(8)			(266)	(274)

In March 2017, the FASB issued amended guidance on retirement benefits (ASU 2017-07) related to net periodic benefit cost for defined benefit plans that requires entities to (1) disaggregate the current service cost component from the other components of net benefit cost and present it with other employee compensation costs in the income statement within operations if such a subtotal is presented; (2) present the other components of net benefit cost separately in the income statement and outside of income from operations; and (3) only capitalize the service cost component when applicable. The Company adopted the new standard as of January 1, 2018 using a retrospective transition method as to the requirement for separate presentation in the income statement of service costs and other components, and a prospective transition method as to the requirement to limit the capitalization of benefit costs to the service cost component. The Company utilized a practical expedient that permits it to use the amounts disclosed in its pension and other postretirement benefit plan note for the prior comparative periods as the estimation basis for applying the retrospective presentation requirements. Upon adoption, net periodic benefit cost (credit) other than service cost of $(512) million and $(531) million for the years ended December 31, 2017 and 2016, respectively, was reclassified to *Other (income) expense, net* from the previous classification within *Cost of sales*, *Selling, general and administrative* expenses and *Research and development* expenses (see Note 15).

In August 2016, the FASB issued guidance on the classification of certain cash receipts and payments in the statement of cash flows intended to reduce diversity in practice. The Company adopted the new standard effective as of January 1, 2018 using a retrospective application. There were no changes to the presentation of the Consolidated Statement of Cash Flows in the previous years presented as a result of adopting the new standard.

In November 2016, the FASB issued guidance requiring that amounts generally described as restricted cash and restricted cash equivalents be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The new standard was effective as of January 1, 2018 and was adopted using a retrospective application. The adoption of the new guidance did not have a material effect on the Company's Consolidated Statement of Cash Flows.

In May 2017, the FASB issued guidance clarifying when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The Company adopted the new standard effective as of January 1, 2018 and will apply the new guidance to future share-based payment award modifications should they occur.

In January 2017, the FASB issued guidance that provides for the elimination of Step 2 from the goodwill impairment test. Under the new guidance, impairment charges are recognized to the extent the carrying amount of a reporting unit exceeds its fair value with certain limitations. The Company adopted the new standard in the fourth quarter of 2018 and applied the new guidance for purposes of its fourth quarter goodwill impairment assessment. The adoption of the new guidance had an immaterial effect on its consolidated financial statements.

Recently Issued Accounting Standards Not Yet Adopted —In February 2016, the FASB issued new accounting guidance for the accounting and reporting of leases and subsequently issued several updates to the new guidance. The new guidance requires that lessees recognize a right-of-use asset and a lease liability recorded on the balance sheet for each of its leases (other than leases that meet the definition of a short-term lease). Leases will be classified as either operating or finance. Operating leases will result in straight-line expense in the income statement (similar to current operating leases) while finance leases will result in more expense being recognized in the earlier years of the lease term (similar to current capital leases). The new standard is effective as of January 1, 2019 and will be adopted using a modified retrospective approach. Merck will elect the transition method that allows for application of the standard at the adoption date rather than at the beginning of the earliest comparative period presented in the financial statements. The Company intends to elect available practical expedients. Merck has implemented a lease accounting software application and has completed data validation of the Company's portfolio of leases, including its assessment of potential embedded leases. Upon adoption, the Company anticipates it will recognize approximately $1 billion of additional assets and corresponding liabilities on its consolidated balance sheet, subject to finalization.

In June 2016, the FASB issued amended guidance on the accounting for credit losses on financial instruments. The guidance introduces an expected loss model for estimating credit losses, replacing the incurred loss model. The new guidance also changes the impairment model for available-for-sale debt securities, requiring the use of an allowance to record estimated credit losses (and subsequent recoveries). The new guidance is effective for interim and annual periods beginning in 2020, with earlier application permitted in 2019. The new guidance is to be applied on a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings in the beginning of the period of adoption. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In April 2018, the FASB issued new guidance on the accounting for costs incurred to implement a cloud computing arrangement that is considered a service arrangement. The new guidance requires the capitalization of such costs, aligning it with the accounting for costs associated with developing or obtaining internal-use software. The new guidance is effective for interim and annual periods beginning in 2020. Early adoption is permitted, including adoption in any interim period. Prospective adoption for eligible costs incurred on or after the date of adoption or retrospective adoption is permitted. The Company is currently evaluating the impact of adoption on its consolidated financial statements and may elect to early adopt this guidance.

In November 2018, the FASB issued new guidance for collaborative arrangements intended to reduce diversity in practice by clarifying whether certain transactions between collaborative arrangement participants should be accounted for under the recently issued guidance on revenue recognition (ASC 606). The new guidance is effective for interim and annual periods beginning in 2020. Early adoption is permitted, including adoption in any interim period. The new guidance is to be applied on a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

3. Acquisitions, Divestitures, Research Collaborations and License Agreements

The Company continues to pursue the acquisition of businesses and establishment of external alliances such as research collaborations and licensing agreements to complement its internal research capabilities. These arrangements often include upfront payments, as well as expense reimbursements or payments to the third party, and milestone, royalty or profit share arrangements, contingent upon the occurrence of certain future events linked to the success of the asset in development. The Company also reviews its marketed products and pipeline to examine candidates which may provide more value through out-licensing and, as part of its portfolio assessment process, may also divest certain assets. Pro forma financial information for acquired businesses is not presented if the historical financial results of the acquired entity are not significant when compared with the Company's financial results.

Recently Announced Transaction

In December 2018, Merck and privately held Antelliq Group (Antelliq) signed a definitive agreement under which Merck will acquire Antelliq from funds advised by BC Partners. Antelliq is a leader in digital animal identification, traceability and monitoring solutions. These solutions help veterinarians, farmers and pet owners gather critical data to improve management, health and well-being of livestock and pets. Merck will make a cash payment of approximately €2.1 billion (approximately $2.4 billion based on exchange rates at the time of the announcement) to acquire all outstanding shares of Antelliq and will assume Antelliq's debt of €1.1 billion (approximately $1.3 billion), which it intends to repay shortly after the closing of the acquisition. The transaction is subject to clearance by antitrust and competition law authorities and other customary closing conditions, and is expected to close in the second quarter of 2019.

2018 Transactions

In 2018, the Company recorded an aggregate charge of $423 million within *Cost of sales* in conjunction with the termination of a collaboration agreement entered into in 2014 with Samsung Bioepis Co., Ltd. (Samsung) for insulin glargine. The charge reflects a termination payment of $155 million, which represents the reimbursement of all fees previously paid by Samsung to Merck under the agreement, plus interest, as well as the release of Merck's ongoing obligations under the agreement. The charge also included fixed asset abandonment charges of $137 million, inventory write-offs of $122 million, as well as other related costs of $9 million. The termination of this agreement has no impact on the Company's other collaboration with Samsung.

In June 2018, Merck acquired Viralytics Limited (Viralytics), an Australian publicly traded company focused on oncolytic immunotherapy treatments for a range of cancers, for AUD 502 million ($378 million). The transaction provided Merck with full rights to *Cavatak* (V937, formerly CVA21), Viralytics's investigational oncolytic immunotherapy. *Cavatak* is based on Viralytics's proprietary formulation of an oncolytic virus (Coxsackievirus Type A21) that has been shown to preferentially infect and kill cancer cells. *Cavatak* is currently being evaluated in multiple Phase 1 and Phase 2 clinical trials, both as an intratumoral and intravenous agent, including in combination with *Keytruda*. Under a previous agreement between Merck and Viralytics, a study is investigating the use of the *Keytruda* and *Cavatak* combination in melanoma, prostate, lung and bladder cancers. The transaction was accounted for as an acquisition of an asset. Merck recorded net assets of $34 million (primarily cash) at the acquisition date and *Research and development* expenses of $344 million in 2018 related to the transaction. There are no future contingent payments associated with the acquisition.

In March 2018, Merck and Eisai Co., Ltd. (Eisai) entered into a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima, an orally available tyrosine kinase inhibitor discovered by Eisai (see Note 4).

2017 Transactions

In October 2017, Merck acquired Rigontec GmbH (Rigontec). Rigontec is a leader in accessing the retinoic acid-inducible gene I pathway, part of the innate immune system, as a novel and distinct approach in cancer immunotherapy to induce both immediate and long-term anti-tumor immunity. Rigontec's lead candidate, MK-4621 (formerly RGT100), is currently in Phase I development evaluating treatment in patients with various tumors. Under the terms of the agreement, Merck made an upfront cash payment of €119 million ($140 million) and may make additional contingent payments of up to €349 million (of which €184 million are related to the achievement of research milestones and regulatory approvals and €165 million are related to the achievement of commercial targets). The transaction was accounted for as an acquisition of an asset and the upfront payment is reflected within *Research and development* expenses in 2017.

In July 2017, Merck and AstraZeneca PLC (AstraZeneca) entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza for multiple cancer types (see Note 4).

In March 2017, Merck acquired a controlling interest in Vallée S.A. (Vallée), a leading privately held producer of animal health products in Brazil. Vallée has an extensive portfolio of products spanning parasiticides, anti-infectives and vaccines that include products for livestock, horses, and companion animals. Under the terms of the agreement, Merck acquired 93.5% of the shares of Vallée for $358 million. Of the total purchase price, $176 million was placed into escrow pending resolution of certain contingent items. The transaction was accounted for as an acquisition of a business. Merck recognized intangible assets of $297 million related to currently marketed products, net deferred tax liabilities of $102 million, other net assets of $32 million and noncontrolling interest of $25 million. In addition, the Company recorded liabilities of $37 million for contingencies identified at the acquisition date and corresponding indemnification assets of $37 million, representing the amounts to be reimbursed to Merck if and when the contingent liabilities are paid. The excess of the consideration transferred over the fair value of net assets acquired of $156 million was recorded as goodwill. The goodwill was allocated to the Animal Health segment and is not deductible for tax purposes. The estimated fair values of identifiable intangible assets related to currently marketed products were determined using an income approach. The probability-adjusted future net cash flows of each product were discounted to present value utilizing a discount rate of 15.5%. Actual cash flows are likely to be different than those assumed. The intangible assets related to currently marketed products are being amortized over their estimated useful lives of 15 years. In the fourth quarter of 2017, Merck acquired an additional 4.5% interest in Vallée for $18 million, which reduced the noncontrolling interest related to Vallée.

2016 Transactions

In July 2016, Merck acquired Afferent Pharmaceuticals (Afferent), a privately held pharmaceutical company focused on the development of therapeutic candidates targeting the P2X3 receptor for the treatment of common, poorly-managed, neurogenic conditions. Afferent's lead investigational candidate, MK-7264 (formerly AF-219), gefapixant, is a selective, non-narcotic, orally-administered P2X3 antagonist being evaluated for the treatment of refractory, chronic cough and for the treatment of endometriosis-related pain. Total consideration transferred of $510 million included cash paid for outstanding Afferent shares of $487 million, as well as share-based compensation payments to settle equity awards attributable to precombination service and cash paid for transaction costs on behalf of Afferent. In addition, former Afferent shareholders are eligible to receive a total of up to an additional $750 million contingent upon the attainment of certain clinical development and commercial milestones for multiple indications and candidates, including MK-7264. This transaction was accounted for as an acquisition of a business. The Company determined the fair value of the contingent consideration was $223 million at the acquisition date utilizing a probability-weighted estimated cash flow stream using an appropriate discount rate dependent on the nature and timing of the milestone payment. Merck recognized an intangible asset for IPR&D of $832 million, net deferred tax liabilities of $258 million, and other net assets of $29 million (primarily consisting of cash acquired). The excess of the consideration transferred over the fair value of net assets acquired of $130 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair value of the identifiable intangible asset related to IPR&D was determined using an income approach. The asset's probability-adjusted future net cash flows were discounted to present value using a discount rate of 11.5%. Actual cash flows are likely to be different than those assumed. In 2018, as a result of the achievement of a clinical development milestone, Merck made a $175 million payment, which was accrued for at estimated fair value at the time of acquisition as noted above. The contingent consideration liability was then remeasured at current fair value at each subsequent reporting period until payment was made (see Note 6).

In June 2016, Merck and Moderna Therapeutics (Moderna) entered into a strategic collaboration and license agreement to develop and commercialize novel messenger RNA (mRNA)-based personalized cancer vaccines. The development program will entail multiple studies in several types of cancer and include the evaluation of mRNA-based personalized cancer vaccines in combination with Merck's *Keytruda*. Pursuant to the terms of the agreement, Merck made an upfront cash payment to Moderna of $200 million, which was recorded in *Research and development* expenses. Following human proof of concept studies, Merck has the right to elect to make an additional payment to Moderna. If Merck exercises this right, the two companies will then equally share costs and profits under a worldwide collaboration for the development of personalized cancer vaccines. Moderna will have the right to elect to co-promote the personalized cancer vaccines in the United States. The agreement entails exclusivity around combinations with *Keytruda*. Moderna and Merck each have the ability to combine mRNA-based personalized cancer vaccines with other (non-PD-1) agents.

In January 2016, Merck acquired IOmet Pharma Ltd (IOmet), a privately held UK-based drug discovery company focused on the development of innovative medicines for the treatment of cancer, with a particular emphasis on the fields of cancer immunotherapy and cancer metabolism. The acquisition provided Merck with IOmet's preclinical pipeline of IDO (indoleamine-2,3-dioxygenase 1), TDO (tryptophan-2,3-dioxygenase), and dual-acting IDO/TDO inhibitors. The transaction was accounted for as an acquisition of a business. Total purchase consideration in the transaction included a cash payment of $150 million and future additional milestone payments of up to $250 million contingent upon certain clinical and regulatory milestones being achieved. The Company determined the fair value of the contingent consideration was $94 million at the acquisition date utilizing a probability-weighted estimated cash flow stream adjusted for the expected timing of each payment utilizing a discount rate of 10.5%. Merck recognized intangible assets for IPR&D of $155 million and net deferred tax assets of $32 million. The excess of the consideration transferred over the fair value of net assets acquired of $57 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair values of the identifiable intangible assets related to IPR&D were determined using an income approach. The assets' probability-adjusted future net cash flows were discounted to present value also using a discount rate of 10.5%. Actual cash flows are likely to be different than those assumed. In 2017, as a result of the achievement of a clinical development milestone, Merck made a $100 million payment, which was accrued for at estimated fair value at the time of acquisition as noted above. The contingent consideration liability was then remeasured at current fair value at each subsequent reporting period until payment was made (see Note 6).

Remicade/Simponi

In 1998, a subsidiary of Schering-Plough entered into a licensing agreement with Centocor Ortho Biotech Inc. (Centocor), a Johnson & Johnson (J&J) company, to market *Remicade,* which is prescribed for the treatment of inflammatory diseases. In 2005, Schering-Plough's subsidiary exercised an option under its contract with Centocor for license rights to develop and commercialize *Simponi*, a fully human monoclonal antibody. The Company has marketing rights to both products throughout Europe, Russia and Turkey. *Remicade* lost market exclusivity in major European markets in 2015 and the Company no longer has market exclusivity in any of its marketing territories. The Company continues to have market exclusivity for *Simponi* in all of its marketing territories. All profits derived from Merck's distribution of the two products in these countries are equally divided between Merck and J&J.

4. Collaborative Arrangements

Merck has entered into collaborative arrangements that provide the Company with varying rights to develop, produce and market products together with its collaborative partners. Both parties in these arrangements are active participants and exposed to significant risks and rewards dependent on the commercial success of the activities of the collaboration. Merck's more significant collaborative arrangements are discussed below.

AstraZeneca

In July 2017, Merck and AstraZeneca entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza for multiple cancer types. Lynparza is an oral poly (ADP-ribose) polymerase (PARP) inhibitor currently approved for certain types of ovarian and breast cancer. The companies are jointly developing and commercializing Lynparza, both as monotherapy and in combination trials with other potential medicines. Independently, Merck and AstraZeneca will develop and commercialize Lynparza in combinations with their respective PD-1 and PD-L1 medicines, *Keytruda* and Imfinzi. The companies will also jointly develop and commercialize AstraZeneca's selumetinib, an oral, potent, selective inhibitor of MEK, part of the mitogen-activated protein kinase (MAPK) pathway, currently being developed for multiple indications. Under the terms of the agreement, AstraZeneca and Merck will share the development and commercialization costs for Lynparza and selumetinib monotherapy and non-PD-L1/PD-1 combination therapy opportunities.

Gross profits from Lynparza and selumetinib product sales generated through monotherapies or combination therapies are shared equally. Merck will fund all development and commercialization costs of *Keytruda* in combination with Lynparza or selumetinib. AstraZeneca will fund all development and commercialization costs of Imfinzi in combination with Lynparza or selumetinib. AstraZeneca is currently the principal on Lynparza sales transactions. Merck records its share of Lynparza product sales, net of cost of sales and commercialization costs, as alliance revenue within the Pharmaceutical segment and its share of development costs associated with the collaboration as part of *Research*

and development expenses. Reimbursements received from AstraZeneca for research and development expenses are recognized as reductions to *Research and development* costs.

As part of the agreement, Merck made an upfront payment to AstraZeneca of $1.6 billion and will make payments of up to $750 million over a multi-year period for certain license options (of which $250 million was paid in December 2017, $400 million was paid in December 2018 and $100 million is expected be paid in 2019). The Company recorded an aggregate charge of $2.35 billion in *Research and development* expenses in 2017 related to the upfront payment and future license option payments. In addition, the agreement provides for additional contingent payments from Merck to AstraZeneca related to the successful achievement of regulatory and sales-based milestones.

In 2018, Merck determined it was probable that annual sales of Lynparza in the future would trigger three sales-based milestone payments from Merck to AstraZeneca aggregating $600 million. Accordingly, in 2018, Merck recorded $600 million of liabilities and a corresponding increase to the intangible asset related to Lynparza, and recognized $58 million of cumulative amortization expense within *Cost of sales*. During 2018, one of the sales-based milestones was triggered, resulting in a $150 million payment to AstraZeneca. In 2018, Merck made an additional $100 million sales-based milestone payment, which was accrued for in 2017 when the Company deemed to the payment to be probable. The remaining $3.4 billion of potential future sales-based milestone payments have not yet been accrued as they are not deemed by the Company to be probable at this time.

In 2018, Lynparza received approval in the United States for the treatment of certain patients with metastatic breast cancer and for use in the first-line maintenance setting for advanced ovarian cancer, triggering capitalized milestone payments of $140 million in the aggregate from Merck to AstraZeneca. Potential future regulatory milestone payments of $1.76 billion remain under the agreement.

The asset balance related to Lynparza (which includes capitalized sales-based and regulatory milestone payments) was $743 million at December 31, 2018 and is included in *Other Assets* on the Consolidated Balance Sheet. The amount is being amortized over its estimated useful life through 2028 as supported by projected future cash flows, subject to impairment testing.

Summarized information related to this collaboration is as follows:

Years Ended December 31	**2018**	2017
Alliance revenue	**$ 187**	$ 20
Cost of sales [1]	**93**	4
Selling, general and administrative	**48**	1
Research and development [2]	**152**	2,419

December 31	**2018**	2017
Receivables from AstraZeneca included in *Other current assets*	**$ 52**	$ 12
Payables to AstraZeneca included in *Accrued and other current liabilities* [3]	**405**	543
Payables to AstraZeneca included *Other Noncurrent Liabilities* [3]	**250**	100

[1] *Represents amortization of capitalized milestone payments.*

[2] *Amount for 2017 includes $2.35 billion related to the upfront payment and future license option payments.*

[3] *Includes accrued milestone and license option payments.*

Eisai

In March 2018, Merck and Eisai announced a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima, an orally available tyrosine kinase inhibitor discovered by Eisai. Under the agreement, Merck and Eisai will develop and commercialize Lenvima jointly, both as monotherapy and in combination with Merck's anti-PD-1 therapy, *Keytruda*. Eisai records Lenvima product sales globally (Eisai is the principal on Lenvima sales transactions), and Merck and Eisai share gross profits equally. Merck records its share of Lenvima product sales, net of cost of sales and commercialization costs, as alliance revenue. Expenses incurred during co-development, including for studies evaluating Lenvima as monotherapy, are shared equally by the two companies and reflected in *Research and development* expenses.

Under the agreement, Merck made an upfront payment to Eisai of $750 million and will make payments of up to $650 million for certain option rights through 2021 (of which $325 million will be paid in March 2019, $200 million is expected to be paid in 2020 and $125 million is expected to be paid in 2021). The Company recorded an aggregate charge of $1.4 billion in *Research and development* expenses in 2018 related to the upfront payment and future option payments. In addition, the agreement provides for Eisai to receive up to $385 million associated with the achievement of certain clinical and regulatory milestones and up to $3.97 billion for the achievement of milestones associated with sales of Lenvima.

In 2018, Merck determined it was probable that annual sales of Lenvima in the future would trigger three sales-based milestone payments from Merck to Eisai aggregating $268 million. Accordingly, in 2018, Merck recorded $268 million of liabilities and a corresponding increase to the intangible asset related to Lenvima, and recognized $24 million of cumulative amortization expense within *Cost of sales*. The remaining $3.71 billion of potential future sales-based milestone payments have not yet been accrued as they are not deemed by the Company to be probable at this time.

In 2018, Lenvima was approved for the treatment of patients with unresectable hepatocellular carcinoma in the United States, the European Union, Japan and China, triggering capitalized milestone payments to Eisai of $250 million in the aggregate. Potential future regulatory milestone payments of $135 million remain under the agreement.

The asset balance related to Lenvima (which includes capitalized sales-based and regulatory milestone payments) was $479 million at December 31, 2018 and is included in *Other Assets* on the Consolidated Balance Sheet. The amount is being amortized over its estimated useful life through 2026 as supported by projected future cash flows, subject to impairment testing.

Summarized information related to this collaboration is as follows:

Year Ended December 31	**2018**
Alliance revenue	**$ 149**
Cost of sales [(1)]	**39**
Selling, general and administrative	**13**
Research and development [(2)]	**1,489**

December 31	**2018**
Receivables from Eisai included in *Other current assets*	**$ 71**
Payables to Eisai included in *Accrued and other current liabilities* [(3)]	**375**
Payables to Eisai included in *Other Noncurrent Liabilities* [(3)]	**543**

[(1)] *Represents amortization of capitalized milestone payments.*

[(2)] *Includes $1.4 billion related to the upfront payment and future option payments.*

[(3)] *Includes accrued milestone and option payments.*

Bayer AG

In 2014, the Company entered into a worldwide clinical development collaboration with Bayer AG (Bayer) to market and develop soluble guanylate cyclase (sGC) modulators including Bayer's Adempas, which is approved to treat pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension. The two companies have implemented a joint development and commercialization strategy. The collaboration also includes clinical development of Bayer's vericiguat, which is in Phase 3 trials for worsening heart failure, as well as opt-in rights for other early-stage sGC compounds in development by Bayer. Merck in turn made available its early-stage sGC compounds under similar terms. Under the agreement, Bayer leads commercialization of Adempas in the Americas, while Merck leads commercialization in the rest of the world. For vericiguat and other potential opt-in products, Bayer will lead commercialization in the rest of world and Merck will lead in the Americas. For all products and candidates included in the agreement, both companies will share in development costs and profits on sales and will have the right to co-promote in territories where they are not the lead. In 2016, Merck began promoting and distributing Adempas in Europe. Transition from Bayer in other Merck territories, including Japan, continued in 2017. Revenue from Adempas includes sales in Merck's marketing territories, as well as Merck's share of profits from the sale of Adempas in Bayer's marketing territories.

In 2018, Merck determined it was probable that annual worldwide sales of Adempas in the future would trigger a $375 million sales-based milestone payment from Merck to Bayer. Accordingly, Merck recorded a $375 million noncurrent liability and a corresponding increase to the intangible asset related to Adempas, and recognized $106 million of cumulative amortization expense within *Cost of sales*. In 2018, the Company made a $350 million milestone payment to Bayer, which was accrued for in 2016 when Merck deemed the payment to be probable. There is an additional $400 million potential future sales-based milestone payment that has not yet been accrued as it is not deemed by the Company to be probable at this time.

The intangible asset balance related to Adempas (which includes the remaining acquired intangible asset balance, as well as capitalized sales-based milestone payments) was $1.0 billion at December 31, 2018 and is included in *Other Intangibles, Net* on the Consolidated Balance Sheet. The amount is being amortized over its estimated useful life through 2027 as supported by projected future cash flows, subject to impairment testing.

Summarized information related to this collaboration is as follows:

Years Ended December 31	**2018**	2017	2016
Net product sales recorded by Merck	**$ 190**	$ 149	$ 88
Merck's profit share from sales in Bayer's marketing territories	**139**	151	81
Total sales	**329**	300	169
Cost of sales [1]	**216**	99	133
Selling, general and administrative	**35**	27	26
Research and development	**127**	101	82

December 31	**2018**	2017
Receivables from Bayer included in *Other current assets*	**$ 32**	$ 33
Payables to Bayer included in *Accrued and other current liabilities* [2]	**—**	350
Payables to Bayer included in *Other Noncurrent Liabilities* [2]	**375**	—

[1] *Includes amortization of intangible assets.*

[2] *Includes accrued milestone payments.*

Aggregate amortization expense related to capitalized license costs recorded within *Cost of sales* was $186 million in 2018, $39 million in 2017 and $30 million in 2016. The estimated aggregate amortization expense for each of the next five years is as follows: 2019, $196 million; 2020, $193 million; 2021, $191 million; 2022, $187 million; 2023, $181 million.

5. Restructuring

In 2010 and 2013, the Company commenced actions under global restructuring programs designed to streamline its cost structure. The actions under these programs include the elimination of positions in sales, administrative and headquarters organizations, as well as the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities. The Company also continues to reduce its global real estate footprint and improve the efficiency of its manufacturing and supply network.

The Company recorded total pretax costs of $658 million in 2018, $927 million in 2017 and $1.1 billion in 2016 related to restructuring program activities. Since inception of the programs through December 31, 2018, Merck has recorded total pretax accumulated costs of approximately $14.1 billion and eliminated approximately 45,510 positions comprised of employee separations, as well as the elimination of contractors and vacant positions. The Company estimates that approximately two-thirds of the cumulative pretax costs are cash outlays, primarily related to employee separation expense. Approximately one-third of the cumulative pretax costs are non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested. The Company has substantially completed the actions under these programs.

For segment reporting, restructuring charges are unallocated expenses.

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The following table summarizes the charges related to restructuring program activities by type of cost:

	Separation Costs	Accelerated Depreciation	Other	Total
Year Ended December 31, 2018				
Cost of sales	**$ —**	**$ 10**	**$ 11**	**$ 21**
Selling, general and administrative	**—**	**2**	**1**	**3**
Research and development	**—**	**(13)**	**15**	**2**
Restructuring costs	**473**	**—**	**159**	**632**
	$ 473	**$ (1)**	**$ 186**	**$ 658**
Year Ended December 31, 2017				
Cost of sales	$ —	$ 52	$ 86	$ 138
Selling, general and administrative	—	2	—	2
Research and development	—	6	5	11
Restructuring costs	552	—	224	776
	$ 552	$ 60	$ 315	$ 927
Year Ended December 31, 2016				
Cost of sales	$ —	$ 77	$ 104	$ 181
Selling, general and administrative	—	8	87	95
Research and development	—	142	—	142
Restructuring costs	216	—	435	651
	$ 216	$ 227	$ 626	$ 1,069

Separation costs are associated with actual headcount reductions, as well as those headcount reductions which were probable and could be reasonably estimated. Positions eliminated under restructuring program activities were approximately 2,160 in 2018, 2,450 in 2017 and 2,625 in 2016.

Accelerated depreciation costs primarily relate to manufacturing, research and administrative facilities and equipment to be sold or closed as part of the programs. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the asset, based upon the anticipated date the site will be closed or divested or the equipment disposed of, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. All the sites have and will continue to operate up through the respective closure dates and, since future undiscounted cash flows were sufficient to recover the respective book values, Merck is recording accelerated depreciation over the revised useful life of the site assets. Anticipated site closure dates, particularly related to manufacturing locations, have been and may continue to be adjusted to reflect changes resulting from regulatory or other factors.

Other activity in 2018, 2017 and 2016 includes $141 million, $267 million and $409 million, respectively, of asset abandonment, shut-down and other related costs. Additionally, other activity includes certain employee-related costs associated with pension and other postretirement benefit plans (see Note 14) and share-based compensation. Other activity also reflects net pretax losses resulting from sales of facilities and related assets of $151 million in 2016.

The following table summarizes the charges and spending relating to restructuring program activities:

	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2017	$ 395	$ —	$ 146	$ 541
Expenses	552	60	315	927
(Payments) receipts, net	(328)	—	(394)	(722)
Non-cash activity	—	(60)	61	1
Restructuring reserves December 31, 2017	619	—	128	747
Expenses	**473**	**(1)**	**186**	**658**
(Payments) receipts, net	**(649)**	**—**	**(238)**	**(887)**
Non-cash activity	**—**	**1**	**15**	**16**

Restructuring reserves December 31, 2018 [1]	**$ 443**	**$ —**	**$ 91**	**$ 534**

[1] *The remaining cash outlays are expected to be substantially completed by the end of 2020.*

6. Financial Instruments

Derivative Instruments and Hedging Activities

The Company manages the impact of foreign exchange rate movements and interest rate movements on its earnings, cash flows and fair values of assets and liabilities through operational means and through the use of various financial instruments, including derivative instruments.

A significant portion of the Company's revenues and earnings in foreign affiliates is exposed to changes in foreign exchange rates. The objectives and accounting related to the Company's foreign currency risk management program, as well as its interest rate risk management activities are discussed below.

Foreign Currency Risk Management

The Company has established revenue hedging, balance sheet risk management and net investment hedging programs to protect against volatility of future foreign currency cash flows and changes in fair value caused by volatility in foreign exchange rates.

The objective of the revenue hedging program is to reduce the variability caused by changes in foreign exchange rates that would affect the U.S. dollar value of future cash flows derived from foreign currency denominated sales, primarily the euro and Japanese yen. To achieve this objective, the Company will hedge a portion of its forecasted foreign currency denominated third-party and intercompany distributor entity sales (forecasted sales) that are expected to occur over its planning cycle, typically no more than two years into the future. The Company will layer in hedges over time, increasing the portion of forecasted sales hedged as it gets closer to the expected date of the forecasted sales. The portion of forecasted sales hedged is based on assessments of cost-benefit profiles that consider natural offsetting exposures, revenue and exchange rate volatilities and correlations, and the cost of hedging instruments. The Company manages its anticipated transaction exposure principally with purchased local currency put options, forward contracts, and purchased collar options.

The fair values of these derivative contracts are recorded as either assets (gain positions) or liabilities (loss positions) in the Consolidated Balance Sheet. Changes in the fair value of derivative contracts are recorded each period in either current earnings or *OCI*, depending on whether the derivative is designated as part of a hedge transaction and, if so, the type of hedge transaction. For derivatives that are designated as cash flow hedges, the unrealized gains or losses on these contracts is recorded in *AOCI* and reclassified into *Sales* when the hedged anticipated revenue is recognized. For those derivatives which are not designated as cash flow hedges, but serve as economic hedges of forecasted sales, unrealized gains or losses are recorded in *Sales* each period. The cash flows from both designated and non-designated contracts are reported as operating activities in the Consolidated Statement of Cash Flows. The Company does not enter into derivatives for trading or speculative purposes.

The Company manages operating activities and net asset positions at each local subsidiary in order to mitigate the effects of exchange on monetary assets and liabilities. The Company also uses a balance sheet risk management program to mitigate the exposure of net monetary assets that are denominated in a currency other than a subsidiary's functional currency from the effects of volatility in foreign exchange. In these instances, Merck principally utilizes forward exchange contracts to offset the effects of exchange on exposures denominated in developed country currencies, primarily the euro and Japanese yen. For exposures in developing country currencies, the Company will enter into forward contracts to partially offset the effects of exchange on exposures when it is deemed economical to do so based on a cost-benefit analysis that considers the magnitude of the exposure, the volatility of the exchange rate and the cost of the hedging instrument. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

Monetary assets and liabilities denominated in a currency other than the functional currency of a given subsidiary are remeasured at spot rates in effect on the balance sheet date with the effects of changes in spot rates reported in *Other (income) expense, net*. The forward contracts are not designated as hedges and are marked to market through *Other (income) expense, net*. Accordingly, fair value changes in the forward contracts help mitigate the changes in the value of the remeasured assets and liabilities attributable to changes in foreign currency exchange rates, except to the extent of the spot-forward differences. These differences are not significant due to the short-term nature of the contracts, which typically have average maturities at inception of less than one year.

The Company also uses forward exchange contracts to hedge its net investment in foreign operations against movements in exchange rates. The forward contracts are designated as hedges of the net investment in a foreign operation. The Company hedges a portion of the net investment in certain of its foreign operations. The unrealized gains or losses on these contracts are recorded in foreign currency translation adjustment within *OCI*, and remain in *AOCI* until either the sale or complete or substantially complete liquidation of the subsidiary. The Company excludes certain portions of the change in fair value of its derivative instruments from the assessment of hedge effectiveness (excluded component). Changes in fair value of the excluded components are recognized in *OCI*. In accordance with the new guidance adopted on January 1, 2018 (see Note 2), the Company has elected to recognize in earnings the initial value of the excluded component on a straight-line basis over the life of the derivative instrument, rather than using the mark-to-market approach. The cash flows from these contracts are reported as investing activities in the Consolidated Statement of Cash Flows.

Foreign exchange risk is also managed through the use of foreign currency debt. The Company's senior unsecured euro-denominated notes have been designated as, and are effective as, economic hedges of the net investment in a foreign operation. Accordingly, foreign currency transaction gains or losses due to spot rate fluctuations on the euro-denominated debt instruments are included in foreign currency translation adjustment within *OCI*.

The effects of the Company's net investment hedges on *OCI* and the Consolidated Statement of Income are shown below:

	Amount of Pretax (Gain) Loss Recognized in Other Comprehensive Income [1]			Amount of Pretax (Gain) Loss Recognized in *Other (income) expense, net* for Amounts Excluded from Effectiveness Testing		
Years Ended December 31	**2018**	2017	2016	**2018**	2017	2016
Net Investment Hedging Relationships						
Foreign exchange contracts	**$ (18)**	$ —	$ 2	**$ (11)**	$ —	$ (1)
Euro-denominated notes	**(183)**	520	(193)	**—**	—	—

[1] *No amounts were reclassified from AOCI into income related to the sale of a subsidiary.*

Interest Rate Risk Management

The Company may use interest rate swap contracts on certain investing and borrowing transactions to manage its net exposure to interest rate changes and to reduce its overall cost of borrowing. The Company does not use leveraged swaps and, in general, does not leverage any of its investment activities that would put principal capital at risk.

In May 2018, four interest rate swaps with notional amounts aggregating $1.0 billion matured. These swaps effectively converted the Company's $1.0 billion, 1.30% fixed-rate notes due 2018 to variable rate debt. In December 2018, in connection with the early repayment of debt, the Company settled three interest rate swaps with notional amounts aggregating $550 million. These swaps effectively converted a portion of the Company's $1.25 billion, 5.00% notes due 2019 to variable rate debt. At December 31, 2018, the Company was a party to 19 pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes as detailed in the table below.

	2018		
Debt Instrument	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
1.85% notes due 2020	$ 1,250	5	$ 1,250
3.875% notes due 2021	1,150	5	1,150
2.40% notes due 2022	1,000	4	1,000
2.35% notes due 2022	1,250	5	1,250

The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in the benchmark London Interbank Offered Rate (LIBOR) swap rate. The fair value changes in the notes attributable to changes in the LIBOR swap rate are recorded in interest expense along with the offsetting fair value changes in the swap contracts. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

The table below presents the location of amounts recorded on the Consolidated Balance Sheet related to cumulative basis adjustments for fair value hedges as of December 31:

	Carrying Amount of Hedged Liabilities		Cumulative Amount of Fair Value Hedging Adjustment Increase (Decrease) Included in the Carrying Amount	
	2018	2017	**2018**	2017
Balance Sheet Line Item in which Hedged Item is Included				
Loans payable and current portion of long-term debt	**$ —**	$ 983	**$ —**	$ (17)
Long-Term Debt [(1)]	**4,560**	5,146	**(82)**	(41)

[(1)] *Amounts include hedging adjustment gains related to discontinued hedging relationships of $11 million at December 31, 2017.*

Presented in the table below is the fair value of derivatives on a gross basis segregated between those derivatives that are designated as hedging instruments and those that are not designated as hedging instruments as of December 31:

		2018			2017		
		Fair Value of Derivative			Fair Value of Derivative		
	Balance Sheet Caption	**Asset**	**Liability**	**U.S. Dollar Notional**	Asset	Liability	U.S. Dollar Notional
Derivatives Designated as Hedging Instruments							
Interest rate swap contracts	Other assets	**$ —**	**$ —**	**$ —**	$ 2	$ —	$ 550
Interest rate swap contracts	Accrued and other current liabilities	**—**	**—**	**—**	—	3	1,000
Interest rate swap contracts	Other noncurrent liabilities	**—**	**81**	**4,650**	—	52	4,650
Foreign exchange contracts	Other current assets	**263**	**—**	**6,222**	51	—	4,216
Foreign exchange contracts	Other assets	**75**	**—**	**2,655**	38	—	1,936
Foreign exchange contracts	Accrued and other current liabilities	**—**	**7**	**774**	—	71	2,014
Foreign exchange contracts	Other noncurrent liabilities	**—**	**1**	**89**	—	1	20
		$ 338	**$ 89**	**$ 14,390**	$ 91	$ 127	$ 14,386
Derivatives Not Designated as Hedging Instruments							
Foreign exchange contracts	Other current assets	**$ 116**	**$ —**	**$ 5,430**	$ 39	$ —	$ 3,778
Foreign exchange contracts	Accrued and other current liabilities	**—**	**71**	**9,922**	—	90	7,431
		$ 116	**$ 71**	**$ 15,352**	$ 39	$ 90	$ 11,209
		$ 454	**$ 160**	**$ 29,742**	$ 130	$ 217	$ 25,595

As noted above, the Company records its derivatives on a gross basis in the Consolidated Balance Sheet. The Company has master netting agreements with several of its financial institution counterparties (see *Concentrations of Credit Risk* below). The following table provides information on the Company's derivative positions subject to these master netting arrangements as if they were presented on a net basis, allowing for the right of offset by counterparty and cash collateral exchanged per the master agreements and related credit support annexes at December 31:

	2018		2017	
	Asset	**Liability**	Asset	Liability
Gross amounts recognized in the consolidated balance sheet	**$ 454**	**$ 160**	$ 130	$ 217
Gross amount subject to offset in master netting arrangements not offset in the consolidated balance sheet	**(121)**	**(121)**	(94)	(94)
Cash collateral received	**(107)**	**—**	(3)	—
Net amounts	**$ 226**	**$ 39**	$ 33	$ 123

The table below provides information regarding the location and amount of pretax (gains) losses of derivatives designated in fair value or cash flow hedging relationships:

	Sales			Other (income) expense, net *(1)*			Other comprehensive income (loss)		
Years Ended December 31	**2018**	2017	2016	**2018**	2017	2016	**2018**	2017	2016
Financial Statement Line Items in which Effects of Fair Value or Cash Flow Hedges are Recorded	**$ 42,294**	$ 40,122	$ 39,807	**$ (402)**	(500)	189	**$ (361)**	$ 316	$ (1,078)
(Gain) loss on fair value hedging relationships									
Interest rate swap contracts									
Hedged items	**—**	—	—	**(27)**	(48)	(29)	**—**	—	—
Derivatives designated as hedging instruments	**—**	—	—	**50**	12	(35)	**—**	—	—
Impact of cash flow hedging relationships									
Foreign exchange contracts									
Amount of gain (loss) recognized in *OCI* on derivatives	**—**	—	—	**—**	—	—	**228**	(562)	210
(Decrease) increase in *Sales* as a result of *AOCI* reclassifications	**(160)**	138	311	**—**	—	—	**160**	(138)	(311)

(1) *Interest expense is a component of* Other (income) expense, net.

The table below provides information regarding the income statement effects of derivatives not designated as hedging instruments:

		Amount of Derivative Pretax (Gain) Loss Recognized in Income		
Years Ended December 31	Income Statement Caption	**2018**	2017	2016
Derivatives Not Designated as Hedging Instruments				
Foreign exchange contracts (1)	Other (income) expense, net	**$ (260)**	$ 110	$ 132
Foreign exchange contracts (2)	Sales	**(8)**	(3)	—

(1) *These derivative contracts mitigate changes in the value of remeasured foreign currency denominated monetary assets and liabilities attributable to changes in foreign currency exchange rates.*

(2) *These derivative contracts serve as economic hedges of forecasted transactions.*

At December 31, 2018, the Company estimates $186 million of pretax net unrealized gains on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from *AOCI* to *Sales*. The amount ultimately reclassified to *Sales* may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.

Investments in Debt and Equity Securities

Information on investments in debt and equity securities at December 31 is as follows:

	2018				2017			
	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses
Corporate notes and bonds	**$ 4,920**	**$ 4,985**	**$ 3**	**$ (68)**	$ 9,806	$ 9,837	$ 9	$ (40)
Asset-backed securities	**1,275**	**1,285**	**1**	**(11)**	1,542	1,548	1	(7)
U.S. government and agency securities	**892**	**895**	**2**	**(5)**	2,042	2,059	—	(17)
Foreign government bonds	**166**	**167**	**—**	**(1)**	733	739	—	(6)
Mortgage-backed securities	**8**	**8**	**—**	**—**	626	634	1	(9)
Commercial paper	**—**	**—**	**—**	**—**	159	159	—	—
Total debt securities	**7,261**	**7,340**	**6**	**(85)**	14,908	14,976	11	(79)
Publicly traded equity securities [1]	**456**				275	265	16	(6)
Total debt and publicly traded equity securities	**$ 7,717**				$ 15,183	$ 15,241	$ 27	$ (85)

[1] *Pursuant to the adoption of ASU 2016-01 (see Note 2), beginning on January 1, 2018, changes in the fair value of publicly traded equity securities are recognized in net income. Unrealized net losses of $35 million were recognized in* Other (income) expense, net *during 2018 on equity securities still held at December 31, 2018.*

At December 31, 2018, the Company also had $568 million of equity investments without readily determinable fair values included in *Other Assets*. During 2018, the Company recognized unrealized gains of $167 million in *Other (income) expense, net* on certain of these equity investments based on favorable observable price changes from transactions involving similar investments of the same investee. In addition, during 2018, the Company recognized unrealized losses of $26 million in *Other (income) expense, net* related to certain of these investments based on unfavorable observable price changes.

Available-for-sale debt securities included in *Short-term investments* totaled $894 million at December 31, 2018. Of the remaining debt securities, $5.8 billion mature within five years. At December 31, 2018 and 2017, there were no debt securities pledged as collateral.

Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company uses a fair value hierarchy which maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest:

Level 1 — Quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 — Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity. Level 3 assets or liabilities are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as assets or liabilities for which the determination of fair value requires significant judgment or estimation. If the inputs used to measure the financial assets and liabilities fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

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Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

Financial assets and liabilities measured at fair value on a recurring basis at December 31 are summarized below:

	Fair Value Measurements Using				Fair Value Measurements Using			
	Quoted Prices In Active Markets for Identical Assets (Level 1)	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**	**Total**	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
		2018				2017		
Assets								
Investments								
Corporate notes and bonds	**$ —**	**$ 4,835**	**$ —**	**$ 4,835**	$ —	$ 9,678	$ —	$ 9,678
Asset-backed securities [1]	**—**	**1,253**	**—**	**1,253**	—	1,476	—	1,476
U.S. government and agency securities	**—**	**731**	**—**	**731**	68	1,767	—	1,835
Foreign government bonds	**—**	**166**	**—**	**166**	—	732	—	732
Mortgage-backed securities	**—**	**—**	**—**	**—**	—	547	—	547
Commercial paper	**—**	**—**	**—**	**—**	—	159	—	159
Publicly traded equity securities	**147**	**—**	**—**	**147**	104	—	—	104
	147	**6,985**	**—**	**7,132**	172	14,359	—	14,531
Other assets [2]								
U.S. government and agency securities	**55**	**106**	**—**	**161**	—	207	—	207
Corporate notes and bonds	**—**	**85**	**—**	**85**	—	128	—	128
Asset-backed securities [1]	**—**	**22**	**—**	**22**	—	66	—	66
Mortgage-backed securities	**—**	**8**	**—**	**8**	—	79	—	79
Foreign government bonds	**—**	**—**	**—**	**—**	—	1	—	1
Publicly traded equity securities	**309**	**—**	**—**	**309**	171	—	—	171
	364	**221**	**—**	**585**	171	481	—	652
Derivative assets [3]								
Forward exchange contracts	**—**	**241**	**—**	**241**	—	48	—	48
Purchased currency options	**—**	**213**	**—**	**213**	—	80	—	80
Interest rate swaps	**—**	**—**	**—**	**—**	—	2	—	2
	—	**454**	**—**	**454**	—	130	—	130
Total assets	**$ 511**	**$ 7,660**	**$ —**	**$ 8,171**	$ 343	$ 14,970	$ —	$ 15,313
Liabilities								
Other liabilities								
Contingent consideration	**$ —**	**$ —**	**$ 788**	**$ 788**	$ —	$ —	$ 935	$ 935
Derivative liabilities [3]								
Interest rate swaps	**—**	**81**	**—**	**81**	—	55	—	55
Forward exchange contracts	**—**	**74**	**—**	**74**	—	162	—	162
Written currency options	**—**	**5**	**—**	**5**	—	—	—	—
	—	**160**	**—**	**160**	—	217	—	217
Total liabilities	**$ —**	**$ 160**	**$ 788**	**$ 948**	$ —	$ 217	$ 935	$ 1,152

[1] *Primarily all of the asset-backed securities are highly-rated (Standard & Poor's rating of AAA and Moody's Investors Service rating of Aaa), secured primarily by auto loan, credit card and student loan receivables, with weighted-average lives of primarily 5 years or less.*

[2] *Investments included in other assets are restricted as to use, primarily for the payment of benefits under employee benefit plans.*

[3] *The fair value determination of derivatives includes the impact of the credit risk of counterparties to the derivatives and the Company's own credit risk, the effects of which were not significant.*

There were no transfers between Level 1 and Level 2 during 2018. As of December 31, 2018, *Cash and cash equivalents* of $8.0 billion include $7.2 billion of cash equivalents (which would be considered Level 2 in the fair value hierarchy).

Contingent Consideration

Summarized information about the changes in liabilities for contingent consideration is as follows:

	2018	2017
Fair value January 1	**$ 935**	$ 891
Changes in estimated fair value [1]	**89**	141
Additions	**8**	3
Payments	**(244)**	(100)
Fair value December 31 [2]	**$ 788**	$ 935

[1] *Recorded in* Research and development *expenses,* Cost of sales *and* Other (income) expense, net. *Includes cumulative translation adjustments.*

[2] *Balance at December 31, 2018 includes $89 million recorded as a current liability for amounts expected to be paid within the next 12 months.*

The changes in the estimated fair value of liabilities for contingent consideration in 2018 were largely attributable to increases in the liabilities recorded in connection with the termination of the SPMSD joint venture in 2016 (see Note 9), partially offset by the reversal of a liability related to the discontinuation of a program obtained in connection with the acquisition of SmartCells (see Note 8). The changes in the estimated fair value of liabilities for contingent consideration in 2017 primarily relate to increases in the liabilities recorded in connection with the termination of the SPMSD joint venture and the clinical progression of a program related to the Afferent acquisition. The payments of contingent consideration in 2018 include $175 million related to the achievement of a clinical milestone in connection with the acquisition of Afferent (see Note 3). The remaining payments in 2018 relate to liabilities recorded in connection with the termination of the SPMSD joint venture. The payments of contingent consideration in 2017 relate to the achievement of a clinical milestone in connection with the acquisition of IOmet (see Note 3).

Other Fair Value Measurements

Some of the Company's financial instruments, such as cash and cash equivalents, receivables and payables, are reflected in the balance sheet at carrying value, which approximates fair value due to their short-term nature.

The estimated fair value of loans payable and long-term debt (including current portion) at December 31, 2018, was $25.6 billion compared with a carrying value of $25.1 billion and at December 31, 2017, was $25.6 billion compared with a carrying value of $24.4 billion. Fair value was estimated using recent observable market prices and would be considered Level 2 in the fair value hierarchy.

Concentrations of Credit Risk

On an ongoing basis, the Company monitors concentrations of credit risk associated with corporate and government issuers of securities and financial institutions with which it conducts business. Credit exposure limits are established to limit a concentration with any single issuer or institution. Cash and investments are placed in instruments that meet high credit quality standards, as specified in the Company's investment policy guidelines.

The majority of the Company's accounts receivable arise from product sales in the United States and Europe and are primarily due from drug wholesalers and retailers, hospitals, government agencies, managed health care providers and pharmacy benefit managers. The Company monitors the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in their credit profile. The Company also continues to monitor global economic conditions, including the volatility associated with international sovereign economies, and associated impacts on the financial markets and its business.

The Company's customers with the largest accounts receivable balances are: McKesson Corporation, AmerisourceBergen Corporation and Cardinal Health, Inc., which represented, in aggregate, approximately 40% of total accounts receivable at December 31, 2018. The Company monitors the creditworthiness of its customers to which it grants credit terms in the normal course of business. Bad debts have been minimal. The Company does not normally require collateral or other security to support credit sales.

Derivative financial instruments are executed under International Swaps and Derivatives Association master agreements. The master agreements with several of the Company's financial institution counterparties also include credit support annexes. These annexes contain provisions that require collateral to be exchanged depending on the value of the derivative assets and liabilities, the Company's credit rating, and the credit rating of the counterparty. Cash collateral received by the Company from various counterparties was $107 million and $3 million at December 31, 2018

and 2017, respectively. The obligation to return such collateral is recorded in *Accrued and other current liabilities*. No cash collateral was advanced by the Company to counterparties as of December 31, 2018 or 2017.

7. Inventories

Inventories at December 31 consisted of:

	2018	2017
Finished goods	**$ 1,658**	$ 1,334
Raw materials and work in process	**5,004**	4,703
Supplies	**194**	201
Total (approximates current cost)	**6,856**	6,238
Increase to LIFO costs	**1**	45
	$ 6,857	$ 6,283
Recognized as:		
Inventories	**$ 5,440**	$ 5,096
Other assets	**1,417**	1,187

Inventories valued under the LIFO method comprised approximately $2.5 billion and $2.2 billion at December 31, 2018 and 2017, respectively. Amounts recognized as *Other assets* are comprised almost entirely of raw materials and work in process inventories. At December 31, 2018 and 2017, these amounts included $1.4 billion and $1.1 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included $7 million and $80 million at December 31, 2018 and 2017, respectively, of inventories produced in preparation for product launches.

8. Goodwill and Other Intangibles

The following table summarizes goodwill activity by segment:

	Pharmaceutical	Animal Health	All Other	Total
Balance January 1, 2017	$ 16,075	$ 1,708	$ 379	$ 18,162
Acquisitions	—	177	—	177
Impairments	—	—	(38)	(38)
Other [(1)]	(9)	(8)	—	(17)
Balance December 31, 2017 [(2)]	16,066	1,877	341	18,284
Acquisitions	**—**	**17**	**24**	**41**
Impairments	**—**	**—**	**(144)**	**(144)**
Other [(1)]	**96**	**(24)**	**—**	**72**
Balance December 31, 2018 [(2)]	**$ 16,162**	**$ 1,870**	**$ 221**	**$ 18,253**

[(1)] *Other includes cumulative translation adjustments on goodwill balances and certain other adjustments.*

[(2)] *Accumulated goodwill impairment losses at December 31, 2018 and 2017 were $369 million and $225 million, respectively.*

The additions to goodwill within the Animal Health segment in 2017 primarily relate to the acquisition of Vallée (see Note 3). The impairments of goodwill within other non-reportable segments in 2018 and 2017 relate to certain businesses within the Healthcare Services segment.

Other intangibles at December 31 consisted of:

	2018			2017		
	Gross Carrying Amount	**Accumulated Amortization**	**Net**	Gross Carrying Amount	Accumulated Amortization	Net
Products and product rights	**$ 46,615**	**$ 37,585**	**$ 9,030**	$ 46,693	$ 34,950	$ 11,743
IPR&D	**1,064**	**—**	**1,064**	1,194	—	1,194
Tradenames	**209**	**107**	**102**	209	97	112
Other	**2,403**	**1,168**	**1,235**	2,035	901	1,134
	$ 50,291	**$ 38,860**	**$ 11,431**	$ 50,131	$ 35,948	$ 14,183

Acquired intangibles include products and product rights, tradenames and patents, which are initially recorded at fair value, assigned an estimated useful life, and amortized primarily on a straight-line basis over their estimated useful lives. Some of the Company's more significant acquired intangibles related to marketed products (included in products and product rights above) at December 31, 2018 include *Zerbaxa*, $2.7 billion; *Sivextro*, $833 million; *Implanon/Nexplanon* $470 million; *Dificid*, $395 million; *Gardasil/Gardasil* 9, $384 million; *Bridion*, $275 million; and *Simponi*, $194 million. The Company has an intangible asset related to Adempas as a result of a collaboration with Bayer (see Note 4) that had a carrying value of $1.0 billion at December 31, 2018 reflected in "Other" in the table above.

During 2017 and 2016, the Company recorded impairment charges related to marketed products and other intangibles of $58 million and $347 million, respectively, within *Cost of sales*. During 2017, the Company recorded an intangible asset impairment charge of $47 million related to *Intron A*, a treatment for certain types of cancers. Sales of *Intron A* are being adversely affected by the availability of new therapeutic options. In 2017, sales of *Intron A* in the United States eroded more rapidly than previously anticipated by the Company, which led to changes in the cash flow assumptions for *Intron A*. These revisions to cash flows indicated that the *Intron A* intangible asset value was not fully recoverable on an undiscounted cash flows basis. The Company utilized market participant assumptions to determine its best estimate of the fair value of the intangible asset related to *Intron A* that, when compared with its related carrying value, resulted in the impairment charge noted above. The remaining charges in 2017 relate to the impairment of customer relationship, tradename and developed technology intangibles for certain businesses in the Healthcare Services segment. In 2016, the Company lowered its cash flow projections for *Zontivity,* a product for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction or with peripheral arterial disease, following several business decisions that reduced sales expectations for *Zontivity* in the United States and Europe. The Company utilized market participant assumptions and considered several different scenarios to determine the fair value of the intangible asset related to *Zontivity* that, when compared with its related carrying value, resulted in an impairment charge of $252 million. Also during 2016, the Company wrote-off $95 million that had been capitalized in connection with in-licensed products Grastek and Ragwitek, allergy immunotherapy tablets that, for business reasons, the Company returned to the licensor.

IPR&D that the Company acquires through business combinations represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. Amounts capitalized as IPR&D are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, the Company will make a separate determination as to the then useful life of the asset and begin amortization.

In 2018, the Company recorded $152 million of IPR&D impairment charges within *Research and development* expenses. Of this amount, $139 million relates to the write-off of the remaining intangible asset balance for a program obtained in connection with the SmartCells acquisition following a decision to terminate the program due to product development issues. The Company previously recorded an impairment charge in 2016 for the other programs obtained in connection with the acquisition of SmartCells as described below. The discontinuation of this clinical development program resulted in a reversal of the related liability for contingent consideration of $60 million (see Note 6).

In 2017, the Company recorded $483 million of IPR&D impairment charges. Of this amount, $240 million resulted from a strategic decision to discontinue the development of the investigational combination regimens

MK-3682B (grazoprevir/ruzasvir/uprifosbuvir) and MK-3682C (ruzasvir/uprifosbuvir) for the treatment of chronic hepatitis C virus (HCV) infection. This decision was made based on a review of available Phase 2 efficacy data and in consideration of the evolving marketplace and the growing number of treatment options available for patients with chronic HCV infection, including *Zepatier*, which is marketed by the Company for the treatment of adult patients with chronic HCV infection. As a result of this decision, the Company recorded an IPR&D impairment charge to write-off the remaining intangible asset related to uprifosbuvir. The Company had previously recorded an impairment charge for uprifosbuvir in 2016 as described below. The IPR&D impairment charges in 2017 also include a charge of $226 million to write-off the intangible asset related to verubecestat, an investigational small molecule inhibitor of the beta-site amyloid precursor protein cleaving enzyme 1 (BACE1), resulting from a decision in February 2018 to stop a Phase 3 study evaluating verubecestat in people with prodromal Alzheimer's disease. The decision to stop the study followed a recommendation by the external Data Monitoring Committee (eDMC), which assessed overall benefit/risk during an interim safety analysis. The eDMC concluded that it was unlikely that positive benefit/risk could be established if the trial continued.

During 2016, the Company recorded $3.6 billion of IPR&D impairment charges. Of this amount, $2.9 billion related to the clinical development program for uprifosbuvir, a nucleotide prodrug that was being evaluated for the treatment of HCV. The Company determined that changes to the product profile, as well as changes to Merck's expectations for pricing and the market opportunity, taken together constituted a triggering event that required the Company to evaluate the uprifosbuvir intangible asset for impairment. Utilizing market participant assumptions, and considering different scenarios, the Company concluded that its best estimate of the fair value of the intangible asset related to uprifosbuvir was $240 million, resulting in the recognition of the impairment charge noted above. The IPR&D impairment charges in 2016 also included charges of $180 million and $143 million related to the discontinuation of programs obtained in connection with the acquisitions of cCAM Biotherapeutics Ltd. and OncoEthix, respectively, resulting from unfavorable efficacy data. An additional $72 million related to programs obtained in connection with the SmartCells acquisition following a decision to terminate the lead compound due to a lack of efficacy and to pursue a back-up compound which reduced projected future cash flows. The IPR&D impairment charges in 2016 also included $112 million related to an in-licensed program for house dust mite allergies that, for business reasons, was returned to the licensor. The remaining IPR&D impairment charges in 2016 primarily related to deprioritized pipeline programs that were deemed to have no alternative use during the period, including a $79 million impairment charge for an investigational candidate for contraception. The discontinuation or delay of certain of these clinical development programs resulted in a reduction of the related liabilities for contingent consideration.

The IPR&D projects that remain in development are subject to the inherent risks and uncertainties in drug development and it is possible that the Company will not be able to successfully develop and complete the IPR&D programs and profitably commercialize the underlying product candidates.

The Company may recognize additional non-cash impairment charges in the future related to other marketed products or pipeline programs and such charges could be material.

Aggregate amortization expense primarily recorded within *Cost of sales* was $2.9 billion in 2018, $3.2 billion in 2017 and $3.8 billion in 2016. The estimated aggregate amortization expense for each of the next five years is as follows: 2019, $1.5 billion; 2020, $1.2 billion; 2021, $1.1 billion; 2022, $1.1 billion; 2023, $1.1 billion.

9. Joint Ventures and Other Equity Method Affiliates

Sanofi Pasteur MSD

In 1994, Merck and Pasteur Mérieux Connaught (now Sanofi Pasteur S.A.) established an equally-owned joint venture (SPMSD) to market vaccines in Europe and to collaborate in the development of combination vaccines for distribution in Europe. Joint venture vaccine sales were $1.0 billion for 2016.

On December 31, 2016, Merck and Sanofi Pasteur (Sanofi) terminated SPMSD and ended their joint vaccines operations in Europe. Under the terms of the termination, Merck acquired Sanofi's 50% interest in SPMSD in exchange for consideration of $657 million comprised of cash, as well as future royalties of 11.5% on net sales of all Merck products that were previously sold by the joint venture through December 31, 2024, which the Company determined had a fair value of $416 million on the date of termination. The Company accounted for this transaction as a step acquisition, which required that Merck remeasure its ownership interest (previously accounted for as an equity method investment) to fair value at the acquisition date. Merck in turn sold to Sanofi its intellectual property rights held by SPMSD in exchange for consideration of $596 million comprised of cash and future royalties of 11.5% on net sales of all Sanofi products that were previously sold by the joint venture through December 31, 2024, which the Company determined had a fair value of $302 million on the date of termination. Excluded from this arrangement are sales of *Vaxelis* (a jointly developed pediatric hexavalent combination vaccine that was approved by the European Commission in 2016 and by the U.S. Food and Drug Administration in 2018). The European marketing rights for *Vaxelis* were transferred to a separate equally-owned joint venture between Sanofi and Merck.

The net impact of the termination of the SPMSD joint venture is as follows:

Products and product rights (8-year useful life)	$	936
Accounts receivable		133
Income taxes payable		(221)
Deferred income tax liabilities		(147)
Other, net		47
Net assets acquired		748
Consideration payable to Sanofi, net		(392)
Derecognition of Merck's previously held equity investment in SPMSD		(183)
Increase in net assets		173
Merck's share of restructuring costs related to the termination		(77)
Net gain on termination of SPMSD joint venture [(1)]	$	96

[(1)] *Recorded in* Other (income) expense, net.

The estimated fair values of identifiable intangible assets related to products and product rights were determined using an income approach through which fair value is estimated based on market participant expectations of each asset's projected net cash flows. The projected net cash flows were then discounted to present value utilizing a discount rate of 11.5%. Actual cash flows are likely to be different than those assumed. Of the amount recorded for products and product rights, $468 million related to *Gardasil/Gardasil* 9.

The fair value of liabilities for contingent consideration related to Merck's future royalty payments to Sanofi of $416 million (reflected in the consideration payable to Sanofi, net, in the table above) was determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows and a risk-adjusted discount rate of 8% used to present value the cash flows. Changes in the inputs could result in a different fair value measurement.

Based on an existing accounting policy election, Merck did not record the $302 million estimated fair value of contingent future royalties to be received from Sanofi on the sale of Sanofi products, but rather is recognizing such amounts as sales occur and the royalties are earned.

The Company incurred $24 million of transaction costs related to the termination of SPMSD included in *Selling, general and administrative* expenses in 2016.

Pro forma financial information for this transaction has not been presented as the results are not significant when compared with the Company's financial results.

AstraZeneca LP

In 1982, Merck entered into an agreement with Astra AB (Astra) to develop and market Astra products under a royalty-bearing license. In 1993, Merck's total sales of Astra products reached a level that triggered the first step in the establishment of a joint venture business carried on by Astra Merck Inc. (AMI), in which Merck and Astra each owned a 50% share. This joint venture, formed in 1994, developed and marketed most of Astra's new prescription medicines in the United States. In 1998, Merck and Astra completed a restructuring of the ownership and operations of the joint venture whereby Merck acquired Astra's interest in AMI, renamed KBI Inc. (KBI), and contributed KBI's operating assets to a new U.S. limited partnership, Astra Pharmaceuticals L.P. (the Partnership), in exchange for a 1% limited partner interest. Astra contributed the net assets of its wholly owned subsidiary, Astra USA, Inc., to the Partnership in exchange for a 99% general partner interest. The Partnership, renamed AstraZeneca LP (AZLP) upon Astra's 1999 merger with Zeneca Group Plc, became the exclusive distributor of the products for which KBI retained rights. Merck earned revenue based on sales of KBI products and earned certain Partnership returns from AZLP.

On June 30, 2014, AstraZeneca exercised its option to purchase Merck's interest in KBI (and redeem Merck's remaining interest in AZLP). A portion of the exercise price, which remained subject to a true-up in 2018 based on actual sales of Nexium and Prilosec from closing in 2014 to June 2018, was deferred and recognized as income as the contingency was eliminated as sales occurred. Once the deferred income amount was fully recognized, in 2016, the Company began recognizing income and a corresponding receivable for amounts that would be due to Merck from AstraZeneca based on the sales performance of Nexium and Prilosec subject to the true-up in June 2018. The Company recognized income of $99 million in 2018, $232 million in 2017, and $98 million in 2016 (including $5 million of remaining deferred income) in *Other (income) expense, net* related to these amounts. In January 2019, the Company received $424 million from AstraZeneca in settlement of these amounts, which concludes the transactions related to the 2014 termination of Company's relationship with AZLP.

10. Loans Payable, Long-Term Debt and Other Commitments

Loans payable at December 31, 2018 included $5.1 billion of commercial paper and $149 million of long-dated notes that are subject to repayment at the option of the holders. Loans payable at December 31, 2017 included $3.0 billion of notes due in 2018 and $73 million of long-dated notes that are subject to repayment at the option of the holders. The weighted-average interest rate of commercial paper borrowings was 2.09% and 0.85% for the years ended December 31, 2018 and 2017, respectively.

Long-term debt at December 31 consisted of:

	2018	2017
2.75% notes due 2025	**$ 2,490**	$ 2,488
3.70% notes due 2045	**1,974**	1,973
2.80% notes due 2023	**1,745**	1,744
4.15% notes due 2043	**1,237**	1,237
1.85% notes due 2020	**1,231**	1,232
2.35% notes due 2022	**1,214**	1,220
1.125% euro-denominated notes due 2021	**1,134**	1,185
3.875% notes due 2021	**1,132**	1,140
1.875% euro-denominated notes due 2026	**1,127**	1,178
2.40% notes due 2022	**983**	993
6.50% notes due 2033	**726**	729
Floating-rate notes due 2020	**699**	699
0.50% euro-denominated notes due 2024	**565**	591
1.375% euro-denominated notes due 2036	**561**	587
2.50% euro-denominated notes due 2034	**560**	585
3.60% notes due 2042	**490**	489
6.55% notes due 2037	**414**	415
5.75% notes due 2036	**338**	338
5.95% debentures due 2028	**306**	306
5.85% notes due 2039	**270**	270
6.40% debentures due 2028	**250**	250
6.30% debentures due 2026	**135**	135
5.00% notes due 2019	**—**	1,260
Other	**225**	309
	$ 19,806	$ 21,353

Other (as presented in the table above) includes $223 million and $300 million at December 31, 2018 and 2017, respectively, of borrowings at variable rates that resulted in effective interest rates of 2.27% and 1.42% for 2018 and 2017, respectively.

With the exception of the 6.30% debentures due 2026, the notes listed in the table above are redeemable in whole or in part, at Merck's option at any time, at varying redemption prices.

In December 2018, the Company exercised a make-whole provision on its $1.25 billion, 5.00% notes due 2019 and repaid this debt. In November 2017, the Company launched tender offers for certain outstanding notes and debentures. The Company paid $810 million in aggregate consideration (applicable purchase price together with accrued interest) to redeem $585 million principal amount of debt that was validly tendered in connection with the tender offers and recognized a loss on extinguishment of debt of $191 million in 2017.

Effective as of November 3, 2009, the Company executed a full and unconditional guarantee of the then existing debt of its subsidiary Merck Sharp & Dohme Corp. (MSD) and MSD executed a full and unconditional guarantee of the then existing debt of the Company (excluding commercial paper), including for payments of principal and interest. These guarantees do not extend to debt issued subsequent to that date.

Certain of the Company's borrowings require that Merck comply with covenants and, at December 31, 2018, the Company was in compliance with these covenants.

The aggregate maturities of long-term debt for each of the next five years are as follows: 2019, no maturities; 2020, $1.9 billion; 2021, $2.3 billion; 2022, $2.2 billion; 2023, $1.7 billion.

The Company has a $6.0 billion credit facility that matures in June 2023. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

Rental expense under operating leases, net of sublease income, was $322 million in 2018, $327 million in 2017 and $292 million in 2016. The minimum aggregate rental commitments under noncancellable leases are as follows: 2019, $188 million; 2020, $198 million; 2021, $150 million; 2022, $134 million; 2023, $84 million and thereafter, $243 million. The Company has no significant capital leases.

11. Contingencies and Environmental Liabilities

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property, and commercial litigation, as well as certain additional matters including governmental and environmental matters. In the opinion of the Company, it is unlikely that the resolution of these matters will be material to the Company's financial position, results of operations or cash flows.

Given the nature of the litigation discussed below and the complexities involved in these matters, the Company is unable to reasonably estimate a possible loss or range of possible loss for such matters until the Company knows, among other factors, (i) what claims, if any, will survive dispositive motion practice, (ii) the extent of the claims, including the size of any potential class, particularly when damages are not specified or are indeterminate, (iii) how the discovery process will affect the litigation, (iv) the settlement posture of the other parties to the litigation and (v) any other factors that may have a material effect on the litigation.

The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. For product liability claims, a portion of the overall accrual is actuarially determined and considers such factors as past experience, number of claims reported and estimates of claims incurred but not yet reported. Individually significant contingent losses are accrued when probable and reasonably estimable. Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable.

The Company's decision to obtain insurance coverage is dependent on market conditions, including cost and availability, existing at the time such decisions are made. The Company has evaluated its risks and has determined that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and, as such, has no insurance for most product liabilities effective August 1, 2004.

Product Liability Litigation

Fosamax

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Fosamax* (*Fosamax* Litigation). As of December 31, 2018, approximately 3,900 cases have been filed and either are pending or conditionally dismissed (as noted below) against Merck in either federal or state court. Plaintiffs in the vast majority of these cases generally allege that they sustained femur fractures and/or other bone injuries (Femur Fractures) in association with the use of *Fosamax*.

In March 2011, Merck submitted a Motion to Transfer to the Judicial Panel on Multidistrict Litigation (JPML) seeking to have all federal cases alleging Femur Fractures consolidated into one multidistrict litigation for coordinated pre-trial proceedings. All federal cases involving allegations of Femur Fracture have been or will be transferred to a multidistrict litigation in the District of New Jersey (Femur Fracture MDL). In the only bellwether case tried to date in the Femur Fracture MDL, *Glynn v. Merck*, the jury returned a verdict in Merck's favor. In addition, in June 2013, the Femur Fracture MDL court granted Merck's motion for judgment as a matter of law in the *Glynn* case and held that the plaintiff's failure to warn claim was preempted by federal law.

In August 2013, the Femur Fracture MDL court entered an order requiring plaintiffs in the Femur Fracture MDL to show cause why those cases asserting claims for a femur fracture injury that took place prior to September 14, 2010, should not be dismissed based on the court's preemption decision in the *Glynn* case. Pursuant to the show cause order, in March 2014, the Femur Fracture MDL court dismissed with prejudice approximately 650 cases on preemption grounds. Plaintiffs in approximately 515 of those cases appealed that decision to the U.S. Court of Appeals for the Third Circuit (Third Circuit). In March 2017, the Third Circuit issued a decision reversing the Femur Fracture MDL

court's preemption ruling and remanding the appealed cases back to the Femur Fracture MDL court. Merck filed a petition for a writ of certiorari to the U.S. Supreme Court in August 2017, seeking review of the Third Circuit's decision. In December 2017, the Supreme Court invited the Solicitor General to file a brief in the case expressing the views of the United States, and in May 2018, the Solicitor General submitted a brief stating that the Third Circuit's decision was wrongly decided and recommended that the Supreme Court grant Merck's cert petition. The Supreme Court granted Merck's petition in June 2018, and an oral argument before the Supreme Court was held on January 7, 2019. The final decision on the Femur Fracture MDL court's preemption ruling is now pending before the Supreme Court.

Accordingly, as of December 31, 2018, nine cases were actively pending in the Femur Fracture MDL, and approximately 1,055 cases have either been dismissed without prejudice or administratively closed pending final resolution by the Supreme Court of the appeal of the Femur Fracture MDL court's preemption order.

As of December 31, 2018, approximately 2,555 cases alleging Femur Fractures have been filed in New Jersey state court and are pending before Judge James Hyland in Middlesex County. The parties selected an initial group of 30 cases to be reviewed through fact discovery. Two additional groups of 50 cases each to be reviewed through fact discovery were selected in November 2013 and March 2014, respectively. A further group of 25 cases to be reviewed through fact discovery was selected by Merck in July 2015, and Merck has continued to select additional cases to be reviewed through fact discovery from 2016 to the present.

As of December 31, 2018, approximately 275 cases alleging Femur Fractures have been filed and are pending in California state court. All of the Femur Fracture cases filed in California state court have been coordinated before a single judge in Orange County, California. In March 2014, the court directed that a group of 10 discovery pool cases be reviewed through fact discovery and subsequently scheduled the *Galper v. Merck* case, which plaintiffs selected, as the first trial. The *Galper* trial began in February 2015 and the jury returned a verdict in Merck's favor in April 2015, and plaintiff appealed that verdict to the California appellate court. In April 2017, the California appellate court issued a decision affirming the lower court's judgment in favor of Merck. The next Femur Fracture trial in California that was scheduled to begin in April 2016 was stayed at plaintiffs' request and a new trial date has not been set.

Additionally, there are four Femur Fracture cases pending in other state courts.

Discovery is ongoing in the Femur Fracture MDL and in state courts where Femur Fracture cases are pending and the Company intends to defend against these lawsuits.

Januvia/Janumet

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Januvia* and/or *Janumet*. As of December 31, 2018, Merck is aware of approximately 1,290 product users alleging that *Januvia* and/or *Janumet* caused the development of pancreatic cancer and other injuries.

Most claims have been filed in multidistrict litigation before the U.S. District Court for the Southern District of California (MDL). Outside of the MDL, the majority of claims have been filed in coordinated proceedings before the Superior Court of California, County of Los Angeles (California State Court).

In November 2015, the MDL and California State Court-in separate opinions-granted summary judgment to defendants on grounds of federal preemption.

Plaintiffs appealed in both forums. In November 2017, the U.S. Court of Appeals for the Ninth Circuit vacated the judgment and remanded for further discovery, which is ongoing. In November 2018, the California state appellate court reversed and remanded on similar grounds.

As of December 31, 2018, eight product users have claims pending against Merck in state courts other than California, including Illinois. In June 2017, the Illinois trial court denied Merck's motion for summary judgment based on federal preemption. Merck appealed, and the Illinois appellate court affirmed in December 2018. Merck intends to appeal that ruling.

In addition to the claims noted above, the Company has agreed to toll the statute of limitations for approximately 50 additional claims. The Company intends to continue defending against these lawsuits.

Vioxx

As previously disclosed, Merck is a defendant in a lawsuit brought by the Attorney General of Utah alleging that Merck misrepresented the safety of *Vioxx*. The lawsuit is pending in Utah state court. Utah seeks damages and penalties under the Utah False Claims Act. A bench trial in this matter is currently scheduled for July 2019.

Propecia/Proscar

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Propecia* and/or *Proscar*. The lawsuits were filed in various federal courts and in state court in New Jersey. The federal lawsuits were then consolidated for pretrial purposes in a federal multidistrict litigation before Judge Brian Cogan of the Eastern District of New York. The matters pending in state court in New Jersey were consolidated before Judge Hyland in Middlesex County (NJ Coordinated Proceedings).

As previously disclosed, on April 9, 2018, Merck and the Plaintiffs' Executive Committee in the *Propecia* MDL and the Plaintiffs' Liaison Counsel in the NJ Coordinated Proceedings entered into an agreement to resolve the above mentioned *Propecia/Proscar* lawsuits for an aggregate amount of $4.3 million. The settlement was subject to certain contingencies, including 95% plaintiff participation and a per plaintiff clawback if the participation rate was less than 100%. The contingencies were satisfied and the settlement agreement was finalized. After the settlement, fewer than 25 cases remain pending in the United States.

The Company intends to defend against any remaining unsettled lawsuits.

Governmental Proceedings

As previously disclosed, the Company has learned that the Prosecution Office of Milan, Italy is investigating interactions between the Company's Italian subsidiary, certain employees of the subsidiary and certain Italian health care providers. The Company understands that this is part of a larger investigation involving engagements between various health care companies and those health care providers. The Company is cooperating with the investigation.

As previously disclosed, the United Kingdom (UK) Competition and Markets Authority (CMA) issued a Statement of Objections against the Company and MSD Sharp & Dohme Limited (MSD UK) in May 2017. In the Statement of Objections, the CMA alleges that MSD UK abused a dominant position through a discount program for *Remicade* over the period from March 2015 to February 2016. The Company and MSD UK are contesting the CMA's allegations.

As previously disclosed, the Company has received an investigative subpoena from the California Insurance Commissioner's Fraud Bureau (Bureau) seeking information from January 1, 2007 to the present related to the pricing and promotion of *Cubicin*. The Bureau is investigating whether Cubist Pharmaceuticals, Inc., which the Company acquired in 2015, unlawfully induced the presentation of false claims for *Cubicin* to private insurers under the California Insurance Code False Claims Act. The Company is cooperating with the investigation.

As previously disclosed, the Company's subsidiaries in China have received and may continue to receive inquiries regarding their operations from various Chinese governmental agencies. Some of these inquiries may be related to matters involving other multinational pharmaceutical companies, as well as Chinese entities doing business with such companies. The Company's policy is to cooperate with these authorities and to provide responses as appropriate.

As previously disclosed, from time to time, the Company receives inquiries and is the subject of preliminary investigation activities from competition and other governmental authorities in markets outside the United States. These authorities may include regulators, administrative authorities, and law enforcement and other similar officials, and these preliminary investigation activities may include site visits, formal or informal requests or demands for documents or materials, inquiries or interviews and similar matters. Certain of these preliminary inquiries or activities may lead to the commencement of formal proceedings. Should those proceedings be determined adversely to the Company, monetary fines and/or remedial undertakings may be required.

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Commercial and Other Litigation

Zetia *Antitrust Litigation*

As previously disclosed, Merck, MSD, Schering Corporation and MSP Singapore Company LLC (collectively, the Merck Defendants) are defendants in putative class action and opt-out lawsuits filed in 2018 on behalf of direct and indirect purchasers of *Zetia* alleging violations of federal and state antitrust laws, as well as other state statutory and common law causes of action. The cases have been consolidated for pretrial purposes in a federal multidistrict litigation before Judge Rebecca Beach Smith in the Eastern District of Virginia. On December 6, 2018, the court denied the Merck Defendants' motions to dismiss or stay the direct purchaser putative class actions pending bilateral arbitration. On February 6, 2019, the magistrate judge issued a report and recommendation recommending that the district judge grant in part and deny in part defendants' motions to dismiss on non-arbitration issues. On February 20, 2019, defendants and retailer opt-out plaintiffs filed objections to the report and recommendation. After responses are filed, the parties will await a decision from the district judge.

Rotavirus Vaccines Antitrust Litigation

As previously disclosed, MSD is a defendant in putative class action lawsuits filed in 2018 on behalf of direct purchasers of *RotaTeq*, alleging violations of federal antitrust laws. The cases were consolidated in the Eastern District of Pennsylvania. On January 23, 2019, the court denied MSD's motions to compel arbitration and to dismiss the consolidated complaint. On February 19, 2019, MSD appealed the court's order on arbitration to the Third Circuit, and on February 22, 2019, the court granted MSD's motion to vacate existing deadlines in the district court in light of the appeal.

Sales Force Litigation

As previously disclosed, in May 2013, Ms. Kelli Smith filed a complaint against the Company in the U.S. District Court for the District of New Jersey on behalf of herself and a putative class of female sales representatives and a putative sub-class of female sales representatives with children, claiming (a) discriminatory policies and practices in selection, promotion and advancement, (b) disparate pay, (c) differential treatment, (d) hostile work environment and (e) retaliation under federal and state discrimination laws. In January 2014, plaintiffs filed an amended complaint adding four additional named plaintiffs. In October 2014, the court denied the Company's motion to dismiss or strike the class claims as premature. In September 2015, plaintiffs filed additional motions, including a motion for conditional certification under the Equal Pay Act; a motion to amend the pleadings seeking to add ERISA and constructive discharge claims and a Company subsidiary as a named defendant; and a motion for equitable relief. Merck filed papers in opposition to the motions. In April 2016, the court granted plaintiff's motion for conditional certification but denied plaintiffs' motions to extend the liability period for their Equal Pay Act claims back to June 2009. In April 2016, the Magistrate Judge granted plaintiffs' request to amend the complaint to add the following: (i) a Company subsidiary as a corporate defendant; (ii) an ERISA claim and (iii) an individual constructive discharge claim for one of the named plaintiffs. Approximately 700 individuals opted-in to this action; the opt-in period has closed. In August 2017, plaintiffs filed their motion for class certification. This motion sought to certify a Title VII pay discrimination class and also sought final collective action certification of plaintiffs' Equal Pay Act claim.

On October 1, 2018, the parties entered into an agreement to fully resolve the Smith sales force litigation. As part of the settlement and in exchange for a full and general release of all individual and class claims, the Company agreed to pay $8.5 million. The settlement agreement, which contains an "opt-out" clause allowing Merck to pull out of the agreement if 30 or more individuals opt out, will be subject to court approval.

On December 18, 2018, plaintiffs filed a motion with the court seeking preliminary approval of the settlement.

Qui Tam Litigation

As previously disclosed, in June 2012, the U.S. District Court for the Eastern District of Pennsylvania unsealed a complaint that has been filed against the Company under the federal False Claims Act by two former employees alleging, among other things, that the Company defrauded the U.S. government by falsifying data in connection with a clinical study conducted on the mumps component of the Company's *M-M-R* II vaccine. The complaint alleges the fraud took place between 1999 and 2001. The U.S. government had the right to participate in and take over the prosecution of this lawsuit, but notified the court that it declined to exercise that right. The two former employees are pursuing the lawsuit without the involvement of the U.S. government. In addition, as previously disclosed, two putative class action lawsuits on behalf of direct purchasers of the *M-M-R* II vaccine, which charge that the Company misrepresented the efficacy of the *M-M-R* II vaccine in violation of federal antitrust laws and various state consumer

protection laws, are pending in the Eastern District of Pennsylvania. In September 2014, the court denied Merck's motion to dismiss the False Claims Act suit and granted in part and denied in part its motion to dismiss the then-pending antitrust suit. As a result, both the False Claims Act suit and the antitrust suits have proceeded into discovery, which is ongoing. The Company continues to defend against these lawsuits.

Merck KGaA Litigation

As previously disclosed, in January 2016, to protect its long-established brand rights in the United States, the Company filed a lawsuit against Merck KGaA, Darmstadt, Germany (KGaA), historically operating as the EMD Group in the United States, alleging it improperly uses the name "Merck" in the United States. KGaA has filed suit against the Company in France, the UK, Germany, Switzerland, Mexico, India, Australia, Singapore, Hong Kong, and China alleging, among other things, unfair competition, trademark infringement and/or corporate name infringement. In the UK, Australia, Singapore, Hong Kong, and India, KGaA also alleges breach of the parties' coexistence agreement. In December 2015, the Paris Court of First Instance issued a judgment finding that certain activities by the Company directed towards France did not constitute trademark infringement and unfair competition while other activities were found to infringe and constitute unfair competition. The Company and KGaA appealed the decision, and the appeal was heard in May 2017. In June 2017, the French appeals court held that certain of the activities by the Company directed to France constituted unfair competition or trademark infringement and, in December 2017, the Company decided not to pursue any further appeal. In January 2016, the UK High Court issued a judgment finding that the Company had breached the co-existence agreement and infringed KGaA's trademark rights as a result of certain activities directed towards the UK based on use of the word MERCK on promotional and information activity. As noted in the UK decision, this finding was not based on the Company's use of the sign MERCK in connection with the sale of products or any material pharmaceutical business transacted in the UK. The Company and KGaA have both appealed this decision, and the appeal was heard in June 2017. In November 2017, the UK Court of Appeals affirmed the decision on the co-existence agreement and remitted for re-hearing issues of trademark infringement, the scope of KGaA's UK trademarks for pharmaceutical products, and the relief to which KGaA would be entitled. The re-hearing was held, and no decision has been handed down. In November 2018, the District Court in Hamburg, Germany dismissed all of KGaA's claims concerning KGaA's EU trademark with respect to the territory of the EU. In accordance with the Judgment of the Court of Justice of the EU delivered in October 2017, the District Court in Hamburg further held that it had no jurisdiction over the claim by KGaA insofar as the claim related to the territory of the UK. KGaA has appealed this decision. Further decisions from the District Court in Hamburg, Germany, in connection with claims concerning KGaA's EU trademark, German trademark and trade name rights as well as unfair competition law with respect to the territory of Germany are expected on February 28, 2019. In January 2019, the Mexican Trademark Office issued a decision on KGaA's action. The court found no trademark infringement by the Company and dismissed all of KGaA's claims for trademark infringement. The court ruled against the Company on KGaA's unfair competition claim. Both KGaA and the Company have appealed this decision.

Patent Litigation

From time to time, generic manufacturers of pharmaceutical products file abbreviated NDAs with the FDA seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned by the Company. To protect its patent rights, the Company may file patent infringement lawsuits against such generic companies. Similar lawsuits defending the Company's patent rights may exist in other countries. The Company intends to vigorously defend its patents, which it believes are valid, against infringement by companies attempting to market products prior to the expiration of such patents. As with any litigation, there can be no assurance of the outcomes, which, if adverse, could result in significantly shortened periods of exclusivity for these products and, with respect to products acquired through acquisitions, potentially significant intangible asset impairment charges.

Inegy — The patents protecting *Inegy* in Europe have expired but supplemental protection certificates (SPCs) have been granted to the Company in many European countries that will expire in April 2019. There are multiple challenges to the SPCs related to *Inegy* throughout Europe and generic products have been launched in Austria, France, Italy, Ireland, Spain, Portugal, Germany, and the Netherlands. The Company has filed for preliminary injunctions in many countries that are still pending decision. Preliminary injunctions are presently in force in Austria, Czech Republic, Greece, Norway, Portugal, and Slovakia. Preliminary injunctions have been denied or revoked in Germany, Ireland, the Netherlands and Spain. The Company is appealing those decisions. In France and Belgium, preliminary injunctions were granted against some companies and denied against others, and appeals are pending. The SPC was held valid in

merits proceedings in Portugal and France. The Company has filed and will continue to file actions for patent infringement seeking damages against those companies that launch generic products before April 2019.

Noxafil — In August 2015, the Company filed a lawsuit against Actavis Laboratories Fl, Inc. (Actavis) in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Noxafil*. In October 2017, the district court held the patent valid and infringed. Actavis appealed this decision. While the appeal was pending, the parties reached a settlement, subject to certain terms of the agreement being met, whereby Actavis can launch its generic version prior to expiry of the patent and pediatric exclusivity under certain conditions. In March 2016, the Company filed a lawsuit against Roxane Laboratories, Inc. (Roxane) in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Noxafil*. In November 2017, the parties reached a settlement whereby Roxane can launch its generic version prior to expiry of the patent under certain conditions. In February 2016, the Company filed a lawsuit against Par Sterile Products LLC, Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc. and Par Pharmaceutical Holdings, Inc. (collectively, Par) in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Noxafil* injection. In October 2016, the parties reached a settlement whereby Par can launch its generic version in January 2023, or earlier under certain conditions. In February 2018, the Company filed a lawsuit against Fresenius Kabi USA, LLC (Fresenius) in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Noxafil*. In November 2018, the Company reached a settlement with Fresenius, whereby Fresenius can launch its generic version of the intravenous product prior to expiry of the patent under certain conditions. In March 2018, the Company filed a lawsuit against Mylan Laboratories Limited in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Noxafil*.

Nasonex — *Nasonex* lost market exclusivity in the United States in 2016. Prior to that, in April 2015, the Company filed a patent infringement lawsuit against Apotex Inc. and Apotex Corp. (Apotex) in respect of Apotex's marketed product that the Company believed was infringing. In January 2018, the Company and Apotex settled this matter with Apotex agreeing to pay the Company $115 million plus certain other consideration.

Januvia, Janumet, Janumet XR — In February 2019, Par Pharmaceutical, Inc. (Par Pharmaceutical) filed suit against the Company in the U.S. District Court for the District of New Jersey, seeking a declaratory judgment of invalidity of a patent owned by the Company covering certain salt and polymorphic forms of sitagliptin that expires in 2026. A judgment in its favor may allow Par Pharmaceutical to bring to market a generic version of *Janumet XR* following the expiration of key patent protection in 2022, but prior to the expiration of the later-granted patent it is challenging. In response, the Company filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Par Pharmaceutical and additional companies that also indicated an intent to market generic versions of *Januvia*, *Janumet*, and *Janumet XR* following expiration of key patent protection in 2022, but prior to the expiration of the later-granted patent owned by the Company covering certain salt and polymorphic forms of sitagliptin that expires in 2026, and a later granted patent owned by the Company covering the *Janumet* formulation which expires in 2028. No schedule for the cases has been set by the court.

Gilead Patent Litigation and Opposition

The Company, through its Idenix Pharmaceuticals, Inc. subsidiary, has pending litigation against Gilead in the United States, Germany, and France based on different patent estates that would be infringed by Gilead's sales of their two products, Sovaldi and Harvoni. Gilead opposed the European patent at the European Patent Office (EPO). Trial in the United States was held in December 2016 and the jury returned a verdict for the Company, awarding damages of $2.54 billion. The Company submitted post-trial motions, including on the issues of enhanced damages and future royalties. Gilead submitted post-trial motions for judgment as a matter of law. A hearing on the motions was held in September 2017. Also, in September 2017, the court denied the Company's motion on enhanced damages, granted its motion on prejudgment interest and deferred its motion on future royalties. In February 2018, the court granted Gilead's motion for judgment as a matter of law and found the patent was invalid for a lack of enablement. The Company appealed this decision. The appellate briefing is completed and the Company is waiting for the oral argument to be scheduled. The EPO opposition division revoked the European patent, and the Company appealed this decision. The cases in France and Germany have been stayed pending the final decision of the EPO.

Other Litigation

There are various other pending legal proceedings involving the Company, principally product liability and intellectual property lawsuits. While it is not feasible to predict the outcome of such proceedings, in the opinion of the Company, either the likelihood of loss is remote or any reasonably possible loss associated with the resolution of such proceedings is not expected to be material to the Company's financial position, results of operations or cash flows either individually or in the aggregate.

Legal Defense Reserves

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of December 31, 2018 and 2017 of approximately $245 million and $160 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

Environmental Matters

As previously disclosed, Merck's facilities in Oss, the Netherlands, were inspected in 2012 by the Province of Brabant (Province) pursuant to the Dutch Hazards of Major Accidents Decree and the sites' environmental permits. The Province issued penalties for alleged violations of regulations governing preventing and managing accidents with hazardous substances, and the government also issued a fine for alleged environmental violations at one of the Oss facilities, which together totaled $235 thousand. The Company was subsequently advised that a criminal investigation had been initiated based upon certain of the issues that formed the basis of the administrative enforcement action by the Province. As previously disclosed, the matter was settled, without any admission of liability, for an aggregate payment of €400 thousand.

The Company and its subsidiaries are parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund, and other federal and state equivalents. These proceedings seek to require the operators of hazardous waste disposal facilities, transporters of waste to the sites and generators of hazardous waste disposed of at the sites to clean up the sites or to reimburse the government for cleanup costs. The Company has been made a party to these proceedings as an alleged generator of waste disposed of at the sites. In each case, the government alleges that the defendants are jointly and severally liable for the cleanup costs. Although joint and several liability is alleged, these proceedings are frequently resolved so that the allocation of cleanup costs among the parties more nearly reflects the relative contributions of the parties to the site situation. The Company's potential liability varies greatly from site to site. For some sites the potential liability is *de minimis* and for others the final costs of cleanup have not yet been determined. While it is not feasible to predict the outcome of many of these proceedings brought by federal or state agencies or private litigants, in the opinion of the Company, such proceedings should not ultimately result in any liability which would have a material adverse effect on the financial position, results of operations, liquidity or capital resources of the Company. The Company has taken an active role in identifying and accruing for these costs and such amounts do not include any reduction for anticipated recoveries of cleanup costs from former site owners or operators or other recalcitrant potentially responsible parties.

In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $71 million and $82 million at December 31, 2018 and 2017, respectively. These liabilities are undiscounted, do not consider potential recoveries from other parties and will be paid out over the periods of remediation for the applicable sites, which are expected to occur primarily over the next 15 years. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued

should exceed $60 million in the aggregate. Management also does not believe that these expenditures should result in a material adverse effect on the Company's financial position, results of operations, liquidity or capital resources for any year.

12. Equity

The Merck certificate of incorporation authorizes 6,500,000,000 shares of common stock and 20,000,000 shares of preferred stock.

Capital Stock

A summary of common stock and treasury stock transactions (shares in millions) is as follows:

	2018		2017		2016	
	Common Stock	**Treasury Stock**	Common Stock	Treasury Stock	Common Stock	Treasury Stock
Balance January 1	**3,577**	**880**	3,577	828	3,577	796
Purchases of treasury stock	**—**	**122**	—	67	—	60
Issuances [(1)]	**—**	**(17)**	—	(15)	—	(28)
Balance December 31	**3,577**	**985**	3,577	880	3,577	828

[(1)] *Issuances primarily reflect activity under share-based compensation plans.*

On October 25, 2018, the Company entered into accelerated share repurchase (ASR) agreements with two third-party financial institutions (Dealers). Under the ASR agreements, Merck agreed to purchase $5 billion of Merck's common stock, in total, with an initial delivery of 56.7 million shares of Merck's common stock, based on the then-current market price, made by the Dealers to Merck, and payments of $5 billion made by Merck to the Dealers on October 29, 2018, which were funded with existing cash and investments, as well as short-term borrowings. The payments to the Dealers were recorded as reductions to shareholders' equity, consisting of a $4 billion increase in treasury stock, which reflects the value of the initial 56.7 million shares received on October 29, 2018, and a $1 billion decrease in other-paid-in capital, which reflects the value of the stock held back by the Dealers pending final settlement. The number of shares of Merck's common stock that Merck may receive, or may be required to remit, upon final settlement under the ASR agreements will be based upon the average daily volume weighted-average price of Merck's common stock during the term of the ASR program, less a negotiated discount. Final settlement of the transaction under the ASR agreements is expected to occur in the first half of 2019, but may occur earlier at the option of the Dealers, or later under certain circumstances. If Merck is obligated to make adjustment payments to the Dealers under the ASR agreements, Merck may elect to satisfy such obligations in cash or in shares of Merck's common stock.

13. Share-Based Compensation Plans

The Company has share-based compensation plans under which the Company grants restricted stock units (RSUs) and performance share units (PSUs) to certain management level employees. In addition, employees and non-employee directors may be granted options to purchase shares of Company common stock at the fair market value at the time of grant. These plans were approved by the Company's shareholders.

At December 31, 2018, 111 million shares collectively were authorized for future grants under the Company's share-based compensation plans. These awards are settled primarily with treasury shares.

Employee stock options are granted to purchase shares of Company stock at the fair market value at the time of grant. These awards generally vest one-third each year over a three-year period, with a contractual term of 7-10 years. RSUs are stock awards that are granted to employees and entitle the holder to shares of common stock as the awards vest. The fair value of the stock option and RSU awards is determined and fixed on the grant date based on the Company's stock price. PSUs are stock awards where the ultimate number of shares issued will be contingent on the Company's performance against a pre-set objective or set of objectives. The fair value of each PSU is determined on the date of grant based on the Company's stock price. For RSUs and PSUs, dividends declared during the vesting period are payable to the employees only upon vesting. Over the PSU performance period, the number of shares of stock that are expected to be issued will be adjusted based on the probability of achievement of a performance target and final compensation expense will be recognized based on the ultimate number of shares issued. RSU and PSU

distributions will be in shares of Company stock after the end of the vesting or performance period, subject to the terms applicable to such awards. PSU awards generally vest after three years. Prior to 2018, RSU awards generally vested after three years; beginning with awards granted in 2018, RSU awards generally vest one-third each year over a three-year period.

Total pretax share-based compensation cost recorded in 2018, 2017 and 2016 was $348 million, $312 million and $300 million, respectively, with related income tax benefits of $55 million, $57 million and $92 million, respectively.

The Company uses the Black-Scholes option pricing model for determining the fair value of option grants. In applying this model, the Company uses both historical data and current market data to estimate the fair value of its options. The Black-Scholes model requires several assumptions including expected dividend yield, risk-free interest rate, volatility, and term of the options. The expected dividend yield is based on historical patterns of dividend payments. The risk-free rate is based on the rate at grant date of zero-coupon U.S. Treasury Notes with a term equal to the expected term of the option. Expected volatility is estimated using a blend of historical and implied volatility. The historical component is based on historical monthly price changes. The implied volatility is obtained from market data on the Company's traded options. The expected life represents the amount of time that options granted are expected to be outstanding, based on historical and forecasted exercise behavior.

The weighted average exercise price of options granted in 2018, 2017 and 2016 was $58.15, $63.88 and $54.63 per option, respectively. The weighted average fair value of options granted in 2018, 2017 and 2016 was $8.26, $7.04 and $5.89 per option, respectively, and were determined using the following assumptions:

Years Ended December 31	**2018**	2017	2016
Expected dividend yield	**3.4 %**	3.6 %	3.8 %
Risk-free interest rate	**2.9 %**	2.0 %	1.4 %
Expected volatility	**19.1 %**	17.8 %	19.6 %
Expected life (years)	**6.1**	6.1	6.2

Summarized information relative to stock option plan activity (options in thousands) is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2018	36,274	$ 46.77		
Granted	**3,520**	**58.15**		
Exercised	**(14,598)**	**40.51**		
Forfeited	**(1,389)**	**53.80**		
Outstanding December 31, 2018	**23,807**	**$ 51.89**	**5.95**	**$ 584**
Exercisable December 31, 2018	**16,184**	**$ 48.85**	**4.82**	**$ 446**

Additional information pertaining to stock option plans is provided in the table below:

Years Ended December 31	**2018**	2017	2016
Total intrinsic value of stock options exercised	**$ 348**	$ 236	$ 444
Fair value of stock options vested	**29**	30	28
Cash received from the exercise of stock options	**591**	499	939

A summary of nonvested RSU and PSU activity (shares in thousands) is as follows:

	RSUs		PSUs	
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested January 1, 2018	13,609	$ 59.32	1,868	$ 60.03
Granted	**7,270**	**58.46**	**1,081**	**57.17**
Vested	**(3,766)**	**59.66**	**(758)**	**57.59**
Forfeited	**(985)**	**59.30**	**(152)**	**60.06**
Nonvested December 31, 2018	**16,128**	**$ 58.85**	**2,039**	**$ 59.42**

At December 31, 2018, there was $560 million of total pretax unrecognized compensation expense related to nonvested stock options, RSU and PSU awards which will be recognized over a weighted average period of 1.9 years. For segment reporting, share-based compensation costs are unallocated expenses.

14. Pension and Other Postretirement Benefit Plans

The Company has defined benefit pension plans covering eligible employees in the United States and in certain of its international subsidiaries. In addition, the Company provides medical benefits, principally to its eligible U.S. retirees and their dependents, through its other postretirement benefit plans. The Company uses December 31 as the year-end measurement date for all of its pension plans and other postretirement benefit plans.

Net Periodic Benefit Cost

The net periodic benefit cost (credit) for pension and other postretirement benefit plans consisted of the following components:

	Pension Benefits								
	U.S.			International			Other Postretirement Benefits		
Years Ended December 31	**2018**	2017	2016	**2018**	2017	2016	**2018**	2017	2016
Service cost	**$ 326**	$ 312	$ 282	**$ 238**	$ 252	$ 238	**$ 57**	$ 57	$ 54
Interest cost	**432**	454	456	**178**	172	204	**69**	81	82
Expected return on plan assets	**(851)**	(862)	(831)	**(431)**	(393)	(382)	**(83)**	(78)	(107)
Amortization of unrecognized prior service cost	**(50)**	(53)	(55)	**(13)**	(11)	(11)	**(84)**	(98)	(106)
Net loss amortization	**232**	180	119	**84**	98	87	**1**	1	3
Termination benefits	**19**	44	23	**2**	4	4	**3**	8	4
Curtailments	**10**	3	5	**1**	(4)	(1)	**(8)**	(31)	(18)
Settlements	**5**	—	—	**13**	5	6	**—**	—	—
Net periodic benefit cost (credit)	**$ 123**	$ 78	$ (1)	**$ 72**	$ 123	$ 145	**$ (45)**	$ (60)	$ (88)

The changes in net periodic benefit cost (credit) year over year for pension plans are largely attributable to changes in the discount rate affecting net loss amortization.

In connection with restructuring actions (see Note 5), termination charges were recorded in 2018, 2017 and 2016 on pension and other postretirement benefit plans related to expanded eligibility for certain employees exiting Merck. Also, in connection with these restructuring activities, curtailments were recorded on pension and other postretirement benefit plans and settlements were recorded on certain U.S. and international pension plans as reflected in the table above.

The components of net periodic benefit cost (credit) other than the service cost component are included in *Other (income) expense, net* (see Note 15), with the exception of certain amounts for termination benefits, curtailments and settlements, which are recorded in *Restructuring costs* if the event giving rise to the termination benefits, curtailment or settlement is related to restructuring actions as noted above.

Obligations and Funded Status

Summarized information about the changes in plan assets and benefit obligations, the funded status and the amounts recorded at December 31 is as follows:

	Pension Benefits				Other Postretirement Benefits	
	U.S.		International			
	2018	2017	**2018**	2017	**2018**	2017
Fair value of plan assets January 1	**$ 10,896**	$ 9,766	**$ 9,339**	$ 7,794	**$ 1,114**	$ 1,019
Actual return on plan assets	**(810)**	1,723	**(289)**	677	**(72)**	161
Company contributions, net	**378**	58	**167**	226	**6**	(4)
Effects of exchange rate changes	**—**	—	**(352)**	843	**—**	—
Benefits paid	**(772)**	(651)	**(202)**	(198)	**(80)**	(62)
Settlements	**(44)**	—	**(106)**	(17)	**—**	—
Other	**—**	—	**23**	14	**—**	—
Fair value of plan assets December 31	**$ 9,648**	$ 10,896	**$ 8,580**	$ 9,339	**$ 968**	$ 1,114
Benefit obligation January 1	**$ 11,904**	$ 10,849	**$ 9,483**	$ 8,372	**$ 1,922**	$ 1,922
Service cost	**326**	312	**238**	252	**57**	57
Interest cost	**432**	454	**178**	172	**69**	81
Actuarial (gains) losses [1]	**(1,258)**	881	**(154)**	(7)	**(341)**	(87)
Benefits paid	**(772)**	(651)	**(202)**	(198)	**(80)**	(62)
Effects of exchange rate changes	**—**	—	**(387)**	916	**(6)**	3
Plan amendments	**—**	—	**10**	(22)	**(9)**	—
Curtailments	**13**	15	**(2)**	(3)	**—**	—
Termination benefits	**19**	44	**2**	4	**3**	8
Settlements	**(44)**	—	**(106)**	(17)	**—**	—
Other	**—**	—	**23**	14	**—**	—
Benefit obligation December 31	**$ 10,620**	$ 11,904	**$ 9,083**	$ 9,483	**$ 1,615**	$ 1,922
Funded status December 31	**$ (972)**	$ (1,008)	**$ (503)**	$ (144)	**$ (647)**	$ (808)
Recognized as:						
Other assets	**$ —**	$ —	**$ 659**	$ 828	**$ —**	$ —
Accrued and other current liabilities	**(47)**	(59)	**(14)**	(17)	**(10)**	(11)
Other noncurrent liabilities	**(925)**	(949)	**(1,148)**	(955)	**(637)**	(797)

[1] *Actuarial (gains) losses in 2018 and 2017 primarily reflect changes in discount rates.*

At December 31, 2018 and 2017, the accumulated benefit obligation was $19.0 billion and $20.5 billion, respectively, for all pension plans, of which $10.4 billion and $11.5 billion, respectively, related to U.S. pension plans.

Information related to the funded status of selected pension plans at December 31 is as follows:

	U.S.		International	
	2018	2017	**2018**	2017
Pension plans with a projected benefit obligation in excess of plan assets				
Projected benefit obligation	**$ 10,620**	$ 11,904	**$ 6,251**	$ 3,323
Fair value of plan assets	**9,648**	10,896	**5,089**	2,352
Pension plans with an accumulated benefit obligation in excess of plan assets				
Accumulated benefit obligation	**$ 9,702**	$ 676	**$ 5,936**	$ 2,120
Fair value of plan assets	**8,966**	—	**5,071**	1,346

Plan Assets

Entities are required to use a fair value hierarchy which maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest:

Level 1 — Quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 — Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity. The Level 3 assets are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as instruments for which the determination of fair value requires significant judgment or estimation. At December 31, 2018 and 2017, $826 million and $488 million, respectively, or approximately 5% and 2%, respectively, of the Company's pension investments were categorized as Level 3 assets.

If the inputs used to measure the financial assets fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

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The fair values of the Company's pension plan assets at December 31 by asset category are as follows:

	Fair Value Measurements Using				Fair Value Measurements Using			
	Quoted Prices In Active Markets for Identical Assets (Level 1)	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**	**Total**	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
	2018				2017			
U.S. Pension Plans								
Assets								
Cash and cash equivalents	**$ 40**	**$ —**	**$ —**	**$ 40**	$ 6	$ —	$ —	$ 6
Investment funds								
Developed markets equities	**169**	**—**	**—**	**169**	390	—	—	390
Emerging markets equities	**121**	**—**	**—**	**121**	138	—	—	138
Equity securities								
Developed markets	**2,172**	**—**	**—**	**2,172**	2,743	—	—	2,743
Fixed income securities								
Government and agency obligations	**—**	**1,509**	**—**	**1,509**	—	757	—	757
Corporate obligations	**—**	**1,246**	**—**	**1,246**	—	900	—	900
Mortgage and asset-backed securities	**—**	**262**	**—**	**262**	—	240	—	240
Other investments	**—**	**—**	**13**	**13**	—	—	15	15
Net assets in fair value hierarchy	**$ 2,502**	**$ 3,017**	**$ 13**	**$ 5,532**	$ 3,277	$ 1,897	$ 15	$ 5,189
Investments measured at NAV [(1)]				**4,116**				5,707
Plan assets at fair value				**$ 9,648**				$ 10,896
International Pension Plans								
Assets								
Cash and cash equivalents	**$ 50**	**$ 3**	**$ —**	**$ 53**	$ 54	$ 19	$ —	$ 73
Investment funds								
Developed markets equities	**461**	**3,071**	**—**	**3,532**	562	3,326	—	3,888
Emerging markets equities	**56**	**112**	**—**	**168**	62	176	—	238
Government and agency obligations	**372**	**2,082**	**—**	**2,454**	249	2,095	—	2,344
Corporate obligations	**4**	**7**	**—**	**11**	5	329	—	334
Fixed income obligations	**7**	**4**	**—**	**11**	7	4	—	11
Real estate [(2)]	**—**	**1**	**1**	**2**	—	1	2	3
Equity securities								
Developed markets	**544**	**—**	**—**	**544**	660	—	—	660
Fixed income securities								
Government and agency obligations	**2**	**291**	**—**	**293**	2	266	—	268
Corporate obligations	**1**	**113**	**—**	**114**	1	118	—	119
Mortgage and asset-backed securities	**—**	**55**	**—**	**55**	—	55	—	55
Other investments								
Insurance contracts [(3)]	**—**	**66**	**811**	**877**	—	67	470	537
Other	**—**	**4**	**1**	**5**	—	6	1	7
Net assets in fair value hierarchy	**$ 1,497**	**$ 5,809**	**$ 813**	**$ 8,119**	$ 1,602	$ 6,462	$ 473	$ 8,537
Investments measured at NAV [(1)]				**461**				802
Plan assets at fair value				**$ 8,580**				$ 9,339

(1) *Certain investments that were measured at net asset value (NAV) per share or its equivalent as a practical expedient have not been classified in the fair value hierarchy. The fair value amounts presented in this table are intended to permit reconciliation of the fair value hierarchy to the fair value of plan assets at December 31, 2018 and 2017.*

(2) *The plans' Level 3 investments in real estate funds are generally valued by market appraisals of the underlying investments in the funds.*

(3) *The plans' Level 3 investments in insurance contracts are generally valued using a crediting rate that approximates market returns and invest in underlying securities whose market values are unobservable and determined using pricing models, discounted cash flow methodologies, or similar techniques.*

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The table below provides a summary of the changes in fair value, including transfers in and/or out, of all financial assets measured at fair value using significant unobservable inputs (Level 3) for the Company's pension plan assets:

	2018				2017			
	Insurance Contracts	**Real Estate**	**Other**	**Total**	Insurance Contracts	Real Estate	Other	Total
U.S. Pension Plans								
Balance January 1	**$ —**	**$ —**	**$ 15**	**$ 15**	$ —	$ —	$ 18	$ 18
Actual return on plan assets:								
Relating to assets still held at December 31	**—**	**—**	**(3)**	**(3)**	—	—	(2)	(2)
Relating to assets sold during the year	**—**	**—**	**4**	**4**	—	—	4	4
Purchases and sales, net	**—**	**—**	**(3)**	**(3)**	—	—	(5)	(5)
Balance December 31	**$ —**	**$ —**	**$ 13**	**$ 13**	$ —	$ —	$ 15	$ 15
International Pension Plans								
Balance January 1	**$ 470**	**$ 2**	**$ 1**	**$ 473**	$ 412	$ 4	$ 1	$ 417
Actual return on plan assets:								
Relating to assets still held at December 31	**(32)**	**—**	**—**	**(32)**	52	—	—	52
Purchases and sales, net	**380**	**(1)**	**—**	**379**	5	(2)	—	3
Transfers into Level 3	**(7)**	**—**	**—**	**(7)**	1	—	—	1
Balance December 31	**$ 811**	**$ 1**	**$ 1**	**$ 813**	**$ 470**	**$ 2**	**$ 1**	**$ 473**

The fair values of the Company's other postretirement benefit plan assets at December 31 by asset category are as follows:

	Fair Value Measurements Using				Fair Value Measurements Using			
	Quoted Prices In Active Markets for Identical Assets (Level 1)	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**	**Total**	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
		2018				2017		
Assets								
Cash and cash equivalents	**$ 78**	**$ —**	**$ —**	**$ 78**	$ 97	$ —	$ —	$ 97
Investment funds								
Developed markets equities	**16**	**—**	**—**	**16**	37	—	—	37
Emerging markets equities	**12**	**—**	**—**	**12**	13	—	—	13
Government and agency obligations	**1**	**—**	**—**	**1**	1	—	—	1
Equity securities								
Developed markets	**200**	**—**	**—**	**200**	256	—	—	256
Fixed income securities								
Government and agency obligations	**—**	**141**	**—**	**141**	—	71	—	71
Corporate obligations	**—**	**116**	**—**	**116**	—	84	—	84
Mortgage and asset-backed securities	**—**	**24**	**—**	**24**	—	23	—	23
Net assets in fair value hierarchy	**$ 307**	**$ 281**	**$ —**	**$ 588**	$ 404	$ 178	$ —	$ 582
Investments measured at NAV [1]				**380**				532
Plan assets at fair value				**$ 968**				$ 1,114

[1] *Certain investments that were measured at net asset value (NAV) per share or its equivalent as a practical expedient have not been classified in the fair value hierarchy. The fair value amounts presented in this table are intended to permit reconciliation of the fair value hierarchy to the fair value of plan assets at December 31, 2018 and 2017.*

The Company has established investment guidelines for its U.S. pension and other postretirement plans to create an asset allocation that is expected to deliver a rate of return sufficient to meet the long-term obligation of each

plan, given an acceptable level of risk. The target investment portfolio of the Company's U.S. pension and other postretirement benefit plans is allocated 30% to 50% in U.S. equities, 15% to 30% in international equities, 30% to 45% in fixed-income investments, and up to 5% in cash and other investments. The portfolio's equity weighting is consistent with the long-term nature of the plans' benefit obligations. The expected annual standard deviation of returns of the target portfolio, which approximates 11%, reflects both the equity allocation and the diversification benefits among the asset classes in which the portfolio invests. For international pension plans, the targeted investment portfolio varies based on the duration of pension liabilities and local government rules and regulations. Although a significant percentage of plan assets are invested in U.S. equities, concentration risk is mitigated through the use of strategies that are diversified within management guidelines.

Expected Contributions

Expected contributions during 2019 are approximately $50 million for U.S. pension plans, approximately $150 million for international pension plans and approximately $15 million for other postretirement benefit plans.

Expected Benefit Payments

Expected benefit payments are as follows:

	U.S. Pension Benefits	International Pension Benefits	Other Postretirement Benefits
2019	$ 638	$ 225	$ 91
2020	661	213	95
2021	680	221	98
2022	685	239	102
2023	709	249	105
2024 — 2028	3,805	1,349	577

Expected benefit payments are based on the same assumptions used to measure the benefit obligations and include estimated future employee service.

Amounts Recognized in Other Comprehensive Income

Net loss amounts reflect experience differentials primarily relating to differences between expected and actual returns on plan assets as well as the effects of changes in actuarial assumptions. Net loss amounts in excess of certain thresholds are amortized into net periodic benefit cost over the average remaining service life of employees. The following amounts were reflected as components of *OCI*:

	Pension Plans						Other Postretirement Benefit Plans		
	U.S.			International					
Years Ended December 31	**2018**	2017	2016	**2018**	2017	2016	**2018**	2017	2016
Net (loss) gain arising during the period	**$ (397)**	$ (19)	$ (743)	**$ (505)**	$ 309	$ (380)	**$ 186**	$ 170	$ (45)
Prior service (cost) credit arising during the period	**(4)**	(13)	(10)	**(10)**	22	(2)	**2**	(31)	(19)
	$ (401)	$ (32)	$ (753)	**$ (515)**	$ 331	$ (382)	**$ 188**	$ 139	$ (64)
Net loss amortization included in benefit cost	**$ 232**	$ 180	$ 119	**$ 84**	$ 98	$ 87	**$ 1**	$ 1	$ 3
Prior service (credit) cost amortization included in benefit cost	**(50)**	(53)	(55)	**(13)**	(11)	(11)	**(84)**	(98)	(106)
	$ 182	$ 127	$ 64	**$ 71**	$ 87	$ 76	**$ (83)**	$ (97)	$ (103)

The estimated net loss (gain) and prior service cost (credit) amounts that will be amortized from *AOCI* into net periodic benefit cost during 2019 are $204 million and $(62) million, respectively, for pension plans (of which $141 million and $(50) million, respectively, relates to U.S. pension plans) and $(7) million and $(78) million, respectively, for other postretirement benefit plans.

Actuarial Assumptions

The Company reassesses its benefit plan assumptions on a regular basis. The weighted average assumptions used in determining U.S. pension and other postretirement benefit plan and international pension plan information are as follows:

	U.S. Pension and Other Postretirement Benefit Plans			International Pension Plans		
December 31	**2018**	2017	2016	**2018**	2017	2016
Net periodic benefit cost						
Discount rate	**3.70 %**	4.30 %	4.70 %	**2.10 %**	2.20 %	2.80 %
Expected rate of return on plan assets	**8.20 %**	8.70 %	8.60 %	**5.10 %**	5.10 %	5.60 %
Salary growth rate	**4.30 %**	4.30 %	4.30 %	**2.90 %**	2.90 %	2.90 %
Benefit obligation						
Discount rate	**4.40 %**	3.70 %	4.30 %	**2.20 %**	2.10 %	2.20 %
Salary growth rate	**4.30 %**	4.30 %	4.30 %	**2.80 %**	2.90 %	2.90 %

For both the pension and other postretirement benefit plans, the discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due. The expected rate of return for both the pension and other postretirement benefit plans represents the average rate of return to be earned on plan assets over the period the benefits included in the benefit obligation are to be paid and is determined on a plan basis. The expected rate of return within each plan is developed considering long-term historical returns data, current market conditions, and actual returns on the plan assets. Using this reference information, the long-term return expectations for each asset category and a weighted average expected return for each plan's target portfolio is developed, according to the allocation among those investment categories. The expected portfolio performance reflects the contribution of active management as appropriate. For 2019, the expected rate of return for the Company's U.S. pension and other postretirement benefit plans will range from 7.70% to 8.10%, as compared to a range of 7.70% to 8.30% in 2018. The decrease is primarily due to a modest shift in asset allocation. The change in the weighted-average expected return on U.S. pension and other postretirement benefit plan assets from 2016 to 2018 is due to the relative weighting of the referenced plans' assets.

The health care cost trend rate assumptions for other postretirement benefit plans are as follows:

December 31	**2018**	2017
Health care cost trend rate assumed for next year	**7.0 %**	7.2 %
Rate to which the cost trend rate is assumed to decline	**4.5 %**	4.5 %
Year that the trend rate reaches the ultimate trend rate	**2032**	2032

A one percentage point change in the health care cost trend rate would have had the following effects:

	One Percentage Point	
	Increase	Decrease
Effect on total service and interest cost components	**$ 11**	**$ (9)**
Effect on benefit obligation	**88**	**(74)**

Savings Plans

The Company also maintains defined contribution savings plans in the United States. The Company matches a percentage of each employee's contributions consistent with the provisions of the plan for which the employee is eligible. Total employer contributions to these plans in 2018, 2017 and 2016 were $136 million, $131 million and $126 million, respectively.

15. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

Years Ended December 31	**2018**	2017	2016
Interest income	**$ (343)**	$ (385)	$ (328)
Interest expense	**772**	754	693
Exchange losses (gains)	**145**	(11)	174
Income on investments in equity securities, net [1]	**(324)**	(352)	(43)
Net periodic defined benefit plan (credit) cost other than service cost	**(512)**	(512)	(531)
Other, net	**(140)**	6	224
	$ (402)	$ (500)	$ 189

[1] *Includes net realized and unrealized gains and losses on investments in equity securities either owned directly or through ownership interests in investment funds.*

Income on investments in equity securities, net, in 2018 reflects the recognition of unrealized net gains pursuant to the prospective adoption of ASU 2016-01 on January 1, 2018 (see Note 2). The increase in income on investments in equity securities, net, in 2017 was driven primarily by higher realized gains on sales.

Other, net (as presented in the table above) in 2018 includes a gain of $115 million related to the settlement of certain patent litigation (see Note 11), income of $99 million related to AstraZeneca's option exercise (see Note 9), and a gain of $85 million resulting from the receipt of a milestone payment for an out-licensed migraine clinical development program. Other, net in 2018 also includes $144 million of goodwill impairment charges related to certain businesses in the Healthcare Services segment (see Note 8), as well as $41 million of charges related to the write-down of assets held for sale to fair value in anticipation of the dissolution of the Company's joint venture with Supera Farma Laboratorios S.A. in Brazil.

Other, net in 2017 includes income of $232 million related to AstraZeneca's option exercise and a $191 million loss on extinguishment of debt (see Note 10).

Other, net in 2016 includes a charge of $625 million related to the previously disclosed settlement of worldwide patent litigation related to *Keytruda*, a gain of $117 million related to the settlement of other patent litigation, gains of $100 million resulting from the receipt of milestone payments for out-licensed migraine clinical development programs, and $98 million of income related to AstraZeneca's option exercise.

Interest paid was $777 million in 2018, $723 million in 2017 and $686 million in 2016.

16. Taxes on Income

A reconciliation between the effective tax rate and the U.S. statutory rate is as follows:

	2018		2017		2016	
	Amount	**Tax Rate**	Amount	Tax Rate	Amount	Tax Rate
U.S. statutory rate applied to income before taxes	**$ 1,827**	**21.0 %**	$ 2,282	35.0 %	$ 1,631	35.0 %
Differential arising from:						
Impact of the TCJA	**289**	**3.3**	2,625	40.3	—	—
Valuation allowances	**269**	**3.1**	632	9.7	(5)	(0.1)
Impact of purchase accounting adjustments, including amortization	**267**	**3.1**	713	10.9	623	13.4
State taxes	**201**	**2.3**	77	1.2	173	3.7
Restructuring	**56**	**0.6**	142	2.2	145	3.1
Foreign earnings	**(245)**	**(2.8)**	(1,654)	(25.4)	(1,546)	(33.2)
R&D tax credit	**(96)**	**(1.1)**	(71)	(1.1)	(58)	(1.3)
Tax settlements	**(22)**	**(0.3)**	(356)	(5.5)	—	—
Other [(1)]	**(38)**	**(0.4)**	(287)	(4.4)	(245)	(5.2)
	$ 2,508	**28.8 %**	$ 4,103	62.9 %	$ 718	15.4 %

[(1)] *Other includes the tax effects of losses on foreign subsidiaries and miscellaneous items.*

The Company's 2017 effective tax rate reflected a provisional impact of 40.3% for the Tax Cuts and Jobs Act (TCJA), which was enacted on December 22, 2017. Among other provisions, the TCJA reduced the U.S. federal corporate statutory tax rate from 35% to 21% effective January 1, 2018, requires companies to pay a one-time transition tax on undistributed earnings of certain foreign subsidiaries, and creates new taxes on certain foreign sourced earnings.

The Company reflected the impact of the TCJA in its 2017 financial statements. However, since application of certain provisions of the TCJA remained subject to further interpretation, in certain instances the Company made reasonable estimates of the effects of the TCJA. In 2018, these amounts were finalized as described below.

The one-time transition tax is based on the Company's post-1986 undistributed earnings and profits (E&P). For a substantial portion of these undistributed E&P, the Company had not previously provided deferred taxes as these earnings were deemed by Merck to be retained indefinitely by subsidiary companies for reinvestment. The Company recorded a provisional amount in 2017 for its one-time transition tax liability of $5.3 billion. This provisional amount was reduced by the reversal of $2.0 billion of deferred taxes that were previously recorded in connection with the merger of Schering-Plough Corporation in 2009 for certain undistributed foreign E&P. On the basis of revised calculations of post-1986 undistributed foreign E&P and finalization of the amounts held in cash or other specified assets, the Company recognized a measurement-period adjustment of $124 million in 2018 related to the transition tax obligation, with a corresponding adjustment to income tax expense during the period, resulting in a revised transition tax obligation of $5.5 billion. The Company anticipates that it will be able to utilize certain foreign tax credits to partially reduce the transition tax payment. As permitted under the TCJA, the Company has elected to pay the one-time transition tax over a period of eight years. After payment of the amount due in 2018, the remaining transition tax liability at December 31, 2018, is $4.9 billion, of which $275 million is included in *Income Taxes Payable* and the remainder of $4.6 billion is included in *Other Noncurrent Liabilities*. As a result of the TCJA, the Company has made a determination it is no longer indefinitely reinvested with respect to its undistributed earnings from foreign subsidiaries and has provided a deferred tax liability for withholding tax that would apply.

In 2017, the Company remeasured its deferred tax assets and liabilities at the new federal statutory tax rate of 21%, which resulted in a provisional deferred tax benefit of $779 million. On the basis of clarifications to the deferred tax benefit calculation, the Company recorded measurement-period adjustments in 2018 of $32 million related to deferred income taxes.

Beginning in 2018, the TCJA includes a tax on “global intangible low-taxed income” (GILTI) as defined in the TCJA. The Company has made an accounting policy election to account for the tax effects of the GILTI tax in the income tax provision in future periods as the tax arises.

The foreign earnings tax rate differentials in the tax rate reconciliation above primarily reflect the impacts of operations in jurisdictions with different tax rates than the United States, particularly Ireland and Switzerland, as well as Singapore and Puerto Rico which operate under tax incentive grants (which begin to expire in 2022), where the earnings had been indefinitely reinvested, thereby yielding a favorable impact on the effective tax rate compared with the U.S. statutory rate of 35% in 2017 and 2016 and 21% in 2018. The foreign earnings tax rate differentials do not include the impact of intangible asset impairment charges, amortization of purchase accounting adjustments or restructuring costs. These items are presented separately as they each represent a significant, separately disclosed pretax cost or charge, and a substantial portion of each of these items relates to jurisdictions with lower tax rates than the United States. Therefore, the impact of recording these expense items in lower tax rate jurisdictions is an unfavorable impact on the effective tax rate compared to the U.S. statutory rate of 35% in 2017 and 2016 and 21% in 2018.

Income before taxes consisted of:

Years Ended December 31	**2018**	2017	2016
Domestic	**$ 3,717**	$ 3,483	$ 518
Foreign	**4,984**	3,038	4,141
	$ 8,701	$ 6,521	$ 4,659

Taxes on income consisted of:

Years Ended December 31	**2018**	2017	2016
Current provision			
Federal	**$ 536**	$ 5,585	$ 1,166
Foreign	**2,281**	1,229	916
State	**200**	(90)	157
	3,017	6,724	2,239
Deferred provision			
Federal	**(402)**	(2,958)	(1,255)
Foreign	**(64)**	75	(225)
State	**(43)**	262	(41)
	(509)	(2,621)	(1,521)
	$ 2,508	$ 4,103	$ 718

Deferred income taxes at December 31 consisted of:

	2018		2017	
	Assets	**Liabilities**	Assets	Liabilities
Product intangibles and licenses	**$ 720**	**$ 1,640**	$ 307	$ 2,256
Inventory related	**32**	**377**	29	499
Accelerated depreciation	**—**	**582**	28	642
Pensions and other postretirement benefits	**565**	**151**	498	192
Compensation related	**291**	**—**	314	—
Unrecognized tax benefits	**174**	**—**	156	—
Net operating losses and other tax credit carryforwards	**715**	**—**	654	—
Other	**621**	**66**	909	52
Subtotal	**3,118**	**2,816**	2,895	3,641
Valuation allowance	**(1,348)**		(900)	
Total deferred taxes	**$ 1,770**	**$ 2,816**	$ 1,995	$ 3,641
Net deferred income taxes		**$ 1,046**		$ 1,646
Recognized as:				
Other assets	**$ 656**		$ 573	
Deferred income taxes		**$ 1,702**		$ 2,219

The Company has net operating loss (NOL) carryforwards in several jurisdictions. As of December 31, 2018, $715 million of deferred taxes on NOL carryforwards relate to foreign jurisdictions. Valuation allowances of $1.3 billion have been established on these foreign NOL carryforwards and other foreign deferred tax assets. The Company has no NOL carryforwards relating to U.S. jurisdictions.

Income taxes paid in 2018, 2017 and 2016 were $1.5 billion, $4.9 billion and $1.8 billion, respectively. Tax benefits relating to stock option exercises were $77 million in 2018, $73 million in 2017 and $147 million in 2016.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	2018	2017	2016
Balance January 1	**$ 1,723**	$ 3,494	$ 3,448
Additions related to current year positions	**221**	146	196
Additions related to prior year positions	**142**	520	75
Reductions for tax positions of prior years [(1)]	**(73)**	(1,038)	(90)
Settlements [(1)]	**(91)**	(1,388)	(92)
Lapse of statute of limitations	**(29)**	(11)	(43)
Balance December 31	**$ 1,893**	$ 1,723	$ 3,494

[(1)] *Amounts reflect the settlements with the IRS as discussed below.*

If the Company were to recognize the unrecognized tax benefits of $1.9 billion at December 31, 2018, the income tax provision would reflect a favorable net impact of $1.8 billion.

The Company is under examination by numerous tax authorities in various jurisdictions globally. The Company believes that it is reasonably possible that the total amount of unrecognized tax benefits as of December 31, 2018 could decrease by up to approximately $750 million in the next 12 months as a result of various audit closures, settlements or the expiration of the statute of limitations. The ultimate finalization of the Company's examinations with relevant taxing authorities can include formal administrative and legal proceedings, which could have a significant impact on the timing of the reversal of unrecognized tax benefits. The Company believes that its reserves for uncertain tax positions are adequate to cover existing risks or exposures.

Expenses for interest and penalties associated with uncertain tax positions amounted to $51 million in 2018, $183 million in 2017 and $134 million in 2016. These amounts reflect the beneficial impacts of various tax

settlements, including those discussed below. Liabilities for accrued interest and penalties were $372 million and $341 million as of December 31, 2018 and 2017, respectively.

In 2017, the Internal Revenue Service (IRS) concluded its examinations of Merck's 2006-2011 U.S. federal income tax returns. As a result, the Company was required to make a payment of approximately $2.8 billion. The Company's reserves for unrecognized tax benefits for the years under examination exceeded the adjustments relating to this examination period and therefore the Company recorded a net $234 million tax benefit in 2017. This net benefit reflects reductions in reserves for unrecognized tax benefits for tax positions relating to the years that were under examination, partially offset by additional reserves for tax positions not previously reserved for, as well as adjustments to reserves for unrecognized tax benefits relating to years which remain open to examination that are affected by this settlement.

The IRS is currently conducting examinations of the Company's tax returns for the years 2012 through 2014. In addition, various state and foreign tax examinations are in progress and for these jurisdictions, the Company's income tax returns are open for examination for the period 2003 through 2018.

17. Earnings per Share

The calculations of earnings per share (shares in millions) are as follows:

Years Ended December 31	**2018**	2017	2016
Net income attributable to Merck & Co., Inc.	**$ 6,220**	$ 2,394	$ 3,920
Average common shares outstanding	**2,664**	2,730	2,766
Common shares issuable [(1)]	**15**	18	21
Average common shares outstanding assuming dilution	**2,679**	2,748	2,787
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	**$ 2.34**	$ 0.88	$ 1.42
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	**$ 2.32**	$ 0.87	$ 1.41

[(1)] *Issuable primarily under share-based compensation plans.*

In 2018, 2017 and 2016, 6 million, 5 million and 13 million, respectively, of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

18. Other Comprehensive Income (Loss)

Changes in *AOCI* by component are as follows:

	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance January 1, 2016, net of taxes	$ 404	$ 41	$ (2,407)	$ (2,186)	$ (4,148)
Other comprehensive income (loss) before reclassification adjustments, pretax	210	(38)	(1,199)	(150)	(1,177)
Tax	(72)	16	363	(19)	288
Other comprehensive income (loss) before reclassification adjustments, net of taxes	138	(22)	(836)	(169)	(889)
Reclassification adjustments, pretax	(314) [1]	(31) [2]	37 [3]	—	(308)
Tax	110	9	—	—	119
Reclassification adjustments, net of taxes	(204)	(22)	37	—	(189)
Other comprehensive income (loss), net of taxes	(66)	(44)	(799)	(169)	(1,078)
Balance December 31, 2016, net of taxes	338	(3)	(3,206)	(2,355)	(5,226)
Other comprehensive income (loss) before reclassification adjustments, pretax	(561)	212	438	235	324
Tax	207	(35)	(106)	166	232
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(354)	177	332	401	556
Reclassification adjustments, pretax	(141) [1]	(291) [2]	117 [3]	—	(315)
Tax	49	56	(30)	—	75
Reclassification adjustments, net of taxes	(92)	(235)	87	—	(240)
Other comprehensive income (loss), net of taxes	(446)	(58)	419	401	316
Balance December 31, 2017, net of taxes	(108)	(61)	(2,787) [4]	(1,954)	(4,910)
Other comprehensive income (loss) before reclassification adjustments, pretax	**228**	**(108)**	**(728)**	**(84)**	**(692)**
Tax	**(55)**	**1**	**169**	**(139)**	**(24)**
Other comprehensive income (loss) before reclassification adjustments, net of taxes	**173**	**(107)**	**(559)**	**(223)**	**(716)**
Reclassification adjustments, pretax	**157** [1]	**97** [2]	**170** [3]	**—**	**424**
Tax	**(33)**	**—**	**(36)**	**—**	**(69)**
Reclassification adjustments, net of taxes	**124**	**97**	**134**	**—**	**355**
Other comprehensive income (loss), net of taxes	**297**	**(10)**	**(425)**	**(223)**	**(361)**
Adoption of ASU 2018-02 (see Note 2)	**(23)**	**1**	**(344)**	**100**	**(266)**
Adoption of ASU 2016-01 (see Note 2)	**—**	**(8)**	**—**	**—**	**(8)**
Balance December 31, 2018, net of taxes	**$ 166**	**$ (78)**	**$ (3,556)** [4]	**$ (2,077)**	**$ (5,545)**

[1] *Relates to foreign currency cash flow hedges that were reclassified from* AOCI *to* Sales.

[2] *Represents net realized (gains) losses on the sales of available-for-sale investments that were reclassified from* AOCI *to* Other (income) expense, net. *In 2017 and 2016, these amounts included both investments in debt and equity securities; however, as a result of the adoption of ASU 2016-01 (see Note 2), in 2018, these amounts relate only to investments in available-for-sale debt securities.*

[3] *Includes net amortization of prior service cost and actuarial gains and losses included in net periodic benefit cost (see Note 14).*

[4] *Includes pension plan net loss of $4.4 billion and $3.5 billion at December 31, 2018 and 2017, respectively, and other postretirement benefit plan net (gain) loss of $(170) million and $(16) million at December 31, 2018 and 2017, respectively, as well as pension plan prior service credit of $314 million and $326 million at December 31, 2018 and 2017, respectively, and other postretirement benefit plan prior service credit of $375 million and $383 million at December 31, 2018 and 2017, respectively.*

19. Segment Reporting

The Company's operations are principally managed on a products basis and include four operating segments, which are the Pharmaceutical, Animal Health, Healthcare Services and Alliances segments. The Pharmaceutical and Animal Health segments are the only reportable segments. The Animal Health segment met the criteria for separate reporting and became a reportable segment in 2018.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. A large component of pediatric and adolescent vaccine sales are made to the U.S. Centers for Disease Control and Prevention Vaccines for Children program, which is funded by the U.S. government. Additionally, the Company sells vaccines to the Federal government for placement into vaccine stockpiles. Sales of vaccines in most major European markets were marketed through the Company's SPMSD joint venture until its termination on December 31, 2016 (see Note 9).

The Animal Health segment discovers, develops, manufactures and markets animal health products, including pharmaceutical and vaccine products, for the prevention, treatment and control of disease in all major livestock and companion animal species, which the Company sells to veterinarians, distributors and animal producers.

The Healthcare Services segment provides services and solutions that focus on engagement, health analytics and clinical services to improve the value of care delivered to patients.

The Alliances segment primarily includes activity from the Company's relationship with AstraZeneca LP related to sales of Nexium and Prilosec, which concluded in 2018 (see Note 9).

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Sales of the Company's products were as follows:

Years Ended December 31	**2018**			2017			2016		
	U.S.	**Int'l**	**Total**	U.S.	Int'l	Total	U.S.	Int'l	Total
Pharmaceutical:									
Oncology									
Keytruda	**$ 4,150**	**$ 3,021**	**$ 7,171**	$ 2,309	$ 1,500	$ 3,809	$ 792	$ 610	$ 1,402
Emend	**312**	**210**	**522**	342	213	556	356	193	549
Temodar	**6**	**209**	**214**	16	256	271	15	268	283
Alliance revenue - Lynparza	**127**	**61**	**187**	—	20	20	—	—	—
Alliance revenue - Lenvima	**95**	**54**	**149**	—	—	—	—	—	—
Vaccines [(1)]									
Gardasil/Gardasil 9	**1,873**	**1,279**	**3,151**	1,565	743	2,308	1,780	393	2,173
ProQuad/M-M-R II/Varivax	**1,430**	**368**	**1,798**	1,374	303	1,676	1,362	279	1,640
Pneumovax 23	**627**	**281**	**907**	581	240	821	447	193	641
RotaTeq	**496**	**232**	**728**	481	204	686	482	169	652
Zostavax	**22**	**195**	**217**	422	246	668	518	168	685
Hospital Acute Care									
Bridion	**386**	**531**	**917**	239	465	704	77	405	482
Noxafil	**353**	**389**	**742**	309	327	636	284	312	595
Invanz	**253**	**243**	**496**	361	241	602	329	233	561
Cubicin	**191**	**176**	**367**	189	193	382	906	181	1,087
Cancidas	**12**	**314**	**326**	20	402	422	25	533	558
Primaxin	**7**	**258**	**265**	10	270	280	4	293	297
Immunology									
Simponi	**—**	**893**	**893**	—	819	819	—	766	766
Remicade	**—**	**582**	**582**	—	837	837	—	1,268	1,268
Neuroscience									
Belsomra	**96**	**164**	**260**	98	112	210	84	70	154
Virology									
Isentress/Isentress HD	**513**	**627**	**1,140**	565	639	1,204	721	666	1,387
Zepatier	**8**	**447**	**455**	771	888	1,660	488	67	555
Cardiovascular									
Zetia	**45**	**813**	**857**	352	992	1,344	1,588	972	2,560
Vytorin	**10**	**487**	**497**	124	627	751	473	668	1,141
Atozet	**—**	**347**	**347**	—	225	225	1	146	146
Adempas	**—**	**329**	**329**	—	300	300	—	169	169
Diabetes									
Januvia	**1,969**	**1,718**	**3,686**	2,153	1,584	3,737	2,286	1,622	3,908
Janumet	**811**	**1,417**	**2,228**	863	1,296	2,158	984	1,217	2,201
Women's Health									
NuvaRing	**722**	**180**	**902**	564	197	761	576	202	777
Implanon/Nexplanon	**495**	**208**	**703**	496	191	686	420	186	606
Diversified Brands									
Singulair	**20**	**688**	**708**	40	692	732	40	874	915
Cozaar/Hyzaar	**23**	**431**	**453**	18	466	484	16	494	511
Nasonex	**23**	**353**	**376**	54	333	387	184	352	537
Arcoxia	**—**	**335**	**335**	—	363	363	—	450	450
Follistim AQ	**115**	**153**	**268**	123	174	298	157	197	355
Dulera	**186**	**28**	**214**	261	26	287	412	24	436

Fosamax	**4**	**205**	**209**	6	235	241	5	279	284
Other pharmaceutical [(2)]	**1,228**	**2,855**	**4,090**	1,148	2,917	4,065	1,261	3,158	4,420
Total Pharmaceutical segment sales	**16,608**	**21,081**	**37,689**	15,854	19,536	35,390	17,073	18,077	35,151
Animal Health:									
Livestock	**528**	**2,102**	**2,630**	471	2,013	2,484	446	1,841	2,287
Companion Animals	**710**	**872**	**1,582**	619	772	1,391	543	648	1,191
Total Animal Health segment sales	**1,238**	**2,974**	**4,212**	1,090	2,785	3,875	989	2,489	3,478
Other segment sales [(3)]	**248**	**2**	**250**	396	1	397	385	—	385
Total segment sales	**18,094**	**24,057**	**42,151**	17,340	22,322	39,662	18,447	20,566	39,014
Other [(4)]	**118**	**26**	**143**	84	376	460	31	763	793
	$ 18,212	**$ 24,083**	**$ 42,294**	$ 17,424	$ 22,698	$ 40,122	$ 18,478	$ 21,329	$ 39,807

U.S. plus international may not equal total due to rounding.

(1) *On December 31, 2016, Merck and Sanofi terminated their equally-owned joint venture, SPMSD, which marketed vaccines in most major European markets (see Note 9). Accordingly, vaccine sales in 2018 and 2017 include sales in the European markets that were previously part of SPMSD. Amounts for 2016 do not include sales of vaccines sold through SPMSD, the results of which are reflected in equity income from affiliates included in* Other (income) expense, net. *Amounts for 2016 do, however, include supply sales to SPMSD.*

(2) *Other pharmaceutical primarily reflects sales of other human health pharmaceutical products, including products within the franchises not listed separately.*

(3) *Represents the non-reportable segments of Healthcare Services and Alliances.*

(4) *Other is primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, as well as third-party manufacturing sales. Other in 2018, 2017 and 2016 also includes approximately $95 million, $85 million and $170 million, respectively, related to the sale of the marketing rights to certain products.*

Consolidated revenues by geographic area where derived are as follows:

Years Ended December 31	**2018**	2017	2016
United States	**$ 18,212**	$ 17,424	$ 18,478
Europe, Middle East and Africa	**12,213**	11,478	10,953
Japan	**3,212**	3,122	2,846
Asia Pacific (other than Japan and China)	**2,909**	2,751	2,483
Latin America	**2,415**	2,339	2,155
China	**2,184**	1,586	1,435
Other	**1,149**	1,422	1,457
	$ 42,294	$ 40,122	$ 39,807

A reconciliation of segment profits to *Income before taxes* is as follows:

Years Ended December 31	**2018**	2017	2016
Segment profits:			
Pharmaceutical segment	**$ 24,292**	$ 22,495	$ 22,141
Animal Health segment	**1,659**	1,552	1,357
Other segments	**103**	275	146
Total segment profits	**26,054**	24,322	23,644
Other profits	**6**	26	481
Unallocated:			
Interest income	**343**	385	328
Interest expense	**(772)**	(754)	(693)
Depreciation and amortization	**(1,334)**	(1,378)	(1,585)
Research and development	**(8,853)**	(9,481)	(9,218)
Amortization of purchase accounting adjustments	**(2,664)**	(3,056)	(3,692)
Restructuring costs	**(632)**	(776)	(651)
Charge related to termination of collaboration agreement with Samsung	**(423)**	—	—
Loss on extinguishment of debt	**—**	(191)	—
Gain on sale of certain migraine clinical development programs	**—**	—	100
Charge related to the settlement of worldwide *Keytruda* patent litigation	**—**	—	(625)
Other unallocated, net	**(3,024)**	(2,576)	(3,430)
	$ 8,701	$ 6,521	$ 4,659

Pharmaceutical segment profits are comprised of segment sales less standard costs, as well as selling, general and administrative expenses and research and development costs directly incurred by the segment. Animal Health segment profits are comprised of segment sales, less all cost of sales, as well as selling, general and administrative expenses and research and development costs directly incurred by the segment. For internal management reporting presented to the chief operating decision maker, Merck does not allocate the remaining cost of sales not included in segment profits as described above, research and development expenses incurred in Merck Research Laboratories, the Company's research and development division that focuses on human health-related activities, or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. In addition, costs related to restructuring activities, as well as the amortization of purchase accounting adjustments are not allocated to segments.

Other profits are primarily comprised of miscellaneous corporate profits, as well as operating profits related to third-party manufacturing sales.

Other unallocated, net includes expenses from corporate and manufacturing cost centers, goodwill and other intangible asset impairment charges, gains or losses on sales of businesses, expense or income related to changes in the estimated fair value of liabilities for contingent consideration, and other miscellaneous income or expense items.

In 2018, the Company adopted a new accounting standard related to the classification of certain defined benefit plan costs (see Note 2), which resulted in a change to the measurement of segment profits. Net periodic benefit cost (credit) other than service cost is no longer included as a component of segment profits. Prior period amounts have been recast to conform to the new presentation.

Equity (income) loss from affiliates and depreciation and amortization included in segment profits is as follows:

	Pharmaceutical	Animal Health	All Other	Total
Year Ended December 31, 2018				
Included in segment profits:				
Equity (income) loss from affiliates	**$ 4**	**$ —**	**$ —**	**$ 4**
Depreciation and amortization	**243**	**82**	**10**	**335**
Year Ended December 31, 2017				
Included in segment profits:				
Equity (income) loss from affiliates	$ 7	$ —	$ —	$ 7
Depreciation and amortization	125	75	12	212
Year Ended December 31, 2016				
Included in segment profits:				
Equity (income) loss from affiliates	$ (105)	$ —	$ —	$ (105)
Depreciation and amortization	160	10	13	183

Property, plant and equipment, net, by geographic area where located is as follows:

December 31	**2018**	2017	2016
United States	**$ 8,306**	$ 8,070	$ 8,114
Europe, Middle East and Africa	**3,706**	3,151	2,732
Asia Pacific (other than Japan and China)	**684**	632	623
Latin America	**264**	271	234
China	**167**	150	152
Japan	**159**	158	164
Other	**5**	7	7
	$ 13,291	$ 12,439	$ 12,026

The Company does not disaggregate assets on a products and services basis for internal management reporting and, therefore, such information is not presented.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Merck & Co., Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Merck & Co., Inc and its subsidiaries (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of income, comprehensive income, equity and cash flows for each of the three years in the period ended December 31, 2018, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for retirement benefits in 2018.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 27, 2019

We have served as the Company's auditor since 2002.

(b) Supplementary Data

Selected quarterly financial data for 2018 and 2017 are contained in the Condensed Interim Financial Data table below.

Condensed Interim Financial Data (Unaudited)

($ in millions except per share amounts)	4th Q [1]	3rd Q [2]	2nd Q	1st Q [3]
2018 [4]				
Sales	**$ 10,998**	**$ 10,794**	**$ 10,465**	**$ 10,037**
Cost of sales	**3,289**	**3,619**	**3,417**	**3,184**
Selling, general and administrative	**2,643**	**2,443**	**2,508**	**2,508**
Research and development	**2,214**	**2,068**	**2,274**	**3,196**
Restructuring costs	**138**	**171**	**228**	**95**
Other (income) expense, net	**110**	**(172)**	**(48)**	**(291)**
Income before taxes	**2,604**	**2,665**	**2,086**	**1,345**
Net income attributable to Merck & Co., Inc.	**1,827**	**1,950**	**1,707**	**736**
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	**$ 0.70**	**$ 0.73**	**$ 0.64**	**$ 0.27**
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	**$ 0.69**	**$ 0.73**	**$ 0.63**	**$ 0.27**
2017 [4] [5]				
Sales	$ 10,433	$ 10,325	$ 9,930	$ 9,434
Cost of sales	3,440	3,307	3,116	3,049
Selling, general and administrative	2,643	2,459	2,500	2,472
Research and development	2,314	4,413	1,782	1,830
Restructuring costs	306	153	166	151
Other (income) expense, net	(149)	(207)	(73)	(71)
Income before taxes	1,879	200	2,439	2,003
Net (loss) income attributable to Merck & Co., Inc.	(1,046)	(56)	1,946	1,551
Basic (loss) earnings per common share attributable to Merck & Co., Inc. common shareholders	$ (0.39)	$ (0.02)	$ 0.71	$ 0.56
(Loss) earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	$ (0.39)	$ (0.02)	$ 0.71	$ 0.56

[1] *Amounts for 2017 include a provisional net tax charge related to the enactment of U.S. tax legislation (see Note 16).*

[2] *Amounts for 2017 include a charge related to the formation of a collaboration with AstraZeneca (see Note 4).*

[3] *Amounts for 2018 include a charge related to the formation of a collaboration with Eisai (see Note 4).*

[4] *Amounts for 2018 and 2017 reflect acquisition and divestiture-related costs (see Note 8) and the impact of restructuring actions (see Note 5).*

[5] *Amounts have been recast as a result of the adoption, on January 1, 2018, of a new accounting standard related to the classification of certain defined benefit plan costs. There was no impact to net income as a result of adopting the new accounting standard (see Note 2).*

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures. Based on their evaluation, as of the end of the period covered by this Form 10-K, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Act)) are effective. For the fourth quarter of 2018, there have been no changes in internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Act. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control — Integrated Framework* issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2018. PricewaterhouseCoopers LLP, an independent registered public accounting firm, has performed its own assessment of the effectiveness of the Company's internal control over financial reporting and its attestation report is included in this Form 10-K filing.

Management's Report

Management's Responsibility for Financial Statements

Responsibility for the integrity and objectivity of the Company's financial statements rests with management. The financial statements report on management's stewardship of Company assets. These statements are prepared in conformity with generally accepted accounting principles and, accordingly, include amounts that are based on management's best estimates and judgments. Nonfinancial information included in the Annual Report on Form 10-K has also been prepared by management and is consistent with the financial statements.

To assure that financial information is reliable and assets are safeguarded, management maintains an effective system of internal controls and procedures, important elements of which include: careful selection, training and development of operating and financial managers; an organization that provides appropriate division of responsibility; and communications aimed at assuring that Company policies and procedures are understood throughout the organization. A staff of internal auditors regularly monitors the adequacy and application of internal controls on a worldwide basis.

To ensure that personnel continue to understand the system of internal controls and procedures, and policies concerning good and prudent business practices, annually all employees of the Company are required to complete Code of Conduct training. This training reinforces the importance and understanding of internal controls by reviewing key corporate policies, procedures and systems. In addition, the Company has compliance programs, including an ethical business practices program to reinforce the Company's long-standing commitment to high ethical standards in the conduct of its business.

The financial statements and other financial information included in the Annual Report on Form 10-K fairly present, in all material respects, the Company's financial condition, results of operations and cash flows. Our formal certification to the Securities and Exchange Commission is included in this Form 10-K filing.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control — Integrated Framework* issued

in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2018.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2018, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

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Kenneth C. Frazier
Chairman, President and Chief Executive Officer

Robert M. Davis
Executive Vice President, Global Services, and Chief Financial Officer

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The required information on directors and nominees is incorporated by reference from the discussion under Proposal 1. Election of Directors of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 28, 2019. Information on executive officers is set forth in Part I of this document on page 32.

The required information on compliance with Section 16(a) of the Securities Exchange Act of 1934 is incorporated by reference from the discussion under the heading "Section 16(a) Beneficial Ownership Reporting Compliance" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 28, 2019.

The Company has a Code of Conduct — *Our Values and Standards* applicable to all employees, including the principal executive officer, principal financial officer, principal accounting officer and Controller. The Code of Conduct is available on the Company's website at *www.merck.com/about/code_of_conduct.pdf*. The Company intends to disclose future amendments to certain provisions of the Code of Conduct, and waivers of the Code of Conduct granted to executive officers and directors, if any, on the website within four business days following the date of any amendment or waiver. Every Merck employee is responsible for adhering to business practices that are in accordance with the law and with ethical principles that reflect the highest standards of corporate and individual behavior.

The required information on the identification of the audit committee and the audit committee financial expert is incorporated by reference from the discussion under the heading "Board Meetings and Committees" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 28, 2019.

Item 11. Executive Compensation.

The information required on executive compensation is incorporated by reference from the discussion under the headings "Compensation Discussion and Analysis", "Summary Compensation Table", "All Other Compensation" table, "Grants of Plan-Based Awards" table, "Outstanding Equity Awards" table, "Option Exercises and Stock Vested" table, "Pension Benefits" table, "Nonqualified Deferred Compensation" table, Potential Payments Upon Termination or a Change in Control, including the discussion under the subheadings "Separation" and "Change in Control", as well as all footnote information to the various tables, of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 28, 2019.

The required information on director compensation is incorporated by reference from the discussion under the heading "Director Compensation" and related "Director Compensation" table and "Schedule of Director Fees" table of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 28, 2019.

The required information under the headings "Compensation and Benefits Committee Interlocks and Insider Participation" and "Compensation and Benefits Committee Report" is incorporated by reference from the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 28, 2019.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information with respect to security ownership of certain beneficial owners and management is incorporated by reference from the discussion under the heading "Stock Ownership Information" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 28, 2019.

Equity Compensation Plan Information

The following table summarizes information about the options, warrants and rights and other equity compensation under the Company's equity compensation plans as of the close of business on December 31, 2018. The table does not include information about tax qualified plans such as the Merck U.S. Savings Plan.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders[1]	23,807,101[2]	$ 51.89	110,977,283
Equity compensation plans not approved by security holders	—	—	—
Total	23,807,101	$ 51.89	110,977,283

(1) *Includes options to purchase shares of Company Common Stock and other rights under the following shareholder-approved plans: the Merck Sharp & Dohme 2004, 2007 and 2010 Incentive Stock Plans, the Merck & Co., Inc. 2006 and 2010 Non-Employee Directors Stock Option Plans, and the Merck & Co., Inc. Schering-Plough 2002 and 2006 Stock Incentive Plans.*

(2) *Excludes approximately 16,128,455 shares of restricted stock units and 2,039,065 performance share units (assuming maximum payouts) under the Merck Sharp & Dohme 2004, 2007 and 2010 Incentive Stock Plans. Also excludes 224,599 shares of phantom stock deferred under the MSD Employee Deferral Program and 582,155 shares of phantom stock deferred under the Merck & Co., Inc. Plan for Deferred Payment of Directors' Compensation.*

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The required information on transactions with related persons is incorporated by reference from the discussion under the heading "Related Person Transactions" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 28, 2019.

The required information on director independence is incorporated by reference from the discussion under the heading "Independence of Directors" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 28, 2019.

Item 14. Principal Accountant Fees and Services.

The information required for this item is incorporated by reference from the discussion under Proposal 4. Ratification of Appointment of Independent Registered Public Accounting Firm for 2019 beginning with the caption "Pre-Approval Policy for Services of Independent Registered Public Accounting Firm" through "Fees for Services Provided by the Independent Registered Public Accounting Firm" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 28, 2019.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this Form 10-K

1. Financial Statements

Consolidated statement of income for the years ended December 31, 2018, 2017 and 2016

Consolidated statement of comprehensive income for the years ended December 31, 2018, 2017 and 2016

Consolidated balance sheet as of December 31, 2018 and 2017

Consolidated statement of equity for the years ended December 31, 2018, 2017 and 2016

Consolidated statement of cash flows for the years ended December 31, 2018, 2017 and 2016

Notes to consolidated financial statements

Report of PricewaterhouseCoopers LLP, independent registered public accounting firm

2. Financial Statement Schedules

Schedules are omitted because they are either not required or not applicable.

Financial statements of affiliates carried on the equity basis have been omitted because, considered individually or in the aggregate, such affiliates do not constitute a significant subsidiary.

3. Exhibits

Exhibit Number		Description
3.1	—	Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) — Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
3.2	—	By-Laws of Merck & Co., Inc. (effective July 22, 2015) — Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed July 28, 2015 (No. 1-6571)
4.1	—	Indenture, dated as of April 1, 1991, between Merck Sharp & Dohme Corp. (f/k/a Schering Corporation) and U.S. Bank Trust National Association (as successor to Morgan Guaranty Trust Company of New York), as Trustee (the 1991 Indenture) — Incorporated by reference to Exhibit 4 to MSD's Registration Statement on Form S-3 (No. 33-39349)
4.2	—	First Supplemental Indenture to the 1991 Indenture, dated as of October 1, 1997 — Incorporated by reference to Exhibit 4(b) to MSD's Registration Statement on Form S-3 filed September 25, 1997 (No. 333-36383)
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4.10	—	Long-term debt instruments under which the total amount of securities authorized does not exceed 10% of Merck & Co., Inc.'s total consolidated assets are not filed as exhibits to this report. Merck & Co., Inc. will furnish a copy of these agreements to the Securities and Exchange Commission on request.
*10.1	—	Merck & Co., Inc. Executive Incentive Plan (as amended and restated effective June 1, 2015) — Incorporated by reference to Merck & Co., Inc.'s Schedule 14A filed April 13, 2015 (No. 1-6571)
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*10.22	—	Retirement Plan for the Directors of Merck & Co., Inc. (amended and restated June 21, 1996) — Incorporated by reference to Exhibit 10.C to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1996 filed August 13, 1996 (No. 1-3305)
*10.23	—	Merck & Co., Inc. Plan for Deferred Payment of Directors' Compensation (effective as amended and restated as of January 1, 2018) — Incorporated by reference to Exhibit 10.24 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2017 filed February 27, 2018 (No. 1-6571)
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10.28	—	Offer Letter between Merck & Co., Inc. and Jennifer Zachary, dated March 16, 2018
21	—	Subsidiaries of Merck & Co., Inc.
23	—	Consent of Independent Registered Public Accounting Firm
24.1	—	Power of Attorney
24.2	—	Certified Resolution of Board of Directors

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31.1	—	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
31.2	—	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer
32.1	—	Section 1350 Certification of Chief Executive Officer
32.2	—	Section 1350 Certification of Chief Financial Officer
101	—	The following materials from Merck & Co., Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2018, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statement of Income, (ii) the Consolidated Statement of Comprehensive Income, (iii) the Consolidated Balance Sheet, (iv) the Consolidated Statement of Equity, (v) the Consolidated Statement of Cash Flows, and (vi) Notes to Consolidated Financial Statements.

* *Management contract or compensatory plan or arrangement.*

† *Certain portions of the exhibit have been omitted pursuant to a request for confidential treatment. The non-public information has been filed separately with the Securities and Exchange Commission pursuant to rule 24b-2 under the Securities Exchange Act of 1934, as amended.*

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: February 27, 2019

MERCK & CO., INC.

By: KENNETH C. FRAZIER
(Chairman, President and Chief Executive Officer)

By: /s/ JENNIFER ZACHARY
Jennifer Zachary
(Attorney-in-Fact)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signatures	Title	Date
KENNETH C. FRAZIER	Chairman, President and Chief Executive Officer; Principal Executive Officer; Director	February 27, 2019
ROBERT M. DAVIS	Executive Vice President, Global Services, and Chief Financial Officer; Principal Financial Officer	February 27, 2019
RITA A. KARACHUN	Senior Vice President Finance-Global Controller; Principal Accounting Officer	February 27, 2019
LESLIE A. BRUN	Director	February 27, 2019
THOMAS R. CECH	Director	February 27, 2019
PAMELA J. CRAIG	Director	February 27, 2019
THOMAS H. GLOCER	Director	February 27, 2019
ROCHELLE B. LAZARUS	Director	February 27, 2019
JOHN H. NOSEWORTHY	Director	February 27, 2019
PAUL B. ROTHMAN	Director	February 27, 2019
PATRICIA F. RUSSO	Director	February 27, 2019
INGE G. THULIN	Director	February 27, 2019
WENDELL P. WEEKS	Director	February 27, 2019
PETER C. WENDELL	Director	February 27, 2019

Jennifer Zachary, by signing her name hereto, does hereby sign this document pursuant to powers of attorney duly executed by the persons named, filed with the Securities and Exchange Commission as an exhibit to this document, on behalf of such persons, all in the capacities and on the date stated, such persons including a majority of the directors of the Company.

By: /S/ JENNIFER ZACHARY
Jennifer Zachary
(Attorney-in-Fact)

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* *Management contract or compensatory plan or arrangement.*

† *Certain portions of the exhibit have been omitted pursuant to a request for confidential treatment. The non-public information has been filed separately with the Securities and Exchange Commission pursuant to rule 24b-2 under the Securities Exchange Act of 1934, as amended.*

10-K 1 mrk1231201710k.htm 2017 FORM 10-K
As filed with the Securities and Exchange Commission on February 27, 2018

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549

FORM 10-K

(MARK ONE)

☒ **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the Fiscal Year Ended December 31, 2017

or

☐ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the transition period from _____ to _____

Commission File No. 1-6571

Merck & Co., Inc.

2000 Galloping Hill Road
Kenilworth, N. J. 07033
(908) 740-4000

Incorporated in New Jersey — *I.R.S. Employer Identification No. 22-1918501*

Securities Registered pursuant to Section 12(b) of the Act:

Title of Each Class	*Name of Each Exchange on which Registered*
Common Stock ($0.50 par value)	New York Stock Exchange
1.125% Notes due 2021	New York Stock Exchange
0.500% Notes due 2024	New York Stock Exchange
1.875% Notes due 2026	New York Stock Exchange
2.500% Notes due 2034	New York Stock Exchange
1.375% Notes due 2036	New York Stock Exchange

Number of shares of Common Stock ($0.50 par value) outstanding as of January 31, 2018: 2,696,190,502.

Aggregate market value of Common Stock ($0.50 par value) held by non-affiliates on June 30, 2017 based on closing price on June 30, 2017: $174,700,000,000.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. **Yes** ☒ **No** ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. **Yes** ☐ **No** ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. **Yes** ☒ **No** ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). **Yes** ☒ **No** ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check One):

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

Documents Incorporated by Reference:

Document	*Part of Form 10-K*
Proxy Statement for the Annual Meeting of Shareholders to be held May 22, 2018, to be filed with the	Part III

Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this report

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PART I

Item 1. Business.

Merck & Co., Inc. (Merck or the Company) is a global health care company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies and animal health products. The Company's operations are principally managed on a products basis and include four operating segments, which are the Pharmaceutical, Animal Health, Healthcare Services and Alliances segments. The Pharmaceutical segment is the only reportable segment.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities.

The Company also has an Animal Health segment that discovers, develops, manufactures and markets animal health products, including vaccines, which the Company sells to veterinarians, distributors and animal producers. The Company's Healthcare Services segment provides services and solutions that focus on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company was incorporated in New Jersey in 1970.

For financial information and other information about the Company's segments, see Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Item 8. "Financial Statements and Supplementary Data" below.

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Product Sales

Total Company sales, including sales of the Company's top pharmaceutical products, as well as total sales of animal health products, were as follows:

($ in millions)	**2017**	2016	2015
Total Sales	**$ 40,122**	$ 39,807	$ 39,498
Pharmaceutical	**35,390**	35,151	34,782
Januvia/Janumet	**5,896**	6,109	6,014
Keytruda	**3,809**	1,402	566
Gardasil/Gardasil 9	**2,308**	2,173	1,908
Zetia/Vytorin	**2,095**	3,701	3,777
ProQuad/M-M-R II/*Varivax*	**1,676**	1,640	1,505
Zepatier	**1,660**	555	—
Isentress/Isentress HD	**1,204**	1,387	1,511
Remicade	**837**	1,268	1,794
Pneumovax 23	**821**	641	542
Simponi	**819**	766	690
Animal Health	**3,875**	3,478	3,331
Other Revenues[1]	**857**	1,178	1,385

[1] *Other revenues are primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, and third-party manufacturing sales.*

Pharmaceutical

The Company's pharmaceutical products include therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. Certain of the products within the Company's franchises are as follows:

Primary Care and Women's Health

Cardiovascular: *Zetia* (ezetimibe) (marketed as *Ezetrol* in most countries outside the United States); *Vytorin* (ezetimibe/simvastatin) (marketed as *Inegy* outside the United States); and *Atozet* (ezetimibe and atorvastatin) (marketed in certain countries outside of the United States), cholesterol modifying medicines; and Adempas (riociguat), a cardiovascular drug for the treatment of pulmonary arterial hypertension.

Diabetes: *Januvia* (sitagliptin) and *Janumet* (sitagliptin/metformin HCl) for the treatment of type 2 diabetes.

General Medicine and Women's Health: *NuvaRing* (etonogestrel/ethinyl estradiol vaginal ring), a vaginal contraceptive product*; Implanon* (etonogestrel implant), a single-rod subdermal contraceptive implant/*Nexplanon* (etonogestrel implant), a single, radiopaque, rod-shaped subdermal contraceptive implant; and *Follistim AQ* (follitropin beta injection) (marketed as *Puregon* in most countries outside the United States), a fertility treatment.

Hospital and Specialty

Hepatitis: *Zepatier* (elbasvir and grazoprevir) for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype (GT) 1 or GT4 infection, with ribavirin in certain patient populations.

HIV: *Isentress/Isentress HD* (raltegravir), an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection.

Hospital Acute Care: *Bridion* (sugammadex) Injection, a medication for the reversal of two types of neuromuscular blocking agents used during surgery; *Noxafil* (posaconazole) for the prevention of invasive fungal infections; *Invanz* (ertapenem sodium) for the treatment of certain infections; *Cancidas* (caspofungin acetate), an anti-fungal product; *Cubicin (*daptomycin for injection), an I.V. antibiotic for complicated skin and skin structure infections or bacteremia, when caused by designated susceptible organisms; and *Primaxin* (imipenem and cilastatin sodium), an anti-bacterial product.

Immunology: *Remicade* (infliximab), a treatment for inflammatory diseases; and *Simponi* (golimumab), a once-monthly subcutaneous treatment for certain inflammatory diseases, which the Company markets in Europe, Russia and Turkey.

Oncology

Keytruda (pembrolizumab), the Company's anti-PD-1 (programmed death receptor-1) therapy, as monotherapy for the treatment of certain patients with non-small-cell lunch cancer (NSCLC), melanoma, classical Hodgkin Lymphoma (cHL), urothelial carcinoma, head and neck squamous cell carcinoma (HNSCC), gastric or gastroesophageal junction adenocarcinoma, and microsatellite instability-high (MSI-H) or mismatch repair deficient cancer, and in combination with pemetrexed and carboplatin in certain patients with NSCLC; *Emend* (aprepitant) for the prevention of chemotherapy-induced and post-operative nausea and vomiting; and *Temodar* (temozolomide) (marketed as *Temodal* outside the United States), a treatment for certain types of brain tumors.

Diversified Brands

Respiratory: *Singulair* (montelukast), a medicine indicated for the chronic treatment of asthma and the relief of symptoms of allergic rhinitis; *Nasonex* (mometasone furoate monohydrate), an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms; and *Dulera* Inhalation Aerosol (mometasone furoate/formoterol fumarate dihydrate), a combination medicine for the treatment of asthma.

Other: *Cozaar* (losartan potassium) and *Hyzaar* (losartan potassium and hydrochlorothiazide), treatments for hypertension; *Arcoxia* (etoricoxib) for the treatment of arthritis and pain, which the Company markets outside the United States; and *Fosamax* (alendronate sodium) (marketed as *Fosamac* in Japan) for the treatment and prevention of osteoporosis.

Vaccines

Gardasil (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant)/ *Gardasil* 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), vaccines to help prevent certain diseases caused by certain types of human papillomavirus (HPV); *ProQuad* (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella; *M-M-R* II (Measles, Mumps and Rubella Virus Vaccine Live), a vaccine to help prevent measles, mumps and rubella; *Varivax* (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox (varicella); *Pneumovax* 23 (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease; *RotaTeq* (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children; and *Zostavax* (Zoster Vaccine Live), a vaccine to help prevent shingles (herpes zoster).

Animal Health

The Animal Health segment discovers, develops, manufactures and markets animal health products, including vaccines. Principal products in this segment include:

Livestock Products: *Nuflor* (Florfenicol) antibiotic range for use in cattle and swine; *Bovilis*/*Vista* vaccine lines for infectious diseases in cattle; *Banamine* (Flunixin meglumine) bovine and swine anti-inflammatory; *Estrumate* (cloprostenol sodium) for the treatment of fertility disorders in cattle; *Matrix* (altrenogest) fertility management for swine; *Resflor* (florfenicol and flunixin meglumine), a combination broad-spectrum antibiotic and non-steroidal anti-inflammatory drug for bovine respiratory disease; *Zuprevo* (Tildipirosin) for bovine respiratory disease; *Zilmax* (zilpaterol hydrochloride) and *Revalor* (trenbolone acetate and estradiol) to improve production efficiencies in beef cattle; *Safe-Guard* (fenbendazole) de-wormer for cattle; *M+Pac* (Mycoplasma Hyopneumoniae Bacterin) swine pneumonia vaccine; and *Porcilis* (Lawsonia intracellularis baterin) and *Circumvent* (Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector) vaccine lines for infectious diseases in swine.

Poultry Products: *Nobilis*/*Innovax* (Live Marek's Disease Vector), vaccine lines for poultry; *Paracox* and *Coccivac* coccidiosis vaccines and *Exzolt*, a systemic treatment for poultry red mite infestations.

Companion Animal Products: *Bravecto* (fluralaner), a line of oral and topical products that kills fleas and ticks in dogs and cats for up to 12 weeks; *Nobivac* vaccine lines for flexible dog and cat vaccination; *Otomax* (Gentamicin sulfate, USP; Betamethasone valerate USP; and Clotrimazole USP ointment)/*Mometamax* (Gentamicin sulfate, USP, Mometasone Furoate Monohydrate and Clotrimazole, USP, Otic Suspension)/*Posatex* (Orbifloxacin, Mometasone Furoate Monohydrate and Posaconazole, Suspension) ear ointments for acute and chronic otitis; *Caninsulin*/*Vetsulin* (porcine insulin zinc suspension) diabetes mellitus treatment for dogs and cats; *Panacur* (fenbendazole)/*Safeguard* (fenbendazole) broad-spectrum anthelmintic (de-wormer) for use in many animals; *Regumate* (altrenogest) fertility management for horses; *Prestige* vaccine line for horses; and *Activyl* (Indoxacrb)/ *Scalibor* (Deltamethrin)/*Exspot* for protecting against bites from fleas, ticks, mosquitoes and sandflies.

Aquaculture Products: *Slice* (Emamectin benzoate) parasiticide for sea lice in salmon; *Aquavac* (Avirulent Live Culture)/*Norvax* vaccines against bacterial and viral disease in fish; *Compact PD* vaccine for salmon; and *Aquaflor* (Florfenicol) antibiotic for farm-raised fish.

For a further discussion of sales of the Company's products, see Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" below.

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2017 Product Approvals

Set forth below is a summary of significant product approvals received by the Company in 2017.

Product	Date	Approval
Keytruda	December 2017	Japanese Ministry of Health, Labour and Welfare approved *Keytruda* for the treatment of patients with radically unresectable urothelial carcinoma who progressed after cancer chemotherapy.
	September 2017	The U.S. Food and Drug Administration (FDA) approved *Keytruda* for previously treated patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction cancer whose tumors express PD-L1.
	September 2017	The European Commission (EC) approved *Keytruda* for the treatment of certain patients with locally advanced or metastatic urothelial carcinoma, a type of bladder cancer.
	May 2017	FDA approved *Keytruda* for the treatment of adult and pediatric patients with previously treated unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient, solid tumors.
	May 2017	FDA approved *Keytruda* for the treatment of certain patients with locally advanced or metastatic urothelial carcinoma, a type of bladder cancer.
	May 2017	FDA approved *Keytruda* in combination with pemetrexed and carboplatin for the first-line treatment of patients with metastatic nonsquamous NSCLC.
	May 2017	EC approved *Keytruda* for the treatment of adult patients with relapsed or refractory classical Hodgkin Lymphoma (cHL) who have failed autologous stem cell transplant (ASCT) and brentuximab vedotin (BV), or who are transplant-eligible and have failed BV.
	March 2017	FDA approved *Keytruda* for the treatment of adult and pediatric patients with refractory cHL, or who have relapsed after three or more prior lines of therapy.
	January 2017	EC approved *Keytruda* for the first-line treatment of metastatic NSCLC in adults whose tumors have high PD-L1 expression with no EGFR or ALK positive tumor mutations.
Lynparza[(1)]	August 2017	FDA approved the oral poly (ADP-ribose) polymerase (PARP) inhibitor, Lynparza (olaparib), as follows: • New use of Lynparza as a maintenance treatment for recurrent, epithelial ovarian, fallopian tube or primary peritoneal adult cancer who are in response to platinum-based chemotherapy, regardless of BRCA status; • New use of Lynparza tablets (2 tablets twice daily) as opposed to capsules (8 capsules twice daily); • Lynparza tablets also now indicated for the use in patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer, who have been treated with three or more prior lines of chemotherapy.
Isentress	November 2017	FDA approved *Isentress* for use in combination with other antiretroviral agents for the treatment of HIV-1 in neonates - newborn patients from birth to four weeks of age - weighing at least 2 kg.

Isentress HD	July 2017	EC approved *Isentress* 600 mg film-coated tablets, in combination with other anti-retroviral medicinal products, as a once-daily treatment of HIV-1 infection in patients who are treatment-naïve or who are virologically suppressed on an initial regimen of *Isentress* 400 mg twice daily.
	May 2017	FDA approved *Isentress HD*, a once-daily dose of *Isentress*, in combination with other antiretroviral agents, for the treatment of HIV-1 infection patients who are treatment-naïve or whose virus has been suppressed on an initial regimen of *Isentress* 400 mg given twice daily.
Prevymis	November 2017	FDA approved *Prevymis* (letermovir) for prophylaxis (prevention) of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).
Steglatro/ Steglujan/ Segluromet[(2)]	December 2017	FDA approved *Steglatro* (ertugliflozin) tablets, an oral sodium-glucose cotransporter 2 (SGLT2) inhibitor, the fixed-dose combination *Steglujan* (ertugliflozin and sitagliptin) tablets, and the fixed-dose combination *Segluromet* (ertugliflozin and metformin hydrochloride) for the treatment of type 2 diabetes.

[(1)] *In July 2017, Merck and AstraZeneca entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza for multiple cancer types.*

[(2)] *In 2013, Merck and Pfizer Inc. announced that they entered into a worldwide collaboration, except Japan, for the co-development and co-promotion of ertugliflozin.*

Competition and the Health Care Environment

Competition

The markets in which the Company conducts its business and the pharmaceutical industry in general are highly competitive and highly regulated. The Company's competitors include other worldwide research-based pharmaceutical companies, smaller research companies with more limited therapeutic focus, generic drug manufacturers and animal health care companies. The Company's operations may be adversely affected by generic and biosimilar competition as the Company's products mature, as well as technological advances of competitors, industry consolidation, patents granted to competitors, competitive combination products, new products of competitors, the generic availability of competitors' branded products, and new information from clinical trials of marketed products or post-marketing surveillance. In addition, patent rights are increasingly being challenged by competitors, and the outcome can be highly uncertain. An adverse result in a patent dispute can preclude commercialization of products or negatively affect sales of existing products and could result in the payment of royalties or in the recognition of an impairment charge with respect to intangible assets associated with certain products. Competitive pressures have intensified as pressures in the industry have grown.

Pharmaceutical competition involves a rigorous search for technological innovations and the ability to market these innovations effectively. With its long-standing emphasis on research and development, the Company is well positioned to compete in the search for technological innovations. Additional resources required to meet market challenges include quality control, flexibility to meet customer specifications, an efficient distribution system and a strong technical information service. The Company is active in acquiring and marketing products through external alliances, such as licensing arrangements and collaborations, and has been refining its sales and marketing efforts to further address changing industry conditions. However, the introduction of new products and processes by competitors may result in price reductions and product displacements, even for products protected by patents. For example, the number of compounds available to treat a particular disease typically increases over time and can result in slowed sales growth or reduced sales for the Company's products in that therapeutic category.

The highly competitive animal health business is affected by several factors including regulatory and legislative issues, scientific and technological advances, product innovation, the quality and price of the Company's products, effective promotional efforts and the frequent introduction of generic products by competitors.

Health Care Environment and Government Regulation

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access. In the United States, federal and state governments for many years also have pursued methods to reduce the cost of drugs and vaccines for which they pay. For example, federal laws require the Company to pay specified rebates for medicines reimbursed by Medicaid and to provide discounts for outpatient medicines purchased by certain Public Health Service entities and hospitals serving a disproportionate share of low income or uninsured patients.

Against this backdrop, the United States enacted major health care reform legislation in 2010 (the Patient Protection and Affordable Care Act (ACA)). Various insurance market reforms have since advanced and state and federal insurance exchanges were launched in 2014. With respect to the effect of the law on the pharmaceutical industry, the law increased the mandated Medicaid rebate from 15.1% to 23.1%, expanded the rebate to Medicaid managed care utilization, and increased the types of entities eligible for the federal 340B drug discount program. The law also requires pharmaceutical manufacturers to pay a 50% point of service discount to Medicare Part D beneficiaries when they are in the Medicare Part D coverage gap (i.e., the so-called "donut hole"). Approximately $385 million, $415 million and $550 million was recorded by Merck as a reduction to revenue in 2017, 2016 and 2015, respectively, related to the donut hole provision. Beginning in 2019, the 50% point of service discount will increase to a 70% point of service discount in the coverage gap, as a result of the Balanced Budget Act of 2018. In addition, the 70% point of service discount will be extended to biosimilar products. Also, pharmaceutical manufacturers are now required to pay an annual non-tax deductible health care reform fee. The total annual industry fee was $4.0 billion in 2017 and will increase to $4.1 billion in 2018. The annual fee will decline to $2.8 billion in 2019 and is currently planned to remain at that amount thereafter. The fee is assessed on each company in proportion to its share of prior year branded pharmaceutical sales to certain government programs, such as Medicare and Medicaid. The Company recorded $210 million, $193 million and $173 million of costs within *Marketing and administrative* expenses in 2017, 2016 and 2015, respectively, for the annual health care reform fee. In February 2016, the Centers for Medicare & Medicaid Services (CMS) issued the Medicaid rebate final rule that implements provisions of the ACA effective April 1, 2016. The rule provides comprehensive guidance on the calculation of Average Manufacturer Price and Best Price; two metrics utilized to determine the rebates drug manufacturers are required to pay to state Medicaid programs. The impact of changes resulting from the issuance of the rule is not material to Merck at this time. However, the Company is still awaiting guidance from CMS on two aspects of the rule that were deferred for later implementation. These include a definition of what constitutes a product 'line extension' and a delay in the participation of the U.S. Territories in the Medicaid Drug Rebate Program until April 1, 2020. The Company will evaluate the financial impact of these two elements when they become effective.

There is significant uncertainty about the future of the ACA in particular and health care laws in general in the United States. The Company is participating in the debate and monitoring how any proposed changes could affect its business. The Company is unable to predict the likelihood of changes to the ACA. Depending on the nature of any repeal and replacement of the ACA, such actions could have a material adverse effect on the Company's results of operations, financial condition or business.

Also, during 2016, the Vermont legislature passed a pharmaceutical cost transparency law. The law requires manufacturers identified by the Vermont Green Mountain Care Board to report certain product price information to the Vermont Attorney General. The Attorney General is then required to submit a report to the legislature. During 2017, Nevada and California passed similar price transparency bills requiring manufacturers to disclose certain pricing information and to provide advance notification of price increases. A number of other states have introduced legislation of this kind and the Company expects that states will continue their focus on pharmaceutical price transparency. The extent to which these proposals will pass into law is unknown at this time.

The Company also faces increasing pricing pressure globally from managed care organizations, government agencies and programs that could negatively affect the Company's sales and profit margins. In the United States, these include (i) practices of managed care organizations, federal and state exchanges, and institutional and governmental purchasers, and (ii) U.S. federal laws and regulations related to Medicare and Medicaid, including the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and the ACA.

Changes to the health care system enacted as part of health care reform in the United States, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries,

could result in further pricing pressures. As an example, health care reform is contributing to an increase in the number of patients in the Medicaid program under which sales of pharmaceutical products are subject to substantial rebates.

In addition, in the effort to contain the U.S. federal deficit, the pharmaceutical industry could be considered a potential source of savings via legislative proposals that have been debated but not enacted. These types of revenue generating or cost saving proposals include additional direct price controls in the Medicare prescription drug program (Part D). In addition, Congress may again consider proposals to allow, under certain conditions, the importation of medicines from other countries. It remains very uncertain as to what proposals, if any, may be included as part of future federal budget deficit reduction proposals that would directly or indirectly affect the Company.

In the U.S. private sector, consolidation and integration among health care providers is a major factor in the competitive marketplace for pharmaceutical products. Health plans and pharmacy benefit managers have been consolidating into fewer, larger entities, thus enhancing their purchasing strength and importance. Private third-party insurers, as well as governments, increasingly employ formularies to control costs by negotiating discounted prices in exchange for formulary inclusion. Failure to obtain timely or adequate pricing or formulary placement for Merck's products or obtaining such pricing or placement at unfavorable pricing could adversely impact revenue. In addition to formulary tier co-pay differentials, private health insurance companies and self-insured employers have been raising co-payments required from beneficiaries, particularly for branded pharmaceuticals and biotechnology products. Private health insurance companies also are increasingly imposing utilization management tools, such as clinical protocols, requiring prior authorization for a branded product if a generic product is available or requiring the patient to first fail on one or more generic products before permitting access to a branded medicine. These same utilization management tools are also used in treatment areas in which the payer has taken the position that multiple branded products are therapeutically comparable. As the U.S. payer market concentrates further and as more drugs become available in generic form, pharmaceutical companies may face greater pricing pressure from private third-party payers.

In order to provide information about the Company's pricing practices, the Company recently posted on its website its Pricing Action Transparency Report for the United States for the years 2010 - 2017. The report provides the Company's average annual list price and net price increases across the Company's U.S. portfolio dating back to 2010. The report shows that the Company's average annual net price increases (after taking sales deductions such as rebates, discounts and returns into account) across the U.S. human health portfolio have been in the low to mid-single digits from 2010 - 2016. In 2017, the average net price across the Company's portfolio declined by 1.9%, reflecting specific in-year dynamics, including the impact of loss of patent protection for three major Merck medicines. Additionally, the weighted average annual discount rate has been steadily increasing over time, reflecting the competitive market for branded medicines and the impact of the ACA. In 2017, the Company's gross U.S. sales were reduced by 45.1% as a result of rebates, discounts and returns.

Efforts toward health care cost containment also remain intense in European countries. The Company faces competitive pricing pressure resulting from generic and biosimilar drugs. In addition, a majority of countries in Europe attempt to contain drug costs by engaging in reference pricing in which authorities examine pre-determined markets for published prices of drugs by brand. The authorities then use price data from those markets to set new local prices for brand-name drugs, including the Company's. Guidelines for examining reference pricing are usually set in local markets and can be changed pursuant to local regulations.

In addition, in Japan, the pharmaceutical industry is subject to government-mandated biennial price reductions of pharmaceutical products and certain vaccines, which will occur again in 2018. Furthermore, the government can order repricings for classes of drugs if it determines that it is appropriate under applicable rules.

Certain markets outside of the United States have also implemented other cost management strategies, such as health technology assessments (HTA), which require additional data, reviews and administrative processes, all of which increase the complexity, timing and costs of obtaining product reimbursement and exert downward pressure on available reimbursement. In the United States, HTAs are also being used by government and private payers.

The Company's focus on emerging markets has continued. Governments in many emerging markets are also focused on constraining health care costs and have enacted price controls and related measures, such as compulsory licenses, that aim to put pressure on the price of pharmaceuticals and constrain market access. The Company anticipates that pricing pressures and market access challenges will continue in 2018 to varying degrees in the emerging markets.

Beyond pricing and market access challenges, other conditions in emerging market countries can affect the Company's efforts to continue to grow in these markets, including potential political instability, significant currency fluctuation and controls, financial crises, limited or changing availability of funding for health care, and other developments that may adversely impact the business environment for the Company. Further, the Company may engage third-party agents to assist in operating in emerging market countries, which may affect its ability to realize continued growth and may also increase the Company's risk exposure.

In addressing cost containment pressures, the Company engages in public policy advocacy with policymakers and continues to work to demonstrate that its medicines provide value to patients and to those who pay for health care. The Company advocates with government policymakers to encourage a long-term approach to sustainable health care financing that ensures access to innovative medicines and does not disproportionately target pharmaceuticals as a source of budget savings. In markets with historically low rates of health care spending, the Company encourages those governments to increase their investments and adopt market reforms in order to improve their citizens' access to appropriate health care, including medicines.

Operating conditions have become more challenging under the global pressures of competition, industry regulation and cost containment efforts. Although no one can predict the effect of these and other factors on the Company's business, the Company continually takes measures to evaluate, adapt and improve the organization and its business practices to better meet customer needs and believes that it is well positioned to respond to the evolving health care environment and market forces.

The pharmaceutical industry is also subject to regulation by regional, country, state and local agencies around the world focused on standards and processes for determining drug safety and effectiveness, as well as conditions for sale or reimbursement.

Of particular importance is the FDA in the United States, which administers requirements covering the testing, approval, safety, effectiveness, manufacturing, labeling, and marketing of prescription pharmaceuticals. In some cases, the FDA requirements and practices have increased the amount of time and resources necessary to develop new products and bring them to market in the United States. At the same time, the FDA has committed to expediting the development and review of products bearing the "breakthrough therapy" designation, which has accelerated the regulatory review process for medicines with this designation.

The European Union (EU) has adopted directives and other legislation concerning the classification, labeling, advertising, wholesale distribution, integrity of the supply chain, enhanced pharmacovigilance monitoring and approval for marketing of medicinal products for human use. These provide mandatory standards throughout the EU, which may be supplemented or implemented with additional regulations by the EU member states. The Company's policies and procedures are already consistent with the substance of these directives; consequently, it is believed that they will not have any material effect on the Company's business.

The Company believes that it will continue to be able to conduct its operations, including launching new drugs, in this regulatory environment. (See "Research and Development" below for a discussion of the regulatory approval process.)

Access to Medicines

As a global health care company, Merck's primary role is to discover and develop innovative medicines and vaccines. The Company also recognizes that it has an important role to play in helping to improve access to its products around the world. The Company's efforts in this regard are wide-ranging and include a set of principles that the Company strives to embed into its operations and business strategies to guide the Company's worldwide approach to expanding access to health care. In addition, the Company has many far-reaching philanthropic programs. The Merck Patient Assistance Program provides medicines and adult vaccines for free to people in the United States who do not have prescription drug or health insurance coverage and who, without the Company's assistance, cannot afford their Merck medicine and vaccines. In 2011, Merck launched "Merck for Mothers," a long-term effort with global health partners to end preventable deaths from complications of pregnancy and childbirth. Merck has also provided funds to the Merck Foundation, an independent organization, which has partnered with a variety of organizations dedicated to improving global health.

Privacy and Data Protection

The Company is subject to a significant number of privacy and data protection laws and regulations globally, many of which place restrictions on the Company's ability to transfer, access and use personal data across its business. The legislative and regulatory landscape for privacy and data protection continues to evolve. There has been increased attention to privacy and data protection issues in both developed and emerging markets with the potential to affect directly the Company's business, including a new EU General Data Protection Regulation, which will become effective in 2018 and impose penalties up to 4% of global revenue, additional laws and regulations enacted in the United States, Europe, Asia and Latin America, increased enforcement and litigation activity in the United States and other developed markets, and increased regulatory cooperation among privacy authorities globally. The Company has adopted a comprehensive global privacy program to manage these evolving risks which has been certified as compliant with and approved by the Asia Pacific Economic Cooperation Cross-Border Privacy Rules System, the EU-U.S. Privacy Shield Program, and the Binding Corporate Rules in the EU.

Distribution

The Company sells its human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers, such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccines are sold primarily to physicians, wholesalers, physician distributors and government entities. The Company's professional representatives communicate the effectiveness, safety and value of the Company's pharmaceutical and vaccine products to health care professionals in private practice, group practices, hospitals and managed care organizations. The Company sells its animal health products to veterinarians, distributors and animal producers.

Raw Materials

Raw materials and supplies, which are generally available from multiple sources, are purchased worldwide and are normally available in quantities adequate to meet the needs of the Company's business.

Patents, Trademarks and Licenses

Patent protection is considered, in the aggregate, to be of material importance to the Company's marketing of its products in the United States and in most major foreign markets. Patents may cover products *per se*, pharmaceutical formulations, processes for or intermediates useful in the manufacture of products or the uses of products. Protection for individual products extends for varying periods in accordance with the legal life of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent and its scope of coverage.

The Food and Drug Administration Modernization Act includes a Pediatric Exclusivity Provision that may provide an additional six months of market exclusivity in the United States for indications of new or currently marketed drugs if certain agreed upon pediatric studies are completed by the applicant. Current U.S. patent law provides additional patent term for periods when the patented product was under regulatory review by the FDA. The EU also provides an additional six months of pediatric market exclusivity attached to a product's Supplementary Protection Certificate (SPC). Japan provides the additional term for pediatric studies attached to market exclusivity unrelated to patent rights.

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Patent portfolios developed for products introduced by the Company normally provide market exclusivity. The Company has the following key patent protection in the United States, the EU and Japan (including the potential for patent term extensions (PTE) and SPCs where indicated) for the following marketed products:

Product	Year of Expiration (U.S.)	Year of Expiration (EU)[1]	Year of Expiration (Japan)
Cancidas	Expired	Expired	2022
Zostavax	Expired	2018 (use)	N/A
Zetia	Expired	2018	2019
Vytorin	Expired	2019	2019
Asmanex	2018 (formulation)	2018 (formulation)	2020 (formulation)
NuvaRing	2018 (delivery system)	2018 (delivery system)	N/A
Emend for Injection	2019[2]	2020[2]	2020
Follistim AQ	2019 (formulation)	2019 (formulation)	2019 (formulation)
Noxafil	2019	2019	N/A
RotaTeq	2019	Expired	Expired
Recombivax	2020 (method of making)	Expired	Expired
Dulera	2020 (combination)	N/A	N/A
Januvia	2022[2]	2022[2]	2025-2026[3]
Janumet	2022[2]	2023	N/A
Janumet XR	2022[2]	N/A	N/A
Isentress	2024	2022[2]	2022
Simponi	N/A[4]	2024	N/A[4]
Adempas[5]	2026[2]	2023 (patents), 2028[2] (SPCs)	2027-2028[3]
Bridion	2026[2] (with pending PTE)	2023	2024
Nexplanon	2027 (device)	2025 (device)	Not Marketed
Bravecto	2027 (with pending PTE)	2025 (patents), 2029 (SPCs)	2029
Gardasil	2028	2021[2]	2017
Gardasil 9	2028	2025 (patents), 2030[2] (SPCs)	N/A
Keytruda	2028	2028 (patents), 2030[2] (SPCs)	2032
Lynparza[6]	2028[2] (with pending PTE)	2024 (patents), 2029[2] (SPCs)	2024[7]
Zerbaxa	2028[2] (with pending PTE)	2023 (patents), 2028[2] (SPCs)	N/A
Sivextro	2028[2]	2024 (patents), 2029[2] (SPCs)	N/A
Belsomra	2029[2]	N/A	2031
Prevymis	2029[2] (with pending PTE)	2024[8]	N/A
Steglatro[9]	2031[2] (with pending PTE)	N/A	N/A
Steglujan[9]	2031 (with pending PTE)	N/A	N/A
Segluromet[9]	2031 (with pending PTE)	N/A	N/A
Zepatier	2031[2]	2030 (patents), 2031[2] (SPCs)	2034 (with pending PTE)

N/A: Currently no marketing approval.

Note: Compound patent unless otherwise noted. Certain of the products listed may be the subject of patent litigation. See Item 8. "Financial Statements and Supplementary Data," Note 11. "Contingencies and Environmental Liabilities" below.

(1) The EU date represents the expiration date for the following five countries: France, Germany, Italy, Spain and the United Kingdom (Major EU Markets). If an SPC has been granted in some but not all Major EU Markets, both the patent expiry date and the SPC expiry date are listed.

(2) Eligible for 6 months Pediatric Exclusivity.

(3) The PTE system in Japan allows for a patent to be extended more than once provided the later approval is directed to a different indication from that of the previous approval. This may result in multiple PTE approvals for a given patent, each with its own expiration date.

(4) The Company has no marketing rights in the U.S. and Japan.

(5) Being commercialized in a worldwide collaboration with Bayer AG.

(6) Being developed and commercialized in a global strategic oncology collaboration with AstraZeneca.

(7) PTE application to be filed by April 2018. Expected expiry 2029.

(8) SPC applications to be filed by July 2018. Expected expiry 2029. Eligible for Pediatric Exclusivity.

(9) Being developed and promoted in a worldwide, except Japan, collaboration with Pfizer.

While the expiration of a product patent normally results in a loss of market exclusivity for the covered pharmaceutical product, commercial benefits may continue to be derived from: (i) later-granted patents on processes and intermediates related to the most economical method of manufacture of the active ingredient of such product; (ii) patents relating to the use of such product; (iii) patents relating to novel compositions and formulations; and (iv) in

the United States and certain other countries, market exclusivity that may be available under relevant law. The effect of product patent expiration on pharmaceutical products also depends upon many other factors such as the nature of the market and the position of the product in it, the growth of the market, the complexities and economics of the process for manufacture of the active ingredient of the product and the requirements of new drug provisions of the Federal Food, Drug and Cosmetic Act or similar laws and regulations in other countries.

Additions to market exclusivity are sought in the United States and other countries through all relevant laws, including laws increasing patent life. Some of the benefits of increases in patent life have been partially offset by an increase in the number of incentives for and use of generic products. Additionally, improvements in intellectual property laws are sought in the United States and other countries through reform of patent and other relevant laws and implementation of international treaties.

The Company has the following key U.S. patent protection for drug candidates under review in the United States by the FDA. Additional patent term may be provided for these pipeline candidates based on Patent Term Restoration and Pediatric Exclusivity.

Under Review (in the U.S.)	Currently Anticipated Year of Expiration (in the U.S.)
V419 (pediatric hexavalent combination vaccine)	2020 (method of making)
MK-1439 (doravirine)	2031
MK-1439A (doravirine/lamivudine/tenofovir disoproxil fumarate)	2031

The Company also has the following key U.S. patent protection for drug candidates in Phase 3 development:

Phase 3 Drug Candidate	Currently Anticipated Year of Expiration (in the U.S.)
V920 (ebola vaccine)	2023
MK-5618 (selumetinib)[1]	2023
MK-7655A (relebactam + imipenem/cilastatin)	2030
MK-1242 (vericiguat)[2]	2031

(1) *Being developed and commercialized in a global strategic oncology collaboration with AstraZeneca.*

(2) *Being developed in a worldwide clinical development collaboration with Bayer AG.*

Unless otherwise noted, the patents in the above charts are compound patents. Each patent is subject to any future patent term restoration of up to five years and six month pediatric market exclusivity, either or both of which may be available. In addition, depending on the circumstances surrounding any final regulatory approval of the compound, there may be other listed patents or patent applications pending that could have relevance to the product as finally approved; the relevance of any such application would depend upon the claims that ultimately may be granted and the nature of the final regulatory approval of the product. Also, regulatory exclusivity tied to the protection of clinical data is complementary to patent protection and, in some cases, may provide more effective or longer lasting marketing exclusivity than a compound's patent estate. In the United States, the data protection generally runs five years from first marketing approval of a new chemical entity, extended to seven years for an orphan drug indication and 12 years from first marketing approval of a biological product.

For further information with respect to the Company's patents, see Item 1A. "Risk Factors" and Item 8. "Financial Statements and Supplementary Data," Note 11. "Contingencies and Environmental Liabilities" below.

Worldwide, all of the Company's important products are sold under trademarks that are considered in the aggregate to be of material importance. Trademark protection continues in some countries as long as used; in other countries, as long as registered. Registration is for fixed terms and can be renewed indefinitely.

Royalty income in 2017 on patent and know-how licenses and other rights amounted to $158 million. Merck also incurred royalty expenses amounting to $944 million in 2017 under patent and know-how licenses it holds.

Research and Development

The Company's business is characterized by the introduction of new products or new uses for existing products through a strong research and development program. At December 31, 2017, approximately 12,650 people

were employed in the Company's research activities. Research and development expenses were $10.2 billion in 2017,

$10.1 billion in 2016 and $6.7 billion in 2015 (which included restructuring costs and acquisition and divestiture-related costs in all years). The Company prioritizes its research and development efforts and focuses on candidates that it believes represent breakthrough science that will make a difference for patients and payers.

The Company maintains a number of long-term exploratory and fundamental research programs in biology and chemistry as well as research programs directed toward product development. The Company's research and development model is designed to increase productivity and improve the probability of success by prioritizing the Company's research and development resources on candidates the Company believes are capable of providing unambiguous, promotable advantages to patients and payers and delivering the maximum value of its approved medicines and vaccines through new indications and new formulations. Merck is pursuing emerging product opportunities independent of therapeutic area or modality (small molecule, biologics and vaccines) and is building its biologics capabilities. The Company is committed to ensuring that externally sourced programs remain an important component of its pipeline strategy, with a focus on supplementing its internal research with a licensing and external alliance strategy focused on the entire spectrum of collaborations from early research to late-stage compounds, as well as access to new technologies.

The Company also reviews its pipeline to examine candidates that may provide more value through out-licensing. The Company continues to evaluate certain late-stage clinical development and platform technology assets to determine their out-licensing or sale potential.

The Company's clinical pipeline includes candidates in multiple disease areas, including cancer, cardiovascular diseases, diabetes, infectious diseases, neurosciences, obesity, pain, respiratory diseases, and vaccines.

In the development of human health products, industry practice and government regulations in the United States and most foreign countries provide for the determination of effectiveness and safety of new chemical compounds through preclinical tests and controlled clinical evaluation. Before a new drug or vaccine may be marketed in the United States, recorded data on preclinical and clinical experience are included in the New Drug Application (NDA) for a drug or the Biologics License Application (BLA) for a vaccine or biologic submitted to the FDA for the required approval.

Once the Company's scientists discover a new small molecule compound or biologic that they believe has promise to treat a medical condition, the Company commences preclinical testing with that compound. Preclinical testing includes laboratory testing and animal safety studies to gather data on chemistry, pharmacology, immunogenicity and toxicology. Pending acceptable preclinical data, the Company will initiate clinical testing in accordance with established regulatory requirements. The clinical testing begins with Phase 1 studies, which are designed to assess safety, tolerability, pharmacokinetics, and preliminary pharmacodynamic activity of the compound in humans. If favorable, additional, larger Phase 2 studies are initiated to determine the efficacy of the compound in the affected population, define appropriate dosing for the compound, as well as identify any adverse effects that could limit the compound's usefulness. In some situations, the clinical program incorporates adaptive design methodology to use accumulating data to decide how to modify aspects of the ongoing clinical study as it continues, without undermining the validity and integrity of the trial. One type of adaptive clinical trial is an adaptive Phase 2a/2b trial design, a two-stage trial design consisting of a Phase 2a proof-of-concept stage and a Phase 2b dose-optimization finding stage. If data from the Phase 2 trials are satisfactory, the Company commences large-scale Phase 3 trials to confirm the compound's efficacy and safety. Another type of adaptive clinical trial is an adaptive Phase 2/3 trial design, a study that includes an interim analysis and an adaptation that changes the trial from having features common in a Phase 2 study (e.g. multiple dose groups) to a design similar to a Phase 3 trial. An adaptive Phase 2/3 trial design reduces timelines by eliminating activities which would be required to start a separate study. Upon completion of Phase 3 trials, if satisfactory, the Company submits regulatory filings with the appropriate regulatory agencies around the world to have the product candidate approved for marketing. There can be no assurance that a compound that is the result of any particular program will obtain the regulatory approvals necessary for it to be marketed.

Vaccine development follows the same general pathway as for drugs. Preclinical testing focuses on the vaccine's safety and ability to elicit a protective immune response (immunogenicity). Pre-marketing vaccine clinical trials are typically done in three phases. Initial Phase 1 clinical studies are conducted in normal subjects to evaluate the safety, tolerability and immunogenicity of the vaccine candidate. Phase 2 studies are dose-ranging studies. Finally, Phase 3 trials provide the necessary data on effectiveness and safety. If successful, the Company submits regulatory filings with the appropriate regulatory agencies.

In the United States, the FDA review process begins once a complete NDA or BLA is submitted, received and accepted for review by the agency. Within 60 days after receipt, the FDA determines if the application is sufficiently complete to permit a substantive review. The FDA also assesses, at that time, whether the application will be granted a priority review or standard review. Pursuant to the Prescription Drug User Fee Act V (PDUFA), the FDA review period target for NDAs or original BLAs is either six months, for priority review, or ten months, for a standard review, from the time the application is deemed sufficiently complete. Once the review timelines are determined, the FDA will generally act upon the application within those timelines, unless a major amendment has been submitted (either at the Company's own initiative or the FDA's request) to the pending application. If this occurs, the FDA may extend the review period to allow for review of the new information, but by no more than three months. Extensions to the review period are communicated to the Company. The FDA can act on an application either by issuing an approval letter or by issuing a Complete Response Letter (CRL) stating that the application will not be approved in its present form and describing all deficiencies that the FDA has identified. Should the Company wish to pursue an application after receiving a CRL, it can resubmit the application with information that addresses the questions or issues identified by the FDA in order to support approval. Resubmissions are subject to review period targets, which vary depending on the underlying submission type and the content of the resubmission.

The FDA has four program designations — Fast Track, Breakthrough Therapy, Accelerated Approval, and Priority Review — to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening conditions. The Fast Track designation provides pharmaceutical manufacturers with opportunities for frequent interactions with FDA reviewers during the product's development and the ability for the manufacturer to do a rolling submission of the NDA/BLA. A rolling submission allows completed portions of the application to be submitted and reviewed by the FDA on an ongoing basis. The Breakthrough Therapy designation provides manufacturers with all of the features of the Fast Track designation as well as intensive guidance on implementing an efficient development program for the product and a commitment by the FDA to involve senior managers and experienced staff in the review. The Accelerated Approval designation allows the FDA to approve a product based on an effect on a surrogate or intermediate endpoint that is reasonably likely to predict a product's clinical benefit and generally requires the manufacturer to conduct required post-approval confirmatory trials to verify the clinical benefit. The Priority Review designation means that the FDA's goal is to take action on the NDA/BLA within six months, compared to ten months under standard review.

In addition, under the Generating Antibiotic Incentives Now Act, the FDA may grant Qualified Infectious Disease Product (QIDP) status to antibacterial or antifungal drugs intended to treat serious or life threatening infections including those caused by antibiotic or antifungal resistant pathogens, novel or emerging infectious pathogens, or other qualifying pathogens. QIDP designation offers certain incentives for development of qualifying drugs, including Priority Review of the NDA when filed, eligibility for Fast Track designation, and a five-year extension of applicable exclusivity provisions under the Food, Drug and Cosmetic Act.

The primary method the Company uses to obtain marketing authorization of pharmaceutical products in the EU is through the "centralized procedure." This procedure is compulsory for certain pharmaceutical products, in particular those using biotechnological processes, and is also available for certain new chemical compounds and products. A company seeking to market an innovative pharmaceutical product through the centralized procedure must file a complete set of safety data and efficacy data as part of a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA). After the EMA evaluates the MAA, it provides a recommendation to the EC and the EC then approves or denies the MAA. It is also possible for new chemical products to obtain marketing authorization in the EU through a "mutual recognition procedure" in which an application is made to a single member state and, if the member state approves the pharmaceutical product under a national procedure, the applicant may submit that approval to the mutual recognition procedure of some or all other member states.

Outside of the United States and the EU, the Company submits marketing applications to national regulatory authorities. Examples of such are the Pharmaceuticals and Medical Devices Agency in Japan, Health Canada, Agência Nacional de Vigilância Sanatária in Brazil, Korea Food and Drug Administration in South Korea, Therapeutic Goods Administration in Australia and China Food and Drug Administration. Each country has a separate and independent review process and timeline. In many markets, approval times can be longer as the regulatory authority requires approval in a major market, such as the United States or the EU, and issuance of a Certificate of Pharmaceutical Product from that market before initiating their local review process.

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Research and Development Update

The Company currently has several candidates under regulatory review in the United States and internationally.

Keytruda is an approved anti-PD-1 therapy in clinical development for expanded indications in different cancer types.

In December 2017, the FDA accepted for review a supplemental BLA for *Keytruda* for the treatment of adult and pediatric patients with refractory primary mediastinal B-cell lymphoma (PMBCL), or who have relapsed after two or more prior lines of therapy. The FDA granted Priority Review status with a PDUFA, or target action, date of April 3, 2018.

Additionally, *Keytruda* has received Breakthrough Therapy designation from the FDA in combination with axitnib as a first-line treatment for patients with advanced or metastatic renal cell carcinoma; for the treatment of high-risk early-stage triple-negative breast cancer in combination with neoadjuvant chemotherapy; and for the treatment of Merkel cell carcinoma. Also, in January 2018, Merck and Eisai Co., Ltd. (Eisai) announced receipt of Breakthrough Therapy designation from the FDA for Eisai's multiple receptor tyrosine kinase inhibitor Lenvima (lenvatinib) in combination with *Keytruda* for the potential treatment of patients with advanced and/or metastatic renal cell carcinoma. The Lenvima and *Keytruda* combination therapy is being jointly developed by Eisai and Merck. This marks the 12th Breakthrough Therapy designation granted to *Keytruda*. The FDA's Breakthrough Therapy designation is intended to expedite the development and review of a candidate that is planned for use, alone or in combination, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

In January 2018, Merck announced that the pivotal Phase 3 KEYNOTE-189 trial investigating *Keytruda* in combination with pemetrexed (Alimta) and cisplatin or carboplatin, for the first-line treatment of patients with metastatic non-squamous NSCLC, met its dual primary endpoints of overall survival (OS) and progression-free survival (PFS). Based on an interim analysis conducted by the independent Data Monitoring Committee, treatment with *Keytruda* in combination with pemetrexed plus platinum chemotherapy resulted in significantly longer OS and PFS than pemetrexed plus platinum chemotherapy alone. Results from KEYNOTE-189 will be presented at an upcoming medical meeting and submitted to regulatory authorities.

In 2017, the FDA placed a full clinical hold on KEYNOTE-183 and KEYNOTE-185 and a partial clinical hold on Cohort 1 of KEYNOTE-023, three combination studies of *Keytruda* with lenalidomide or pomalidomide versus lenalidomide or pomalidomide alone in the blood cancer multiple myeloma. This decision followed a review of data by the Data Monitoring Committee in which more deaths were observed in the *Keytruda* arms of KEYNOTE-183 and KEYNOTE-185. The FDA determined that the data available at the time indicated that the risks of *Keytruda* plus pomalidomide or lenalidomide outweighed any potential benefit for patients with multiple myeloma. All patients enrolled in KEYNOTE-183 and KEYNOTE-185 and those in the *Keytruda*/lenalidomide/ dexamethasone cohort in KEYNOTE-023 have discontinued investigational treatment with *Keytruda*. This clinical hold does not apply to other studies with *Keytruda*.

The *Keytruda* clinical development program consists of more than 700 clinical trials, including more than 400 trials that combine *Keytruda* with other cancer treatments. These studies encompass more than 30 cancer types including: bladder, colorectal, esophageal, gastric, head and neck, hepatocellular, Hodgkin lymphoma, non-Hodgkin lymphoma, melanoma, nasopharyngeal, NSCLC, ovarian, PMBCL, prostate, renal, small-cell lung and triple-negative breast, many of which are currently in Phase 3 clinical development. Further trials are being planned for other cancers.

MK-8835, ertugliflozin, an investigational oral SGLT-2 inhibitor in development to help improve glycemic control in adults with type 2 diabetes, and two fixed-dose combination products (MK-8835A, ertugliflozin and *Januvia*, and MK-8835B, ertugliflozin and metformin) are under review in the EU. In January 2018, the Committee for Medicinal Products for Human Use (CHMP) of the EMA adopted a positive opinion recommending approval of these medicines. The CHMP positive opinion will be considered by the EC. Ertugliflozin and the two fixed-dose combination products were approved by the FDA in December 2017.

MK-0431J is an investigational fixed-dose combination of sitagliptin and ipragliflozin under review with the Japan Pharmaceuticals and Medical Devices Agency. MK-0431 is being developed for commercialization in Japan

in collaboration with Astellas Pharma Inc. (Astellas). Ipragliflozin, an SGLT2 inhibitor, co-developed by Astellas and Kotobuki Pharmaceutical Co., Ltd. (Kotobuki), is approved for use in Japan and is being co-promoted with Merck and Kotobuki.

MK-1439, doravirine, is an investigational, non-nucleoside reverse transcriptase inhibitor for the treatment of HIV-1 infection. In January 2018, Merck announced that the FDA accepted for review two NDAs for doravirine. The NDAs include data for doravirine as a once-daily tablet for use in combination with other antiretroviral agents, and for use of doravirine with lamivudine and tenofovir disoproxil fumarate in a once-daily fixed-dose combination single tablet as a complete regimen (MK-1439A). The PDUFA action date for both applications is October 23, 2018.

V419 is an investigational pediatric hexavalent combination vaccine, DTaP5-IPV-Hib-HepB, under review with the FDA that is being developed and, if approved, will be commercialized through a joint venture between Merck and Sanofi. This vaccine is designed to help protect against six important diseases - diphtheria, tetanus, pertussis (whooping cough), polio (poliovirus types 1, 2, and 3), invasive disease caused by *Haemophilus influenzae* type b (Hib), and hepatitis B. In November 2015, the FDA issued a CRL with respect to the BLA for V419. Both companies are working to provide additional data requested by the FDA. V419 is being marketed as *Vaxelis* in the EU.

In addition to the candidates under regulatory review, the Company has several drug candidates in Phase 3 clinical development in addition to the *Keytruda* programs discussed above.

MK-7655A is a combination of relebactam, an investigational beta-lactamase inhibitor, and imipenem/cilastatin (an approved carbapenem antibiotic). The FDA has designated this combination a QIDP with designated Fast Track status for the treatment of hospital-acquired bacterial pneumonia, ventilator-associated bacterial pneumonia, complicated intra-abdominal infections and complicated urinary tract infections.

MK-7339, Lynparza (olaparib), is an oral PARP inhibitor currently approved for certain types of ovarian and breast cancer. In July 2017, Merck and AstraZeneca entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza for multiple cancer types.

MK-5618, selumetinib, is an oral, potent, selective inhibitor of MEK, part of the mitogen-activated protein kinase (MAPK) pathway, currently being developed for multiple cancer types. Additionally, in February 2018, the FDA granted Orphan Drug designation for selumetinib for the treatment of neurofibromatosis type 1. The development of selumetinib is part of the global strategic oncology collaboration between Merck and AstraZeneca reference above.

V920 is an investigational rVSV-ZEBOV (Ebola) vaccine candidate being studied in large scale Phase 2/3 clinical trials. In November 2014, Merck and NewLink Genetics announced an exclusive licensing and collaboration agreement for the investigational Ebola vaccine. In December 2015, Merck announced that the application for Emergency Use Assessment and Listing (EUAL) for V920 was accepted for review by the World Health Organization (WHO). According to the WHO, the EUAL process is designed to expedite the availability of vaccines needed for public health emergencies such as another outbreak of Ebola. The decision to grant V920 EUAL status will be based on data regarding quality, safety, and efficacy/effectiveness; as well as a risk/benefit analysis for emergency use. While EUAL designation allows for emergency use, the vaccine remains investigational and has not yet been licensed for commercial distribution. In July 2016, Merck announced that the FDA granted V920 Breakthrough Therapy designation, and that the EMA granted the vaccine candidate PRIME (PRIority MEdicines) status. In December 2016, end of study results from the WHO ring vaccination trial were reported in Lancet supporting the July 2015 interim assessment that V920 offers substantial protection against Ebola virus disease, with no reported cases among vaccinated individuals from 10 days after vaccination in both randomized and non-randomized clusters. Results from other ongoing studies to be included in the first regulatory filing are anticipated in the first half of 2018.

MK-1242, vericiguat, is an investigational treatment for heart failure being studied in patients suffering from chronic heart failure. The development of vericiguat is part of a worldwide strategic collaboration between Merck and Bayer.

V212 is an inactivated varicella zoster virus (VZV) vaccine in development for the prevention of herpes zoster. The Company completed a Phase 3 trial in autologous hematopoietic cell transplant patients and another Phase 3 trial in patients with solid tumor malignancies undergoing chemotherapy and hematological malignancies. The study in autologous hematopoietic cell transplant patients met its primary endpoints and Merck presented the

results from this study at the American Society for Blood and Marrow Transplantation Meetings in February 2017. The study in

patients with solid tumor malignancies undergoing chemotherapy met its primary endpoints, but the primary efficacy endpoint was not met in patients with hematologic malignancies. Merck will present the results from this study at an upcoming scientific meeting. Due to the competitive environment, the development of V212 is currently on hold.

MK-7264 is a selective, non-narcotic, orally-administered P2X3-receptor agonist being developed for the treatment of refractory, chronic cough. Merck plans to initiate a Phase 3 clinical trial in the first half of 2018. MK-7264 was originally developed by Afferent Pharmaceuticals, which was acquired by the Company in 2016.

The Company also discontinued certain drug candidates.

In February 2018, Merck announced that it will be stopping protocol 019, also known as the APECS study, a Phase 3 study evaluating verubecestat, MK-8931, an investigational small molecule inhibitor of the beta-site amyloid precursor protein cleaving enzyme 1 (BACE1), in people with prodromal Alzheimer's disease. The decision to stop the study follows a recommendation by the external Data Monitoring Committee (eDMC), which assessed overall benefit/risk during a recent interim safety analysis. The eDMC concluded that it was unlikely that positive benefit/risk could be established if the trial continued.

In 2017, Merck announced that it will not submit applications for regulatory approval for MK-0859, anacetrapib, the Company's investigational cholesteryl ester transfer protein (CETP) inhibitor. The decision followed a thorough review of the clinical profile of anacetrapib, including discussions with external experts.

Also in 2017, Merck made a strategic decision to discontinue the development of the investigational combination regimens MK-3682B (grazoprevir/ruzasvir/uprifosbuvir) and MK-3682C (ruzasvir/uprifosbuvir) for the treatment of HCV infection. This decision was made based on a review of available Phase 2 efficacy data and in consideration of the evolving marketplace and the growing number of treatment options available for patients with chronic HCV infection, including *Zepatier*, which is currently marketed by the Company for the treatment of adult patients with chronic HCV infection.

The chart below reflects the Company's research pipeline as of February 23, 2018. Candidates shown in Phase 3 include specific products and the date such candidate entered into Phase 3 development. Candidates shown in Phase 2 include the most advanced compound with a specific mechanism or, if listed compounds have the same mechanism, they are each currently intended for commercialization in a given therapeutic area. Small molecules and biologics are given MK-number designations and vaccine candidates are given V-number designations. Except as otherwise noted, candidates in Phase 1, additional indications in the same therapeutic area (other than with respect to *Keytruda*) and additional claims, line extensions or formulations for in-line products are not shown.

Phase 2	Phase 3 (Phase 3 entry date)	Under Review
Cancer MK-3475 *Keytruda* Advanced Solid Tumors Ovarian Prostate **Chronic Cough** MK-7264 **Diabetes Mellitus** MK-8521*(2)* **HIV Infection** MK-8591 **Pneumoconjugate Vaccine** V114 **Schizophrenia** MK-8189	**Bacterial Infection** MK-7655A (relebactam+imipenem/cilastatin) (October 2015) **Cancer** MK-3475 *Keytruda* Breast (October 2015) Colorectal (November 2015) Esophageal (December 2015) Gastric (May 2015) (EU) Head and Neck (November 2014) (EU) Hepatocellular (May 2016) Nasopharyngeal (April 2016) Renal (October 2016) Small-Cell Lung (May 2017) MK-7339 Lynparza*(1)* Pancreatic (December 2014) Prostate (April 2017) MK-5618 (selumetinib) *(1)* Thyroid (June 2013) **Ebola Vaccine** V920 (March 2015) **Heart Failure** MK-1242 (vericiguat) (September 2016)*(1)* **Herpes Zoster** V212 (inactivated VZV vaccine) (December 2010)*(2)* **HIV** MK-1439 (doravirine) (December 2014) (EU) MK-1439A (doravirine/lamivudine/tenofovir disoproxil fumarate) (June 2015) (EU)	**New Molecular Entities/Vaccines** **Diabetes Mellitus** MK-0431J (sitagliptin+ipragliflozin) (Japan)*(1)* MK-8835 (ertugliflozin) (EU)*(1)* MK-8835A (ertugliflozin+sitagliptin) (EU)*(1)* MK-8835B (ertugliflozin+metformin) (EU)*(1)* **HIV** MK-1439 (doravirine) (U.S.) MK-1439A (doravirine/lamivudine/tenofovir disoproxil fumarate) (U.S.) **Pediatric Hexavalent Combination Vaccine** V419 (U.S.)*(3)* **Certain Supplemental Filings** MK-3475 *Keytruda* Relapsed or Refractory Primary Mediastinal B-Cell Lymphoma (PMBCL) (U.S.) MK-7339 Lynparza*(1)* Broader Approval for Ovarian Cancer (EU) **Footnotes:** *(1)* Being developed in a collaboration. *(2)* Development is currently on hold. *(3)* V419 is an investigational pediatric hexavalent combination vaccine, DTaP5-IPV-Hib-HepB, that is being developed and, if approved, will be commercialized through a partnership of Merck and Sanofi. In November 2015, the FDA issued a CRL with respect to V419. Both companies are working to provide additional data requested by the FDA.

Employees

As of December 31, 2017, the Company had approximately 69,000 employees worldwide, with approximately 26,700 employed in the United States, including Puerto Rico. Approximately 29% of worldwide employees of the Company are represented by various collective bargaining groups.

Restructuring Activities

The Company incurs substantial costs for restructuring program activities related to Merck's productivity and cost reduction initiatives, as well as in connection with the integration of certain acquired businesses. In 2010 and 2013, the Company commenced actions under global restructuring programs designed to streamline its cost structure. The actions under these programs include the elimination of positions in sales, administrative and headquarters organizations, as well as the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities. The Company also continues to reduce its global real estate footprint and improve the efficiency of its manufacturing and supply network. Since inception of the programs through December 31, 2017, Merck has eliminated approximately 43,350 positions comprised of employee separations, as well as the elimination of contractors and vacant positions. The Company has substantially completed the actions under these programs.

Environmental Matters

The Company believes that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on the Company. The Company is also remediating

environmental contamination resulting from past industrial activity at certain of its sites. Expenditures for remediation and environmental liabilities were $11 million in 2017, and are estimated at $56 million in the aggregate for the years 2018 through 2022. These amounts do not consider potential recoveries from other parties. The Company has taken an active role in identifying and accruing for these costs and, in management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $82 million and $83 million at December 31, 2017 and 2016, respectively. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed $63 million in the aggregate. Management also does not believe that these expenditures should have a material adverse effect on the Company's financial position, results of operations, liquidity or capital resources for any year.

Merck believes that climate change could present risks to its business. Some of the potential impacts of climate change to its business include increased operating costs due to additional regulatory requirements, physical risks to the Company's facilities, water limitations and disruptions to its supply chain. These potential risks are integrated into the Company's business planning including investment in reducing energy, water use and greenhouse gas emissions. The Company does not believe these risks are material to its business at this time.

Geographic Area Information

The Company's operations outside the United States are conducted primarily through subsidiaries. Sales worldwide by subsidiaries outside the United States as a percentage of total Company sales were 57% of sales in 2017, 54% of sales in 2016 and 56% of sales in 2015.

The Company's worldwide business is subject to risks of currency fluctuations, governmental actions and other governmental proceedings abroad. The Company does not regard these risks as a deterrent to further expansion of its operations abroad. However, the Company closely reviews its methods of operations and adopts strategies responsive to changing economic and political conditions.

Merck has operations in countries located in Latin America, the Middle East, Africa, Eastern Europe and Asia Pacific. Business in these developing areas, while sometimes less stable, offers important opportunities for growth over time.

Financial information about geographic areas of the Company's business is provided in Item 8. "Financial Statements and Supplementary Data" below.

Available Information

The Company's Internet website address is *www.merck.com*. The Company will make available, free of charge at the "Investors" portion of its website, its Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after such reports are electronically filed with, or furnished to, the U.S. Securities and Exchange Commission (SEC). In addition, the Company will provide without charge a copy of its Annual Report on Form 10-K, including financial statements and schedules, upon the written request of any shareholder to Merck Shareholder Services, Merck & Co., Inc., 2000 Galloping Hill Road, K1-3049, Kenilworth, NJ 07033 U.S.A.

The Company's corporate governance guidelines and the charters of the Board of Directors' four standing committees are available on the Company's website at *www.merck.com/about/leadership* and all such information is available in print to any stockholder who requests it from the Company.

Item 1A. Risk Factors.

Investors should carefully consider all of the information set forth in this Form 10-K, including the following risk factors, before deciding to invest in any of the Company's securities. The risks below are not the only ones the Company faces. Additional risks not currently known to the Company or that the Company presently deems immaterial may also impair its business operations. The Company's business, financial condition, results of operations or prospects could be materially adversely affected by any of these risks. This Form 10-K also contains forward-looking statements that involve risks and uncertainties. The Company's results could materially differ from those anticipated in these

forward-looking statements as a result of certain factors, including the risks it faces described below and elsewhere. See "Cautionary Factors that May Affect Future Results" below.

The Company is dependent on its patent rights, and if its patent rights are invalidated or circumvented, its business would be adversely affected.

Patent protection is considered, in the aggregate, to be of material importance to the Company's marketing of human health products in the United States and in most major foreign markets. Patents covering products that it has introduced normally provide market exclusivity, which is important for the successful marketing and sale of its products. The Company seeks patents covering each of its products in each of the markets where it intends to sell the products and where meaningful patent protection is available.

Even if the Company succeeds in obtaining patents covering its products, third parties or government authorities may challenge or seek to invalidate or circumvent its patents and patent applications. It is important for the Company's business to defend successfully the patent rights that provide market exclusivity for its products. The Company is often involved in patent disputes relating to challenges to its patents or claims by third parties of infringement against the Company. The Company defends its patents both within and outside the United States, including by filing claims of infringement against other parties. See Item 8. "Financial Statements and Supplementary Data," Note 11. "Contingencies and Environmental Liabilities" below. In particular, manufacturers of generic pharmaceutical products from time to time file abbreviated NDAs with the FDA seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned or licensed by the Company. The Company normally responds by defending its patent, including by filing lawsuits alleging patent infringement. Patent litigation and other challenges to the Company's patents are costly and unpredictable and may deprive the Company of market exclusivity for a patented product or, in some cases, third-party patents may prevent the Company from marketing and selling a product in a particular geographic area.

Additionally, certain foreign governments have indicated that compulsory licenses to patents may be granted in the case of national emergencies or in other circumstances, which could diminish or eliminate sales and profits from those regions and negatively affect the Company's results of operations. Further, court decisions relating to other companies' patents, potential legislation relating to patents, as well as regulatory initiatives may result in a more general weakening of intellectual property protection.

If one or more important products lose patent protection in profitable markets, sales of those products are likely to decline significantly as a result of generic versions of those products becoming available. In addition, if products that were measured at fair value and capitalized in connection with acquisitions experience difficulties in the market that negatively impact product cash flows, the Company may recognize material non-cash impairment charges with respect to the value of those products. The Company's results of operations may be adversely affected by the lost sales unless and until the Company has successfully launched commercially successful replacement products.

A chart listing the patent protection for certain of the Company's marketed products, and U.S. patent protection for candidates under review and Phase 3 candidates is set forth above in Item 1. "Business — Patents, Trademarks and Licenses."

As the Company's products lose market exclusivity, the Company generally experiences a significant and rapid loss of sales from those products.

The Company depends upon patents to provide it with exclusive marketing rights for its products for some period of time. Loss of patent protection for one of the Company's products typically leads to a significant and rapid loss of sales for that product, as lower priced generic versions of that drug become available. In the case of products that contribute significantly to the Company's sales, the loss of market exclusivity can have a material adverse effect on the Company's business, cash flow, results of operations, financial position and prospects. For example, pursuant to an agreement with a generic manufacturer, that manufacturer launched in the United States a generic version of *Zetia* in December 2016. In addition, the Company lost U.S. patent protection for *Vytorin* in April 2017. As a result, the Company experienced a significant and rapid loss of sales of *Zetia* and *Vytorin* in the United States in 2017, which the Company expects will continue in 2018. In addition, the patent that provides U.S. market exclusivity for *NuvaRing* will expire in April 2018 and the Company anticipates a significant decline in U.S. *NuvaRing* sales thereafter.

Key products generate a significant amount of the Company's profits and cash flows, and any events that adversely affect the markets for its leading products could have a material and negative impact on results of operations and cash flows.

The Company's ability to generate profits and operating cash flow depends largely upon the continued profitability of the Company's key products, such as *Januvia*, *Janumet*, *Keytruda*, *Gardasil/Gardasil* 9 and *Isentress*. As a result of the Company's dependence on key products, any event that adversely affects any of these products or the markets for any of these products could have a significant adverse impact on results of operations and cash flows. These events could include loss of patent protection, increased costs associated with manufacturing, generic or over-the-counter availability of the Company's product or a competitive product, the discovery of previously unknown side effects, results of post-approval trials, increased competition from the introduction of new, more effective treatments and discontinuation or removal from the market of the product for any reason. Such events could have a material adverse effect on the sales of any such products.

For example, in 2018, the Company anticipates that sales of *Zepatier* will be materially unfavorably affected by increasing competition and declining patient volumes. The Company also anticipates that sales of *Zostavax* will be materially unfavorably affected due to competition.

The Company's research and development efforts may not succeed in developing commercially successful products and the Company may not be able to acquire commercially successful products in other ways; in consequence, the Company may not be able to replace sales of successful products that have lost patent protection.

Like other major pharmaceutical companies, in order to remain competitive, the Company must continue to launch new products each year. Expected declines in sales of products after the loss of market exclusivity mean that the Company's future success is dependent on its pipeline of new products, including new products that it may develop through collaborations and joint ventures and products that it is able to obtain through license or acquisition. To accomplish this, the Company commits substantial effort, funds and other resources to research and development, both through its own dedicated resources and through various collaborations with third parties. There is a high rate of failure inherent in the research and development process for new drugs. As a result, there is a high risk that funds invested by the Company in research programs will not generate financial returns. This risk profile is compounded by the fact that this research has a long investment cycle. To bring a pharmaceutical compound from the discovery phase to market may take a decade or more and failure can occur at any point in the process, including later in the process after significant funds have been invested.

For a description of the research and development process, see Item 1. "Business — Research and Development" above. Each phase of testing is highly regulated and during each phase there is a substantial risk that the Company will encounter serious obstacles or will not achieve its goals, therefore, the Company may abandon a product in which it has invested substantial amounts of time and resources. Some of the risks encountered in the research and development process include the following: pre-clinical testing of a new compound may yield disappointing results; competing products from other manufacturers may reach the market first; clinical trials of a new drug may not be successful; a new drug may not be effective or may have harmful side effects; a new drug may not be approved by the regulators for its intended use; it may not be possible to obtain a patent for a new drug; payers may refuse to cover or reimburse the new product; or sales of a new product may be disappointing.

The Company cannot state with certainty when or whether any of its products now under development will be approved or launched; whether it will be able to develop, license or otherwise acquire compounds, product candidates or products; or whether any products, once launched, will be commercially successful. The Company must maintain a continuous flow of successful new products and successful new indications or brand extensions for existing products sufficient both to cover its substantial research and development costs and to replace sales that are lost as profitable products lose market exclusivity or are displaced by competing products or therapies. Failure to do so in the short term or long term would have a material adverse effect on the Company's business, results of operations, cash flow, financial position and prospects.

The Company's success is dependent on the successful development and marketing of new products, which are subject to substantial risks.

Products that appear promising in development may fail to reach the market or fail to succeed for numerous reasons, including the following:

- findings of ineffectiveness, superior safety or efficacy of competing products, or harmful side effects in clinical or pre-clinical testing;
- failure to receive the necessary regulatory approvals, including delays in the approval of new products and new indications, and uncertainties about the time required to obtain regulatory approvals and the benefit/risk standards applied by regulatory agencies in determining whether to grant approvals;
- failure in certain markets to obtain reimbursement commensurate with the level of innovation and clinical benefit presented by the product;
- lack of economic feasibility due to manufacturing costs or other factors; and
- preclusion from commercialization by the proprietary rights of others.

In the future, if certain pipeline programs are cancelled or if the Company believes that their commercial prospects have been reduced, the Company may recognize material non-cash impairment charges for those programs that were measured at fair value and capitalized in connection with acquisitions.

Failure to successfully develop and market new products in the short term or long term would have a material adverse effect on the Company's business, results of operations, cash flow, financial position and prospects.

The Company's products, including products in development, cannot be marketed unless the Company obtains and maintains regulatory approval.

The Company's activities, including research, preclinical testing, clinical trials and manufacturing and marketing its products, are subject to extensive regulation by numerous federal, state and local governmental authorities in the United States, including the FDA, and by foreign regulatory authorities, including in the EU and Japan. In the United States, the FDA is of particular importance to the Company, as it administers requirements covering the testing, approval, safety, effectiveness, manufacturing, labeling and marketing of prescription pharmaceuticals. In many cases, the FDA requirements have increased the amount of time and money necessary to develop new products and bring them to market in the United States. Regulation outside the United States also is primarily focused on drug safety and effectiveness and, in many cases, cost reduction. The FDA and foreign regulatory authorities have substantial discretion to require additional testing, to delay or withhold registration and marketing approval and to otherwise preclude distribution and sale of a product.

Even if the Company is successful in developing new products, it will not be able to market any of those products unless and until it has obtained all required regulatory approvals in each jurisdiction where it proposes to market the new products. Once obtained, the Company must maintain approval as long as it plans to market its new products in each jurisdiction where approval is required. The Company's failure to obtain approval, significant delays in the approval process, or its failure to maintain approval in any jurisdiction will prevent it from selling the new products in that jurisdiction until approval is obtained, if ever. The Company would not be able to realize revenues for those new products in any jurisdiction where it does not have approval.

Developments following regulatory approval may adversely affect sales of the Company's products.

Even after a product reaches market, certain developments following regulatory approval, including results in post-approval Phase 4 trials or other studies, may decrease demand for the Company's products, including the following:

- the re-review of products that are already marketed;
- the recall or loss of marketing approval of products that are already marketed;

- changing government standards or public expectations regarding safety, efficacy or labeling changes; and

- greater scrutiny in advertising and promotion.

In the past several years, clinical trials and post-marketing surveillance of certain marketed drugs of the Company and of competitors within the industry have raised concerns that have led to recalls, withdrawals or adverse labeling of marketed products. Clinical trials and post-marketing surveillance of certain marketed drugs also have raised concerns among some prescribers and patients relating to the safety or efficacy of pharmaceutical products in general that have negatively affected the sales of such products. In addition, increased scrutiny of the outcomes of clinical trials has led to increased volatility in market reaction. Further, these matters often attract litigation and, even where the basis for the litigation is groundless, considerable resources may be needed to respond.

In addition, following in the wake of product withdrawals and other significant safety issues, health authorities such as the FDA, the EMA and Japan's Pharmaceutical and Medical Device Agency have increased their focus on safety when assessing the benefit/risk balance of drugs. Some health authorities appear to have become more cautious when making decisions about approvability of new products or indications and are re-reviewing select products that are already marketed, adding further to the uncertainties in the regulatory processes. There is also greater regulatory scrutiny, especially in the United States, on advertising and promotion and, in particular, direct-to-consumer advertising.

If previously unknown side effects are discovered or if there is an increase in negative publicity regarding known side effects of any of the Company's products, it could significantly reduce demand for the product or require the Company to take actions that could negatively affect sales, including removing the product from the market, restricting its distribution or applying for labeling changes. Further, in the current environment in which all pharmaceutical companies operate, the Company is at risk for product liability and consumer protection claims and civil and criminal governmental actions related to its products, research and/or marketing activities.

The Company faces intense competition from lower cost generic products.

In general, the Company faces increasing competition from lower-cost generic products. The patent rights that protect its products are of varying strengths and durations. In addition, in some countries, patent protection is significantly weaker than in the United States or in the EU. In the United States and the EU, political pressure to reduce spending on prescription drugs has led to legislation and other measures that encourage the use of generic and biosimilar products. Although it is the Company's policy to actively protect its patent rights, generic challenges to the Company's products can arise at any time, and the Company's patents may not prevent the emergence of generic competition for its products.

Loss of patent protection for a product typically is followed promptly by generic substitutes, reducing the Company's sales of that product. Availability of generic substitutes for the Company's drugs may adversely affect its results of operations and cash flow. In addition, proposals emerge from time to time in the United States and other countries for legislation to further encourage the early and rapid approval of generic drugs. Any such proposal that is enacted into law could worsen this substantial negative effect on the Company's sales and, potentially, its business, cash flow, results of operations, financial position and prospects.

The Company faces intense competition from competitors' products which, in addition to other factors, could in certain circumstances lead to non-cash impairment charges.

The Company's products face intense competition from competitors' products. This competition may increase as new products enter the market. In such an event, the competitors' products may be safer or more effective, more convenient to use or more effectively marketed and sold than the Company's products. Alternatively, in the case of generic competition, including the generic availability of competitors' branded products, they may be equally safe and effective products that are sold at a substantially lower price than the Company's products. As a result, if the Company fails to maintain its competitive position, this could have a material adverse effect on its business, cash flow, results of operations, financial position and prospects. In addition, if products that were measured at fair value and capitalized in connection with acquisitions experience difficulties in the market that negatively impact product cash flows, the Company may recognize material non-cash impairment charges with respect to the value of those products.

The Company faces continued pricing pressure with respect to its products.

The Company faces continued pricing pressure globally and, particularly in mature markets, from managed care organizations, government agencies and programs that could negatively affect the Company's sales and profit margins. In the United States, these include (i) practices of managed care groups and institutional and governmental purchasers, (ii) U.S. federal laws and regulations related to Medicare and Medicaid, including the Medicare Prescription Drug Improvement and Modernization Act of 2003 and the ACA, and (iii) state activities aimed at increasing price transparency. Changes to the health care system enacted as part of health care reform in the United States, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, could result in further pricing pressures. In addition, in the U.S., larger customers may, in the future, ask for and receive higher rebates on drugs in certain highly competitive categories. The Company must also compete to be placed on formularies of managed care organizations. Exclusion of a product from a formulary can lead to reduced usage in the managed care organization.

In order to provide information about the Company's pricing practices, the Company recently posted on its website its Pricing Action Transparency Report for the United States for the years 2010 - 2017. The report provides the Company's average annual list price and net price increases across the Company's U.S. portfolio dating back to 2010. The report shows that the Company's average annual net price increases (after taking sales deductions such as rebates, discounts and returns into account) across the U.S. human health portfolio have been in the low to mid-single digits from 2010 - 2016. In 2017, the average net price across the Company's portfolio declined by 1.9%, reflecting specific in-year dynamics, including the impact of loss of patent protection for three major Merck medicines. Additionally, the weighted average annual discount rate has been steadily increasing over time, reflecting the competitive market for branded medicines and the impact of the ACA. In 2017, the Company's gross U.S. sales were reduced by 45.1% as a result of rebates, discounts and returns.

Outside the United States, numerous major markets, including the EU and Japan, have pervasive government involvement in funding health care and, in that regard, fix the pricing and reimbursement of pharmaceutical and vaccine products. Consequently, in those markets, the Company is subject to government decision making and budgetary actions with respect to its products.

The Company expects pricing pressures to continue in the future.

The health care industry in the United States will continue to be subject to increasing regulation and political action.

The Company believes that the health care industry will continue to be subject to increasing regulation as well as political and legal action, as future proposals to reform the health care system are considered by the Executive branch, Congress and state legislatures.

In 2010, the United States enacted major health care reform legislation in the form of the ACA. Various insurance market reforms have advanced and state and federal insurance exchanges were launched in 2014. With respect to the effect of the law on the pharmaceutical industry, the law increased the mandated Medicaid rebate from 15.1% to 23.1%, expanded the rebate to Medicaid managed care utilization, and increased the types of entities eligible for the federal 340B drug discount program.

The law also requires pharmaceutical manufacturers to pay a 50% point of service discount to Medicare Part D beneficiaries when they are in the Medicare Part D coverage gap (i.e., the so-called "donut hole"). In 2017, the Company's revenue was reduced by $385 million due to this requirement. Beginning in 2019, the 50% point of service discount will increase to a 70% point of service discount in the coverage gap, as a result of the Balanced Budget Act of 2018. In addition, the 70% point of service discount will be extended to biosimilar products. Also, pharmaceutical manufacturers are now required to pay an annual non-tax deductible health care reform fee. The total annual industry fee was $4.0 billion in 2017 and will be $4.1 billion in 2018. The fee is assessed on each company in proportion to its share of prior year branded pharmaceutical sales to certain government programs, such as Medicare and Medicaid. In 2017, the Company recorded $210 million of costs for this annual fee.

On January 21, 2016, the Centers for Medicare & Medicaid Services (CMS) issued the Medicaid rebate final rule that implements provisions of the ACA effective April 1, 2016. The rule provides comprehensive guidance on the calculation of Average Manufacturer Price and Best Price; two metrics utilized to determine the rebates drug

manufacturers are required to pay to state Medicaid programs. The impact of changes resulting from the issuance of the rule is not material to Merck, at this time. However, the Company is still awaiting guidance from CMS on two aspects of the rule that were deferred for later implementation. These include a definition of what constitutes a product 'line extension' and a delay in the participation of the U.S. Territories in the Medicaid Drug Rebate Program until April 1, 2020. The Company will evaluate the financial impact of these two elements when they become effective.

The Company cannot predict the likelihood of future changes in the health care industry in general, or the pharmaceutical industry in particular, or what impact they may have on the Company's results of operations, financial condition or business.

The Company is increasingly dependent on sophisticated software applications and computing infrastructure. In 2017, the Company experienced a network cyber-attack that led to a disruption of its worldwide operations, including manufacturing, research and sales operations. The Company could be a target of future cyber-attacks.

The Company is increasingly dependent on sophisticated software applications and complex information technology systems and computing infrastructure (collectively, "IT systems") to conduct critical operations. Disruption, degradation, or manipulation of these IT systems through intentional or accidental means could impact key business processes. Cyber-attacks against the Company's IT systems could result in exposure of confidential information, the modification of critical data, and/or the failure of critical operations. Misuse of these IT systems could result in the disclosure of sensitive personal information or the theft of trade secrets, intellectual property, or other confidential business information. The Company continues to leverage new and innovative technologies across the enterprise to improve the efficacy and efficiency of its business processes; the use of which can create new risks.

On June 27, 2017, the Company experienced a network cyber-attack that led to a disruption of its worldwide operations, including manufacturing, research and sales operations. All of the Company's manufacturing sites are now operational, manufacturing active pharmaceutical ingredient (API), formulating, packaging and shipping product. The Company's external manufacturing was not impacted. Throughout this time, Merck continued to fulfill orders and ship product.

Due to the cyber-attack, as anticipated, the Company was unable to fulfill orders for certain products in certain markets, which had an unfavorable effect on sales in 2017 of approximately $260 million. In addition, the Company recorded manufacturing-related expenses, primarily unfavorable manufacturing variances, in *Materials and Production* costs, as well as expenses related to remediation efforts in *Marketing and Administrative* expenses and *Research and Development* expenses, which aggregated $285 million in 2017, net of insurance recoveries of approximately $45 million. Due to a residual backlog of orders, the Company anticipates that in 2018 sales will be unfavorably affected in certain markets by approximately $200 million from the cyber-attack. Merck does not expect a significant impairment to the value of intangible assets related to marketed products or inventories as a result of the cyber-attack.

The Company has insurance coverage insuring against costs resulting from cyber-attacks and has received proceeds. However, there may be disputes with the insurers about the availability of the insurance coverage for claims related to this incident.

Additionally, the temporary production shut-down from the cyber-attack contributed to the Company's inability to meet higher than expected demand for *Gardasil* 9, which resulted in Merck's decision to borrow doses of *Gardasil* 9 from the U.S. Centers for Disease Control and Prevention Pediatric Vaccine Stockpile. The Company subsequently replenished a portion of the borrowed doses in 2017. The net effect of the borrowing and subsequent partial replenishment was a reduction in sales of $125 million in 2017. The Company anticipates it will replenish the remaining borrowed doses in the second half of 2018.

The Company has implemented a variety of measures to further enhance its systems to guard against similar attacks in the future, and also is pursuing an enterprise-wide effort to enhance the Company's resiliency against future cyber-attacks, including incidents similar to the June 2017 attack. The objective of these efforts is not only to protect against future cyber-attacks, but also to improve the speed of the Company's recovery from such attacks and enable continued business operations to the greatest extent possible during any recovery period.

Although the aggregate impact of cyber-attacks and network disruptions, including the June 2017 cyber-attack, on the Company's operations and financial condition has not been material to date, the Company continues to be a

target of events of this nature and expects them to continue. The Company monitors its data, information technology and personnel usage of Company IT systems to reduce these risks and continues to do so on an ongoing basis for any current or potential threats. There can be no assurance that the Company's efforts to protect its data and IT systems will be successful in preventing disruptions to its operations, including its manufacturing, research and sales operations. Any such disruption could result in loss of revenue, or the loss of critical or sensitive information from the Company's or the Company's third party providers' databases or IT systems and could also result in financial, legal, business or reputational harm to the Company and potentially substantial remediation costs.

Changes in laws and regulations could materially adversely affect the Company's business.

All aspects of the Company's business, including research and development, manufacturing, marketing, pricing, sales, litigation and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a material adverse effect on the Company's business.

In particular, there is significant uncertainty about the future of the ACA and health care laws in general in the United States. The Company is participating in the debate and monitoring how any proposed changes could affect its business. The Company is unable to predict the likelihood of changes to the ACA. Depending on the nature of any repeal and replacement of the ACA, such actions could have a material adverse effect on the Company's results of operations, financial condition or business.

The uncertainty in global economic conditions together with austerity measures being taken by certain governments could negatively affect the Company's operating results.

Uncertainty in global economic and geopolitical conditions may result in a slowdown to the global economy that could affect the Company's business by reducing the prices that drug wholesalers and retailers, hospitals, government agencies and managed health care providers may be able or willing to pay for the Company's products or by reducing the demand for the Company's products, which could in turn negatively impact the Company's sales and result in a material adverse effect on the Company's business, cash flow, results of operations, financial position and prospects.

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access. In the United States, pricing pressures continue on many of the Company's products and, in several international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. In addition, other austerity measures negatively affected the Company's revenue performance in 2017. The Company anticipates these pricing actions, including the biennial price reductions in Japan that will occur again in 2018, and other austerity measures will continue to negatively affect revenue performance in 2018.

If credit and economic conditions worsen, the resulting economic and currency impacts in the affected markets and globally could have a material adverse effect on the Company's results.

The Company has significant global operations, which expose it to additional risks, and any adverse event could have a material negative impact on the Company's results of operations.

The extent of the Company's operations outside the United States is significant. Risks inherent in conducting a global business include:

- changes in medical reimbursement policies and programs and pricing restrictions in key markets;
- multiple regulatory requirements that could restrict the Company's ability to manufacture and sell its products in key markets;
- trade protection measures and import or export licensing requirements, including the imposition of trade sanctions or similar restrictions by the United States or other governments;
- foreign exchange fluctuations;

- diminished protection of intellectual property in some countries; and
- possible nationalization and expropriation.

In addition, there may be changes to the Company's business and political position if there is instability, disruption or destruction in a significant geographic region, regardless of cause, including war, terrorism, riot, civil insurrection or social unrest; and natural or man-made disasters, including famine, flood, fire, earthquake, storm or disease. For example, in 2017, the Company's lone manufacturing plant in Puerto Rico was negatively affected by Hurricane Maria.

On June 23, 2016, the United Kingdom (UK) held a referendum in which voters approved an exit from the EU, commonly referred to as "Brexit". As a result of the referendum, the British government has begun negotiating the terms of the UK's future relationship with the EU. Although it is unknown what those terms will be, it is possible that there will be greater restrictions on imports and exports between the UK and EU countries, increased regulatory complexities, and cross boarder labor issues that could adversely impact the Company's business operations in the UK.

Failure to attract and retain highly qualified personnel could affect its ability to successfully develop and commercialize products.

The Company's success is largely dependent on its continued ability to attract and retain highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical research and development, governmental regulation and commercialization. Competition for qualified personnel in the pharmaceutical industry is intense. The Company cannot be sure that it will be able to attract and retain quality personnel or that the costs of doing so will not materially increase.

In the past, the Company has experienced difficulties and delays in manufacturing certain of its products, including vaccines.

Merck has, in the past, experienced difficulties in manufacturing certain of its products, including vaccines. In addition, the network cyber-attack experienced by the Company in June 2017 led to a disruption of the Company's operations, including its manufacturing operations. The Company may, in the future, experience difficulties and delays inherent in manufacturing its products, such as (i) failure of the Company or any of its vendors or suppliers to comply with Current Good Manufacturing Practices and other applicable regulations and quality assurance guidelines that could lead to manufacturing shutdowns, product shortages and delays in product manufacturing; (ii) construction delays related to the construction of new facilities or the expansion of existing facilities, including those intended to support future demand for the Company's products; and (iii) other manufacturing or distribution problems including changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, changes in types of products produced, or physical limitations that could impact continuous supply. Manufacturing difficulties can result in product shortages, leading to lost sales and reputational harm to the Company.

The Company may not be able to realize the expected benefits of its investments in emerging markets.

The Company has been taking steps to increase its sales in emerging markets. However, there is no guarantee that the Company's efforts to expand sales in these markets will succeed. Some countries within emerging markets may be especially vulnerable to periods of global financial instability or may have very limited resources to spend on health care. In order for the Company to successfully implement its emerging markets strategy, it must attract and retain qualified personnel. The Company may also be required to increase its reliance on third-party agents within less developed markets. In addition, many of these countries have currencies that fluctuate substantially and, if such currencies devalue and the Company cannot offset the devaluations, the Company's financial performance within such countries could be adversely affected.

In addition, in China, commercial and economic conditions may adversely affect the Company's growth prospects in that market. While the Company continues to believe that China represents an important growth opportunity, these events, coupled with heightened scrutiny of the health care industry, may continue to have an impact on product pricing and market access generally. The Company anticipates that the reported inquiries made by various governmental authorities involving multinational pharmaceutical companies in China may continue.

For all these reasons, sales within emerging markets carry significant risks. However, a failure to maintain the Company's presence in emerging markets could have a material adverse effect on the business, financial condition or results of the Company's operations.

The Company is exposed to market risk from fluctuations in currency exchange rates and interest rates.

The Company operates in multiple jurisdictions and virtually all sales are denominated in currencies of the local jurisdiction. Additionally, the Company has entered and will enter into acquisition, licensing, borrowings or other financial transactions that may give rise to currency and interest rate exposure.

Since the Company cannot, with certainty, foresee and mitigate against such adverse fluctuations, fluctuations in currency exchange rates and interest rates could negatively affect the Company's results of operations, financial position and cash flows as occurred with respect to Venezuela in 2015 and 2016.

In order to mitigate against the adverse impact of these market fluctuations, the Company will from time to time enter into hedging agreements. While hedging agreements, such as currency options and forwards and interest rate swaps, may limit some of the exposure to exchange rate and interest rate fluctuations, such attempts to mitigate these risks may be costly and not always successful.

The Company is subject to evolving and complex tax laws, which may result in additional liabilities that may affect results of operations.

The Company is subject to evolving and complex tax laws in the jurisdictions in which it operates. Significant judgment is required for determining the Company's tax liabilities, and the Company's tax returns are periodically examined by various tax authorities. The Company believes that its accrual for tax contingencies is adequate for all open years based on past experience, interpretations of tax law, and judgments about potential actions by tax authorities; however, due to the complexity of tax contingencies, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued.

In addition, the Company may be affected by changes in tax laws, such as tax rate changes, new tax laws, and revised tax law interpretations in domestic and foreign jurisdictions.

Further, on December 22, 2017, the U.S. Tax Cuts and Jobs Act of 2017 (TCJA) became law. The final impact of the TCJA on the Company may differ from the estimates reported, possibly materially, due to such factors as changes in interpretations and assumptions made, additional guidance that may be issued, and actions taken by the Company as a result of the TCJA, among others.

Pharmaceutical products can develop unexpected safety or efficacy concerns.

Unexpected safety or efficacy concerns can arise with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals, or declining sales, as well as product liability, consumer fraud and/or other claims, including potential civil or criminal governmental actions.

Reliance on third party relationships and outsourcing arrangements could adversely affect the Company's business.

The Company depends on third parties, including suppliers, alliances with other pharmaceutical and biotechnology companies, and third party service providers, for key aspects of its business including development, manufacture and commercialization of its products and support for its information technology systems. Failure of these third parties to meet their contractual, regulatory and other obligations to the Company or the development of factors that materially disrupt the relationships between the Company and these third parties could have a material adverse effect on the Company's business.

Negative events in the animal health industry could have a negative impact on future results of operations.

Future sales of key animal health products could be adversely affected by a number of risk factors including certain risks that are specific to the animal health business. For example, the outbreak of disease carried by animals, such as Bovine Spongiform Encephalopathy or mad cow disease, could lead to their widespread death and precautionary

destruction as well as the reduced consumption and demand for animals, which could adversely impact the Company's results of operations. Also, the outbreak of any highly contagious diseases near the Company's main production sites could require the Company to immediately halt production of vaccines at such sites or force the Company to incur substantial expenses in procuring raw materials or vaccines elsewhere. Other risks specific to animal health include epidemics and pandemics, government procurement and pricing practices, weather and global agribusiness economic events. As the Animal Health segment of the Company's business becomes more significant, the impact of any such events on future results of operations would also become more significant.

Biologics and vaccines carry unique risks and uncertainties, which could have a negative impact on future results of operations.

The successful development, testing, manufacturing and commercialization of biologics and vaccines, particularly human and animal health vaccines, is a long, expensive and uncertain process. There are unique risks and uncertainties with biologics and vaccines, including:

- There may be limited access to, and supply of, normal and diseased tissue samples, cell lines, pathogens, bacteria, viral strains and other biological materials. In addition, government regulations in multiple jurisdictions, such as the United States and the EU, could result in restricted access to, or transport or use of, such materials. If the Company loses access to sufficient sources of such materials, or if tighter restrictions are imposed on the use of such materials, the Company may not be able to conduct research activities as planned and may incur additional development costs.

- The development, manufacturing and marketing of biologics and vaccines are subject to regulation by the FDA, the EMA and other regulatory bodies. These regulations are often more complex and extensive than the regulations applicable to other pharmaceutical products. For example, in the United States, a BLA, including both preclinical and clinical trial data and extensive data regarding the manufacturing procedures, is required for human vaccine candidates, and FDA approval is generally required for the release of each manufactured commercial lot.

- Manufacturing biologics and vaccines, especially in large quantities, is often complex and may require the use of innovative technologies to handle living micro-organisms. Each lot of an approved biologic and vaccine must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, the Company may be required to provide pre-clinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes.

- Biologics and vaccines are frequently costly to manufacture because production ingredients are derived from living animal or plant material, and most biologics and vaccines cannot be made synthetically. In particular, keeping up with the demand for vaccines may be difficult due to the complexity of producing vaccines.

- The use of biologically derived ingredients can lead to variability in the manufacturing process and could lead to allegations of harm, including infections or allergic reactions, which allegations would be reviewed through a standard investigation process that could lead to closure of product facilities due to possible contamination. Any of these events could result in substantial costs.

Product liability insurance for products may be limited, cost prohibitive or unavailable.

As a result of a number of factors, product liability insurance has become less available while the cost has increased significantly. The Company is subject to a substantial number of product liability claims. See Item 8. "Financial Statements and Supplementary Data," Note 11. "Contingencies and Environmental Liabilities" below for more information on the Company's current product liability litigation. With respect to product liability, the Company self-insures substantially all of its risk, as the availability of commercial insurance has become more restrictive. The Company has evaluated its risks and has determined that the cost of obtaining product liability insurance outweighs the likely

benefits of the coverage that is available and, as such, has no insurance for certain product liabilities effective August 1, 2004, including liability for legacy Merck products first sold after that date. The Company will continually assess the most efficient means to address its risk; however, there can be no guarantee that insurance coverage will be obtained or, if obtained, will be sufficient to fully cover product liabilities that may arise.

Social media platforms present risks and challenges.

The inappropriate and/or unauthorized use of certain media vehicles could cause brand damage or information leakage or could lead to legal implications, including from the improper collection and/or dissemination of personally identifiable information. In addition, negative or inaccurate posts or comments about the Company or its products on any social networking web site could damage the Company's reputation, brand image and goodwill. Further, the disclosure of non-public Company-sensitive information by the Company's workforce or others through external media channels could lead to information loss. Although there is an internal Company Social Media Policy that guides employees on appropriate personal and professional use of social media about the Company, the processes in place may not completely secure and protect information. Identifying new points of entry as social media continues to expand also presents new challenges.

Cautionary Factors that May Affect Future Results

(Cautionary Statements Under the Private Securities Litigation Reform Act of 1995)

This report and other written reports and oral statements made from time to time by the Company may contain so-called "forward-looking statements," all of which are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially from those set forth in the statements. One can identify these forward-looking statements by their use of words such as "anticipates," "expects," "plans," "will," "estimates," "forecasts," "projects" and other words of similar meaning, or negative variations of any of the foregoing. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address the Company's growth strategy, financial results, product development, product approvals, product potential, and development programs. One must carefully consider any such statement and should understand that many factors could cause actual results to differ materially from the Company's forward-looking statements. These factors include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. No forward-looking statement can be guaranteed and actual future results may vary materially. The Company does not assume the obligation to update any forward-looking statement. The Company cautions you not to place undue reliance on these forward-looking statements. Although it is not possible to predict or identify all such factors, they may include the following:

- Competition from generic and/or biosimilar products as the Company's products lose patent protection.

- Increased "brand" competition in therapeutic areas important to the Company's long-term business performance.

- The difficulties and uncertainties inherent in new product development. The outcome of the lengthy and complex process of new product development is inherently uncertain. A drug candidate can fail at any stage of the process and one or more late-stage product candidates could fail to receive regulatory approval. New product candidates may appear promising in development but fail to reach the market because of efficacy or safety concerns, the inability to obtain necessary regulatory approvals, the difficulty or excessive cost to manufacture and/or the infringement of patents or intellectual property rights of others. Furthermore, the sales of new products may prove to be disappointing and fail to reach anticipated levels.

- Pricing pressures, both in the United States and abroad, including rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and health care reform, pharmaceutical reimbursement and pricing in general.

- Changes in government laws and regulations, including laws governing intellectual property, and the enforcement thereof affecting the Company's business.

- Efficacy or safety concerns with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales.
- Significant changes in customer relationships or changes in the behavior and spending patterns of purchasers of health care products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing health care insurance coverage.
- Legal factors, including product liability claims, antitrust litigation and governmental investigations, including tax disputes, environmental concerns and patent disputes with branded and generic competitors, any of which could preclude commercialization of products or negatively affect the profitability of existing products.
- Cyber-attacks on the Company's information technology systems, which could disrupt the Company's operations.
- Lost market opportunity resulting from delays and uncertainties in the approval process of the FDA and foreign regulatory authorities.
- Increased focus on privacy issues in countries around the world, including the United States and the EU. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect directly the Company's business, including recently enacted laws in a majority of states in the United States requiring security breach notification.
- Changes in tax laws including changes related to the taxation of foreign earnings.
- Changes in accounting pronouncements promulgated by standard-setting or regulatory bodies, including the Financial Accounting Standards Board and the SEC, that are adverse to the Company.
- Economic factors over which the Company has no control, including changes in inflation, interest rates and foreign currency exchange rates.

This list should not be considered an exhaustive statement of all potential risks and uncertainties. See "Risk Factors" above.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

The Company's corporate headquarters is located in Kenilworth, New Jersey. The Company's U.S. commercial operations are headquartered in Upper Gwynedd, Pennsylvania. The Company's U.S. pharmaceutical business is conducted through divisional headquarters located in Upper Gwynedd, Pennsylvania and Kenilworth, New Jersey. The Company's vaccines business is conducted through divisional headquarters located in Upper Gwynedd, Pennsylvania. Merck's Animal Health global headquarters is located in Madison, New Jersey. Principal U.S. research facilities are located in Rahway and Kenilworth, New Jersey, West Point, Pennsylvania, Palo Alto, California, Boston, Massachusetts, and Elkhorn, Nebraska (Animal Health). Principal research facilities outside the United States are located in Switzerland and China. Merck's manufacturing operations are headquartered in Whitehouse Station, New Jersey. The Company also has production facilities for human health products at nine locations in the United States and Puerto Rico. Outside the United States, through subsidiaries, the Company owns or has an interest in manufacturing plants or other properties in Japan, Singapore, South Africa, and other countries in Western Europe, Central and South America, and Asia.

Capital expenditures were $1.9 billion in 2017, $1.6 billion in 2016 and $1.3 billion in 2015. In the United States, these amounted to $1.2 billion in 2017, $1.0 billion in 2016 and $879 million in 2015. Abroad, such expenditures amounted to $728 million in 2017, $594 million in 2016 and $404 million in 2015.

The Company and its subsidiaries own their principal facilities and manufacturing plants under titles that they consider to be satisfactory. The Company believes that its properties are in good operating condition and that its machinery and equipment have been well maintained. Plants for the manufacture of products are suitable for their intended purposes and have capacities and projected capacities adequate for current and projected needs for existing

Company products. Some capacity of the plants is being converted, with any needed modification, to the requirements of newly introduced and future products.

Item 3. Legal Proceedings.

The information called for by this Item is incorporated herein by reference to Item 8. “Financial Statements and Supplementary Data,” Note 11. “Contingencies and Environmental Liabilities”.

Item 4. Mine Safety Disclosures.

Not Applicable.

Executive Officers of the Registrant (ages as of February 1, 2018)

All officers listed below serve at the pleasure of the Board of Directors. None of these officers was elected pursuant to any arrangement or understanding between the officer and any other person(s).

Name	Age	Offices and Business Experience
Kenneth C. Frazier	63	Chairman, President and Chief Executive Officer (since December 2011)
Sanat Chattopadhyay	58	Executive Vice President and President, Merck Manufacturing Division (since March 2016); Senior Vice President, Operations, Merck Manufacturing Division (November 2009-March 2016)
Robert M. Davis	51	Executive Vice President, Chief Financial Officer & Global Services (since April 2016); Executive Vice President and Chief Financial Officer (April 2014-April 2016); Corporate Vice President and President, Medical Products, Baxter International, Inc. (2010-March 2014)
Richard R. DeLuca, Jr.	55	Executive Vice President and President, Merck Animal Health (since September 2011)
Julie L. Gerberding	62	Executive Vice President and Chief Patient Officer, Strategic Communications, Global Public Policy and Population Health (since July 2016); Executive Vice President for Strategic Communications, Global Public Policy and Population Health (January 2015-July 2016); President, Merck Vaccines (January 2010-January 2015)
Mirian M. Graddick-Weir	63	Executive Vice President, Human Resources (since November 2009)
Michael J. Holston*	55	Executive Vice President and General Counsel (since July 2015); Executive Vice President and Chief Ethics and Compliance Officer (June 2012-July 2015)
Rita A. Karachun	54	Senior Vice President Finance - Global Controller (since March 2014); Assistant Controller (November 2009-March 2014)
Roger M. Perlmutter, M.D., Ph.D.	65	Executive Vice President and President, Merck Research Laboratories (since April 2013)
Adam H. Schechter	53	Executive Vice President and President, Global Human Health (since May 2010)
Ashley Watson	49	Senior Vice President, Chief Ethics and Compliance Officer (since March 2015); Senior Vice President, Deputy General Counsel and Chief Ethics & Compliance Officer, Hewlett-Packard Company (January 2011 - March 2015)

* *On February 21, 2018, Mr. Holston notified the Company that he will resign from his position with the Company, effective April 1, 2018.*

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

The principal market for trading of the Company's Common Stock is the New York Stock Exchange (NYSE) under the symbol MRK. The Common Stock market price information set forth in the table below is based on historical NYSE market prices.

The following table also sets forth, for the calendar periods indicated, the cash dividends paid per common share and the high and low sales prices of the Company's Common Stock as reported by the NYSE.

Cash Dividends Paid per Common Share

	Year	4th Q	3rd Q	2nd Q	1st Q
2017	**$ 1.88**	**$ 0.47**	**$ 0.47**	**$ 0.47**	**$ 0.47**
2016	$ 1.84	$ 0.46	$ 0.46	$ 0.46	$ 0.46

Common Stock Market Prices

2017	**4th Q**	**3rd Q**	**2nd Q**	**1st Q**
High	**64.90**	**66.41**	**66.40**	**66.80**
Low	**53.63**	**61.16**	**61.87**	**59.05**
2016				
High	$ 65.46	$ 64.00	$ 57.87	$ 53.60
Low	$ 58.29	$ 57.18	$ 52.44	$ 47.97

As of January 31, 2018, there were approximately 121,125 shareholders of record of the Company's Common Stock.

Issuer purchases of equity securities for the three months ended December 31, 2017 were as follows:

Issuer Purchases of Equity Securities

Period	Total Number of Shares Purchased[1]	Average Price Paid Per Share	($ in millions) Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs[1]
October 1 — October 31	2,172,335	$63.38	$2,605
November 1 — November 30	11,850,338	$55.03	$1,953
December 1 — December 31	16,285,000	$56.05	$11,040
Total	30,307,673	$56.17	$11,040

[1] *All shares purchased during the period were made as part of a plan approved by the Board of Directors in March 2015 to purchase up to $10 billion in Merck shares. In November 2017, the Board of Directors authorized additional purchases of up to $10 billion of Merck's common stock for its treasury. Shares are approximated.*

Performance Graph

The following graph assumes a $100 investment on December 31, 2012, and reinvestment of all dividends, in each of the Company's Common Shares, the S&P 500 Index, and a composite peer group of major pharmaceutical companies, which are: AbbVie Inc., Amgen Inc., AstraZeneca plc, Bristol-Myers Squibb Company, Johnson & Johnson, Eli Lilly and Company, GlaxoSmithKline plc, Novartis AG, Pfizer Inc., Roche Holding AG, and Sanofi SA.

Comparison of Five-Year Cumulative Total Return*
Merck & Co., Inc., Composite Peer Group and S&P 500 Index

	End of Period Value	2017/2012 CAGR**
MERCK	$162	10%
PEER GRP.**	185	13%
S&P 500	208	16%

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	2012	2013	2014	2015	2016	2017
MERCK	100.00	126.90	148.70	142.70	164.30	161.80
PEER GRP.	100.00	134.60	150.20	154.70	151.60	184.70
S&P 500	100.00	132.40	150.50	152.50	170.80	208.10

* *Compound Annual Growth Rate*

** *Peer group average was calculated on a market cap weighted basis.*

This Performance Graph will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that the Company specifically incorporates it by reference. In addition, the Performance Graph will not be deemed to be "soliciting material" or to be "filed" with the SEC or subject to Regulation 14A or 14C, other than as provided in Regulation S-K, or to the liabilities of section 18 of the Securities Exchange Act of 1934, except to the extent that the Company specifically requests that such information be treated as soliciting material or specifically incorporates it by reference into a filing under the Securities Act or the Exchange Act.

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Item 6. Selected Financial Data.

The following selected financial data should be read in conjunction with Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and consolidated financial statements and notes thereto contained in Item 8. "Financial Statements and Supplementary Data" of this report.

Merck & Co., Inc. and Subsidiaries
($ in millions except per share amounts)

	2017 [1]	2016 [2]	2015 [3]	2014 [4]	2013
Results for Year:					
Sales	**$ 40,122**	$ 39,807	$ 39,498	$ 42,237	$ 44,033
Materials and production	**12,775**	13,891	14,934	16,768	16,954
Marketing and administrative	**9,830**	9,762	10,313	11,606	11,911
Research and development	**10,208**	10,124	6,704	7,180	7,503
Restructuring costs	**776**	651	619	1,013	1,709
Other (income) expense, net	**12**	720	1,527	(11,613)	411
Income before taxes	**6,521**	4,659	5,401	17,283	5,545
Taxes on income	**4,103**	718	942	5,349	1,028
Net income	**2,418**	3,941	4,459	11,934	4,517
Less: Net income attributable to noncontrolling interests	**24**	21	17	14	113
Net income attributable to Merck & Co., Inc.	**2,394**	3,920	4,442	11,920	4,404
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	**$ 0.88**	$ 1.42	$ 1.58	$ 4.12	$ 1.49
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	**$ 0.87**	$ 1.41	$ 1.56	$ 4.07	$ 1.47
Cash dividends declared	**5,177**	5,135	5,115	5,156	5,132
Cash dividends declared per common share	**$ 1.89**	$ 1.85	$ 1.81	$ 1.77	$ 1.73
Capital expenditures	**1,888**	1,614	1,283	1,317	1,548
Depreciation	**1,455**	1,611	1,593	2,471	2,225
Average common shares outstanding (millions)	**2,730**	2,766	2,816	2,894	2,963
Average common shares outstanding assuming dilution (millions)	**2,748**	2,787	2,841	2,928	2,996
Year-End Position:					
Working capital	**$ 6,152**	$ 13,410	$ 10,550	$ 14,198	$ 17,461
Property, plant and equipment, net	**12,439**	12,026	12,507	13,136	14,973
Total assets	**87,872**	95,377	101,677	98,096	105,370
Long-term debt	**21,353**	24,274	23,829	18,629	20,472
Total equity	**34,569**	40,308	44,767	48,791	52,326
Year-End Statistics:					
Number of stockholders of record	**121,700**	129,500	135,500	142,000	149,400
Number of employees	**69,000**	68,000	68,000	70,000	77,000

[1] *Amounts for 2017 include a provisional net tax charge related to the enactment of U.S. tax legislation and a charge related to the formation of a collaboration with AstraZeneca.*

[2] *Amounts for 2016 include a charge related to the settlement of worldwide patent litigation related to* Keytruda.

[3] *Amounts for 2015 include a net charge related to the settlement of* Vioxx *shareholder class action litigation, foreign exchange losses related to Venezuela, gains on the dispositions of businesses and other assets and the favorable benefit of certain tax items.*

[4] *Amounts for 2014 reflect the divestiture of Merck's Consumer Care business on October 1, 2014, including a gain on the sale, as well as a gain recognized on an option exercise by AstraZeneca, gains on the dispositions of other businesses and assets, and a loss on extinguishment of debt.*

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Description of Merck's Business

Merck & Co., Inc. (Merck or the Company) is a global health care company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies and animal health products. The Company's operations are principally managed on a products basis and include four operating segments, which are the Pharmaceutical, Animal Health, Healthcare Services and Alliances segments. The Pharmaceutical segment is the only reportable segment.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. On December 31, 2016, Merck and Sanofi Pasteur S.A. (Sanofi) terminated their equally-owned joint venture, Sanofi Pasteur MSD (SPMSD), which developed and marketed vaccines in Europe. Beginning in 2017, Merck is recording vaccine sales and incurring costs as a result of operating its vaccines business in the European markets that were previously part of the SPMSD joint venture, which was accounted for as an equity method affiliate.

The Company also has an Animal Health segment that discovers, develops, manufactures and markets animal health products, including vaccines, which the Company sells to veterinarians, distributors and animal producers. The Company's Healthcare Services segment provides services and solutions that focus on engagement, health analytics and clinical services to improve the value of care delivered to patients.

Overview

During 2017, Merck continued to bring innovation to patients and physicians, expanding its focus in oncology and advancing other programs in its late-stage pipeline. Throughout 2017, *Keytruda*, the Company's anti-PD-1 (programmed death receptor-1) therapy, received approval for several additional indications globally, including U.S. Food and Drug Administration (FDA) approval in combination with pemetrexed and carboplatin, a commonly used chemotherapy regimen, for the first-line treatment of metastatic nonsquamous non-small-cell lung cancer (NSCLC), irrespective of PD-L1 expression. *Keytruda* is the only anti-PD-1 treatment approved in the first-line setting as both monotherapy and combination therapy for appropriate patients with metastatic NSCLC. In addition, Lynparza, an oral poly (ADP-ribose) polymerase (PARP) inhibitor, which is being developed in a collaboration, received FDA approval for the treatment of patients with germline BRCA-mutated, HER2-negative metastatic breast cancer who have been previously treated with chemotherapy. Additionally, in November 2017, the FDA approved *Prevymis* for prophylaxis (prevention) of cytomegalovirus (CMV) infection and disease, and in December 2017, the FDA approved *Steglatro, Steglujan* and *Segluromet* for the treatment of type 2 diabetes. In January 2018, *Prevymis* was also approved in the European Union (EU).

Worldwide sales were $40.1 billion in 2017, an increase of 1% compared with 2016. Sales growth was driven primarily by the launches of *Keytruda*, *Zepatier* and *Bridion*, as well as positive performance from Merck's Animal Health business. In addition, revenue in 2017 benefited from the sale of vaccines in the markets that were previously part of the now-terminated SPMSD vaccines joint venture. Growth in these areas was largely offset by the effects of generic and biosimilar competition that resulted in sales declines for products including *Zetia*, *Vytorin*, *Cubicin* and *Remicade*.

Augmenting Merck's portfolio and pipeline with external innovation remains an important component of the Company's overall strategy. In July 2017, Merck and AstraZeneca entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza for multiple cancer types. Lynparza is an oral PARP inhibitor currently approved for certain types of ovarian and breast cancer. The companies will develop and commercialize Lynparza both as monotherapy and in combination trials with other potential medicines. Independently, Merck and AstraZeneca will develop and commercialize Lynparza in combinations with their respective PD-1 and PD-L1 medicines. The companies will also jointly develop and commercialize AstraZeneca's selumetinib, an oral, potent, selective inhibitor of MEK, part of the mitogen-activated protein kinase (MAPK) pathway, currently being

developed for multiple indications including thyroid cancer. In addition, in October 2017, Merck acquired Rigontec GmbH (Rigontec), a leader in accessing the retinoic acid-inducible gene I pathway, part of the innate immune system, as a novel and distinct approach in cancer immunotherapy to induce both immediate and long-term anti-tumor immunity. Also, in March 2017, Merck acquired a controlling interest in Vallée S.A. (Vallée), a leading privately held producer of animal health products in Brazil.

Merck continues to prioritize resources to maximize opportunities for ongoing and upcoming product launches. *Keytruda* is launching around the world in multiple indications. In 2017, Merck achieved multiple additional regulatory milestones for *Keytruda*, including approval from the FDA as combination therapy for appropriate patients with metastatic NSCLC as noted above, as well as monotherapy approval for the treatment of certain patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma; for the treatment of certain patients with locally advanced or metastatic urothelial carcinoma, a type of bladder cancer; for the treatment of adult and pediatric patients with classical Hodgkin lymphoma (cHL); and for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient solid tumors. During 2017, *Keytruda* also received approval in the EU for the treatment of certain patients with cHL and urothelial carcinoma.

Merck continues to evaluate its pipeline, focusing its research efforts on the opportunities it believes have the greatest potential to address unmet medical needs. In addition to the recent regulatory approvals discussed above, the Company has continued to advance other programs in its late-stage pipeline with several regulatory submissions. MK-1439, doravirine, an investigational, non-nucleoside reverse transcriptase inhibitor for the treatment of HIV-1 infection, and MK-1439A, doravirine with lamivudine and tenofovir disoproxil fumarate, are currently under review with the FDA. In addition, the FDA accepted for review a supplemental Biologics License Application (BLA) for *Keytruda* for the treatment of adult and pediatric patients with refractory primary mediastinal B-cell lymphoma (PMBCL) that is refractory to or has relapsed after two prior lines of therapy. Additionally, *Steglatro, Steglujan* and *Segluromet* are under review in the EU.

The Company's Phase 3 oncology programs include *Keytruda* in the therapeutic areas of breast, colorectal, esophageal, gastric, head and neck, hepatocellular, nasopharyngeal, renal and small-cell lung cancers; Lynparza for pancreatic and prostate cancer; and selumetinib for thyroid cancer. Additionally, the Company has candidates in Phase 3 clinical development in several other therapeutic areas (see "Research and Development" below).

The Company continues to support its innovation strategy by remaining disciplined and prioritizing resources wherever possible to not only fund investment in the many opportunities in Merck's pipeline that it believes can help drive long-term growth, but also fund near-term opportunities to grow revenue. *Research and development* expenses in 2017 reflect increased clinical development spending as the Company continues to invest in the pipeline.

In November 2017, Merck's Board of Directors raised the Company's quarterly dividend to $0.48 per share from $0.47 per share. During 2017, the Company returned $9.2 billion to shareholders through dividends and share repurchases.

Earnings per common share assuming dilution attributable to common shareholders (EPS) for 2017 were $0.87 compared with $1.41 in 2016. EPS in both years reflect the impact of acquisition and divestiture-related costs, which in 2016 includes a charge related to the uprifosbuvir clinical development program, as well as restructuring costs and certain other items, which in 2017 include a provisional net tax charge related to the recent enactment of U.S. tax legislation and an aggregate charge related to the formation of a collaboration with AstraZeneca. Non-GAAP EPS, which exclude these items, were $3.98 in 2017 and $3.78 in 2016 (see "Non-GAAP Income and Non-GAAP EPS" below).

Cyber-attack

On June 27, 2017, the Company experienced a network cyber-attack that led to a disruption of its worldwide operations, including manufacturing, research and sales operations. All of the Company's manufacturing sites are now operational, manufacturing active pharmaceutical ingredient (API), formulating, packaging and shipping product. The Company's external manufacturing was not impacted. Throughout this time, Merck continued to fulfill orders and ship product.

Due to the cyber-attack, as anticipated, the Company was unable to fulfill orders for certain products in certain markets, which had an unfavorable effect on sales in 2017 of approximately $260 million. In addition, the

Company recorded manufacturing-related expenses, primarily unfavorable manufacturing variances, in *Materials and production* costs, as well as expenses related to remediation efforts in *Marketing and administrative* expenses and *Research and development* expenses, which aggregated approximately $285 million in 2017, net of insurance recoveries of approximately $45 million. Due to a residual backlog of orders for certain products, the Company anticipates that in 2018 sales will be unfavorably affected in certain markets by approximately $200 million from the cyber-attack. Merck does not expect a significant impairment to the value of intangible assets related to marketed products or inventories as a result of the cyber-attack.

As referenced above, the Company has insurance coverage insuring against costs resulting from cyber-attacks and has received insurance proceeds. However, there may be disputes with the insurers about the availability of the insurance coverage for claims related to this incident.

Additionally, the temporary production shut-down from the cyber-attack contributed to the Company's inability to meet higher than expected demand for *Gardasil* 9, which resulted in Merck's decision to borrow doses of *Gardasil* 9 from the U.S. Centers for Disease Control and Prevention (CDC) Pediatric Vaccine Stockpile. The Company subsequently replenished a portion of the borrowed doses in 2017. The net effect of the borrowing and subsequent partial replenishment was a reduction in sales of $125 million in 2017. The Company anticipates it will replenish the remaining borrowed doses in the second half of 2018.

Hurricane Maria

In September 2017, Hurricane Maria made direct landfall on Puerto Rico. The Company has one plant in Puerto Rico that makes a limited number of its pharmaceutical products, and the Company also works with contract manufacturers on the island. Merck's plant did not sustain substantial damage, and production activities at the plant have resumed. While power has been restored to the facility, it is not yet fully reliable and the plant continues to be prepared to use alternative sources of power and water. The Company is making progress to fully restore normal operations despite the significant damage to the island's infrastructure. Supply chains within Puerto Rico are improving, but are not yet fully restored. There was an immaterial impact to sales in 2017 and the Company expects an immaterial impact to sales in 2018.

Operating Results

Sales

Worldwide sales were $40.1 billion in 2017, an increase of 1% compared with 2016. Sales growth in 2017 was driven primarily by higher sales of recently launched products including *Keytruda, Zepatier* and *Bridion*. Additionally, sales in 2017 benefited from the December 31, 2016 termination of SPMSD, which marketed vaccines in most major European markets. In 2017, Merck began recording vaccine sales in the markets that were previously part of the SPMSD joint venture resulting in incremental vaccine sales of approximately $400 million during 2017. Higher sales of *Pneumovax* 23 and Adempas, as well as animal health products also contributed to revenue growth in 2017. These increases were largely offset by the effects of generic competition for certain products including *Zetia*, which lost U.S. market exclusivity in December 2016, *Vytorin*, which lost U.S. market exclusivity in April 2017, *Cubicin* due to U.S. patent expiration in June 2016, and *Cancidas*, which lost EU patent protection in April 2017. Revenue growth was also offset by continued biosimilar competition for *Remicade* and ongoing generic erosion for products including *Singulair* and *Nasonex*. Collectively, the sales decline attributable to the above products affected by generic and biosimilar competition was $3.3 billion in 2017. Lower sales of other products within the Diversified Brands franchise that includes certain products approaching the expiration of their marketing exclusivity or are no longer protected by patents in developed markets, including *Dulera* Inhalation Aerosol, as well as lower combined sales of the diabetes franchise of *Januvia* and *Janumet*, and declines in sales of *Isentress/Isentress HD* also partially offset revenue growth. Additionally, sales in 2017 were reduced by $125 million due to a borrowing the Company made from the CDC Pediatric Vaccine Stockpile of doses of *Gardasil* 9 as discussed below. Also, as anticipated, the Company was unable to fulfill orders for certain products in certain markets due to the cyber-attack, which had an unfavorable effect on sales in 2017 of approximately $260 million.

Sales in the United States were $17.4 billion in 2017, a decline of 6% compared with $18.5 billion in 2016. The decrease was driven primarily by the effects of generic competition for *Zetia* and *Vytorin*, *Cubicin*, and declines of products within Diversified Brands including *Nasonex* and *Dulera* Inhalation Aerosol. Lower sales of *Januvia/Janumet*, *Gardasil/Gardasil* 9, *Isentress/Isentress HD* and *Zostavax*, also contributed to the U.S. sales decline in 2017.

These declines were partially offset by higher sales of *Keytruda*, *Zepatier*, *Bridion*, and *Pneumovax* 23, along with higher sales of animal health products.

International sales were $22.7 billion in 2017, an increase of 6% compared with $21.3 billion in 2016, primarily reflecting growth in *Keytruda* and *Zepatier*, and higher sales of vaccines due to the termination of the SPMSD joint venture, as well as higher sales of animal health products. Sales growth was partially offset by ongoing biosimilar competition for *Remicade*, as well as generic erosion for *Cancidas* and products within Diversified Brands. International sales represented 57% and 54% of total sales in 2017 and 2016, respectively.

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. In the United States, pricing pressures continue on many of the Company's products and, in several international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. In addition, other austerity measures negatively affected the Company's revenue performance in 2017. The Company anticipates these pricing actions, including the biennial price reductions in Japan that will occur again in 2018, and other austerity measures will continue to negatively affect revenue performance in 2018.

Worldwide sales were $39.8 billion in 2016, an increase of 1% compared with 2015. Foreign exchange unfavorably affected global sales performance by 2% in 2016, which includes a lower benefit from revenue hedging activities as compared with 2015. Revenue growth primarily reflects higher sales of *Keytruda*, the launch of the HCV treatment *Zepatier,* and growth in vaccine products, including *Gardasil/Gardasil* 9, *Varivax* and *Pneumovax* 23. Also contributing to sales growth in 2016 were higher sales of hospital acute care products including *Bridion* and *Noxafil*, growth within the diabetes franchise of *Januvia* and *Janumet*, as well as higher sales of animal health products, particularly *Bravecto*. These increases were largely offset by sales declines attributable to the ongoing effects of generic and biosimilar competition for certain products, including *Remicade* and *Nasonex*, along with other products within Diversified Brands. Declines in *Isentress* and *Dulera* Inhalation Aerosol also partially offset revenue growth in 2016. Sales performance in 2016 reflects a decline of approximately $625 million due to reduced operations by the Company in Venezuela as a result of the economic conditions and volatility in that country.

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Sales of the Company's products were as follows:

($ in millions)	2017			2016			2015		
	U.S.	**Int'l**	**Total**	U.S.	Int'l	Total	U.S.	Int'l	Total
Primary Care and Women's Health									
Cardiovascular									
Zetia	**$ 352**	**$ 992**	**$ 1,344**	$ 1,588	$ 972	$ 2,560	$ 1,612	$ 914	$ 2,526
Vytorin	**124**	**627**	**751**	473	668	1,141	479	771	1,251
Atozet	**—**	**225**	**225**	1	146	146	2	34	36
Adempas	**—**	**300**	**300**	—	169	169	—	30	30
Diabetes									
Januvia	**2,153**	**1,584**	**3,737**	2,286	1,622	3,908	2,263	1,601	3,863
Janumet	**863**	**1,296**	**2,158**	984	1,217	2,201	976	1,175	2,151
General Medicine and Women's Health									
NuvaRing	**564**	**197**	**761**	576	202	777	515	216	732
Implanon/Nexplanon	**496**	**191**	**686**	420	186	606	367	221	588
Follistim AQ	**123**	**174**	**298**	157	197	355	160	223	383
Hospital and Specialty									
Hepatitis									
Zepatier	**771**	**888**	**1,660**	488	67	555	—	—	—
HIV									
Isentress/Isentress HD	**565**	**639**	**1,204**	721	666	1,387	797	714	1,511
Hospital Acute Care									
Bridion	**239**	**465**	**704**	77	405	482	—	353	353
Noxafil	**309**	**327**	**636**	284	312	595	212	275	487
Invanz	**361**	**241**	**602**	329	233	561	322	247	569
Cancidas	**20**	**402**	**422**	25	533	558	24	548	573
Cubicin [(1)]	**189**	**193**	**382**	906	181	1,087	1,030	97	1,127
Primaxin	**10**	**270**	**280**	4	293	297	8	305	313
Immunology									
Remicade	**—**	**837**	**837**	—	1,268	1,268	—	1,794	1,794
Simponi	**—**	**819**	**819**	—	766	766	—	690	690
Oncology									
Keytruda	**2,309**	**1,500**	**3,809**	792	610	1,402	393	173	566
Emend	**342**	**213**	**556**	356	193	549	326	209	535
Temodar	**16**	**256**	**271**	15	268	283	7	306	312
Diversified Brands									
Respiratory									
Singulair	**40**	**692**	**732**	40	874	915	39	892	931
Nasonex	**54**	**333**	**387**	184	352	537	449	409	858
Dulera	**261**	**26**	**287**	412	24	436	515	21	536
Other									
Cozaar/Hyzaar	**18**	**466**	**484**	16	494	511	30	637	667
Arcoxia	**—**	**363**	**363**	—	450	450	—	471	471
Fosamax	**6**	**235**	**241**	5	279	284	12	347	359
Vaccines [(2)]									
Gardasil/Gardasil 9	**1,565**	**743**	**2,308**	1,780	393	2,173	1,520	388	1,908
ProQuad/M-M-R II*/Varivax*	**1,374**	**303**	**1,676**	1,362	279	1,640	1,290	214	1,505
Pneumovax 23	**581**	**240**	**821**	447	193	641	378	164	542
RotaTeq	**481**	**204**	**686**	482	169	652	447	163	610

Zostavax	**422**	**246**	**668**	518	168	685	592	157	749
Other pharmaceutical *(3)*	**1,246**	**3,049**	**4,295**	1,345	3,228	4,574	1,473	3,785	5,256
Total Pharmaceutical segment sales	**15,854**	**19,536**	**35,390**	17,073	18,077	35,151	16,238	18,544	34,782
Other segment sales *(4)*	**1,486**	**2,785**	**4,272**	1,374	2,489	3,862	1,213	2,454	3,667
Total segment sales	**17,340**	**22,321**	**39,662**	18,447	20,566	39,013	17,451	20,998	38,449
Other *(5)*	**84**	**377**	**460**	31	763	794	68	981	1,049
	$ 17,424	**$ 22,698**	**$ 40,122**	$ 18,478	$ 21,329	$ 39,807	$ 17,519	$ 21,979	$ 39,498

U.S. plus international may not equal total due to rounding.

(1) Sales of Cubicin *in 2015 represent sales subsequent to the Cubist acquisition date.*

(2) On December 31, 2016, Merck and Sanofi terminated their equally-owned joint venture, SPMSD, which marketed vaccines in most major European markets (see Note 9). Accordingly, vaccine sales in 2017 include sales in the European markets that were previously part of SPMSD. Amounts for 2016 and 2015 do not include sales of vaccines sold through SPMSD, the results of which are reflected in equity income from affiliates included in Other (income) expense, net. *Amounts for 2016 and 2015 do, however, include supply sales to SPMSD.*

(3) Other pharmaceutical primarily reflects sales of other human health pharmaceutical products, including products within the franchises not listed separately.

(4) Represents the non-reportable segments of Animal Health, Healthcare Services and Alliances.

(5) Other is primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, as well as third-party manufacturing sales. Other in 2017 and 2016 also includes $85 million and $170 million, respectively, related to the sale of the marketing rights to certain products.

Pharmaceutical Segment

Primary Care and Women's Health

Cardiovascular

Combined global sales of *Zetia* (marketed in most countries outside the United States as *Ezetrol*), *Vytorin* (marketed outside the United States as *Inegy*), and *Atozet* (marketed in certain countries outside of the United States), medicines for lowering LDL cholesterol, were $2.3 billion in 2017, a decline of 40% compared with 2016. The sales decline was driven by lower volumes and pricing of *Zetia* and *Vytorin* in the United States as a result of generic competition. By agreement, a generic manufacturer launched a generic version of *Zetia* in the United States in December 2016. The U.S. patent and exclusivity periods for *Zetia* and *Vytorin* otherwise expired in April 2017. Accordingly, the Company is experiencing rapid and substantial declines in U.S. *Zetia* and *Vytorin* sales and expects the declines to continue. The Company will lose market exclusivity in major European markets for *Ezetrol* in April 2018 and for *Inegy* in April 2019 and anticipates sales declines in these markets thereafter. Sales of *Ezetrol* and *Inegy* in these markets were $552 million and $457 million, respectively, in 2017. Combined worldwide sales of *Zetia*, *Vytorin* and *Atozet* were $3.8 billion in 2016, growth of 1% compared with 2015, reflecting volume growth in Europe and higher pricing in the United States, largely offset by lower sales in Venezuela due to reduced operations by the Company in that country and lower volumes in the United States reflecting in part generic competition for *Zetia*.

Pursuant to a collaboration with Bayer AG (Bayer) (see Note 4 to the consolidated financial statements), Merck has lead commercial rights for Adempas, a cardiovascular drug for the treatment of pulmonary arterial hypertension, in countries outside the Americas while Bayer has lead rights in the Americas, including the United States. The companies share profits equally under the collaboration. In 2016, Merck began promoting and distributing Adempas in Europe. Transition from Bayer in other Merck territories, including Japan, continued in 2017. Merck recorded sales for Adempas of $300 million in 2017, $169 million in 2016 and $30 million in 2015, which includes sales in Merck's marketing territories, as well as Merck's share of profits from the sale of Adempas in Bayer's marketing territories.

Diabetes

Worldwide combined sales of *Januvia* and *Janumet*, medicines that help lower blood sugar levels in adults with type 2 diabetes, were $5.9 billion in 2017, a decline of 3% compared with 2016 including a 1% favorable effect from foreign exchange. The sales decline was driven primarily by ongoing pricing pressure partially offset by continued volume growth globally. Combined global sales of *Januvia* and *Janumet* were $6.1 billion in 2016, an increase of 2% compared with 2015. Sales growth was driven primarily by higher volumes in the United States, Europe and Canada, partially offset by pricing pressures in the United States and Europe, and lower sales in Venezuela due to the Company's reduced operations in that country.

In April 2017, Merck announced that the FDA issued a Complete Response Letter (CRL) regarding Merck's supplemental New Drug Applications (NDA) for *Januvia*, *Janumet* and *Janumet XR* (sitagliptin and metformin HCl extended-release). With these applications, Merck is seeking to include data from TECOS (Trial Evaluating Cardiovascular Outcomes with Sitagliptin) in the prescribing information of sitagliptin-containing medicines. Merck is taking actions to respond to the CRL.

In December 2017, the FDA approved *Steglatro* (ertugliflozin) tablets, an oral sodium-glucose cotransporter 2 (SGLT2) inhibitor, and the fixed-dose combination *Steglujan* (ertugliflozin and sitagliptin) tablets, the only fixed-dose combination of an SGLT2 inhibitor and dipeptidyl peptidase-4 inhibitor *Januvia* (sitagliptin). The FDA also approved the fixed-dose combination *Segluromet* (ertugliflozin and metformin hydrochloride). *Steglatro*, *Steglujan* and *Segluromet* are indicated to improve glycemic control in adults with type 2 diabetes mellitus. These products are part of a worldwide (except Japan) collaboration between Merck and Pfizer Inc. (Pfizer) for the co-development and co-promotion of ertugliflozin. As a result of FDA approval, Merck will make a $60 million payment to Pfizer, which was accrued for in the fourth quarter of 2017. The amount was capitalized and will be amortized over its estimated useful life, subject to impairment testing. Merck will exclusively promote *Steglatro* and the two fixed-dose combination products in the United States. Merck and Pfizer will share revenues and certain costs on a 60%/40% basis, with Merck having the 60% share, and Pfizer may be entitled to additional milestone payments. In January 2018, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending approval of ertugliflozin and the two fixed-dose combination products. The CHMP positive opinion will be considered by the European Commission (EC). If approval of any of the products in the EU is received, Merck will make an additional $40 million milestone payment to Pfizer.

General Medicine and Women's Health

Worldwide sales of *NuvaRing*, a vaginal contraceptive product, were $761 million in 2017, a decline of 2% compared with 2016 including a 1% favorable effect from foreign exchange. The sales decline was driven primarily by lower sales in the United States reflecting lower volumes that were partially offset by higher pricing, and lower demand in Europe. Global sales of *NuvaRing* were $777 million in 2016, an increase of 6% compared with 2015 including a 1% unfavorable effect from foreign exchange. Sales growth largely reflects higher pricing in the United States, partially offset by volume declines in Europe. The patent that provides U.S. market exclusivity for *NuvaRing* will expire in April 2018 and the Company anticipates a significant decline in U.S. *NuvaRing* sales thereafter.

Worldwide sales of *Implanon/Nexplanon*, single-rod subdermal contraceptive implants, grew to $686 million in 2017, an increase of 13% compared with 2016, primarily reflecting higher pricing and volume growth in the United States. Global sales of *Implanon/Nexplanon* were $606 million in 2016, an increase of 3% compared with 2015 including a 3% unfavorable effect from foreign exchange. Sales growth reflects higher demand in the United States, partially offset by declines in international markets, particularly in Venezuela.

Hospital and Specialty

Hepatitis

Global sales of *Zepatier*, a treatment for chronic hepatitis C (HCV) infection, were $1.7 billion in 2017 and $555 million in 2016. Sales growth was driven primarily by higher sales in Europe, the United States and Japan following product launch in 2016. Merck has also launched *Zepatier* in other international markets. The Company is beginning to experience the unfavorable effects of increasing competition and declining patient volumes and anticipates that sales of *Zepatier* in the future will be materially adversely affected by these factors.

HIV

Worldwide sales of *Isentress/Isentress HD,* an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, were $1.2 billion in 2017, a decline of 13% compared with 2016. The sales decline primarily reflects lower demand in the United States and Europe due to competitive pressures. In May 2017, the FDA approved *Isentress HD*, a once-daily dose of *Isentress.* In July 2017, the EC granted marketing authorization for the once-daily dose of *Isentress* (where it will be marketed as *Isentress* 600 mg). Global sales of *Isentress* were $1.4 billion in 2016, a decline of 8% compared with 2015 including a 2% unfavorable effect from foreign exchange. The sales decline was driven primarily by lower volumes in the United States, as well as lower demand and pricing in Europe due to competitive pressures, partially offset by a favorable adjustment to discount reserves in the United States.

Hospital Acute Care

Global sales of *Bridion*, for the reversal of two types of neuromuscular blocking agents used during surgery, were $704 million in 2017, growth of 46% compared with 2016, driven by strong global demand, particularly in the United States. Worldwide sales were $482 million in 2016, growth of 37% compared with 2015 including a 2% favorable effect from foreign exchange. Sales growth reflects volume growth in most markets, including in the United States where it was approved by the FDA in December 2015, partially offset by a decline in Venezuela due to reduced operations by the Company in this country.

Worldwide sales of *Noxafil*, for the prevention of invasive fungal infections, were $636 million in 2017, an increase of 7% compared with 2016, primarily reflecting higher demand and pricing in the United States, as well as volume growth in Europe. Global sales of *Noxafil* grew 22% in 2016 to $595 million driven primarily by higher pricing in the United States, volume growth in Europe reflecting an ongoing positive impact from the approval of new formulations, and higher demand in the Asia Pacific region. Foreign exchange unfavorably affected global sales performance by 3% in 2016.

Global sales of *Invanz*, for the treatment of certain infections, were $602 million in 2017, an increase of 7% compared with 2016, driven primarily by higher sales in the United States, reflecting higher pricing that was partially offset by lower demand, as well as higher demand in Brazil. Worldwide sales of *Invanz* were $561 million in 2016, a decline of 1% compared with 2015 including a 2% unfavorable effect from foreign exchange. Sales performance in 2016 reflects higher pricing in the United States, largely offset by a decline in Venezuela. The patent that provided U.S.

market exclusivity for *Invanz* expired in November 2017 and the Company anticipates a significant decline in U.S. *Invanz* sales in future periods.

Global sales of *Cancidas*, an anti-fungal product sold primarily outside of the United States, were $422 million in 2017, a decline of 24% compared with 2016, driven primarily by generic competition in certain European markets. The EU compound patent for *Cancidas* expired in April 2017. Accordingly, the Company is experiencing a significant decline in *Cancidas* sales in these European markets and expects the decline to continue. Worldwide sales of *Cancidas* were $558 million in 2016, a decline of 3% compared with 2015, reflecting a 4% unfavorable effect from foreign exchange and pricing declines in Europe that were offset by higher volumes in China.

Global sales of *Cubicin*, an I.V. antibiotic for complicated skin and skin structure infections or bacteremia when caused by designated susceptible organisms, were $382 million in 2017, a decline of 65% compared with 2016, and were $1.1 billion in 2016, a decline of 4% compared with 2015. The U.S. composition patent for *Cubicin* expired in June 2016. Accordingly, the Company is experiencing a rapid and substantial decline in U.S. *Cubicin* sales as a result of generic competition and expects the decline to continue. The Company anticipates it will lose market exclusivity for *Cubicin* in some European markets in early 2018.

In November 2017, Merck announced that the FDA approved *Prevymis* (letermovir) for prophylaxis (prevention) of CMV infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant. As a result of FDA approval, Merck made a €105 million ($125 million) milestone payment to AiCuris in 2017. This amount was capitalized and will be amortized over its estimated useful life, subject to impairment testing. In January 2018, *Prevymis* was approved by the EC and, as a result, Merck will make an additional €30 million milestone payment to AiCuris. Merck also has filed *Prevymis* for regulatory approval in other markets including Japan.

Immunology

Sales of *Remicade,* a treatment for inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were $837 million in 2017, a decline of 34% compared with 2016, and were $1.3 billion in 2016, a decline of 29% compared with 2015. Foreign exchange unfavorably affected sales performance by 1% in 2016. The Company lost market exclusivity for *Remicade* in major European markets in 2015 and no longer has market exclusivity in any of its marketing territories. The Company is experiencing pricing and volume declines in these markets as a result of biosimilar competition and expects the declines to continue.

Sales of *Simponi*, a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were $819 million in 2017, growth of 7% compared with 2016 including a 1% favorable effect from foreign exchange. Sales growth primarily reflects higher demand in Europe. Sales of *Simponi* were $766 million in 2016, an increase of 11% compared with 2015 including a 3% unfavorable effect from foreign exchange. Sales growth was driven primarily by higher volumes in Europe reflecting in part an ongoing positive impact from the ulcerative colitis indication.

Oncology

Sales of *Keytruda*, an anti-PD-1 therapy, were $3.8 billion in 2017, $1.4 billion in 2016 and $566 million in 2015. The year-over-year increases were driven by volume growth in all markets, particularly in the United States, Europe and Japan as the Company continues to launch *Keytruda* with multiple new indications globally. U.S. sales of *Keytruda* were $2.3 billion in 2017, $792 million in 2016 and $393 million in 2015. Sales in the United States continue to build across the multiple approved indications, in particular for the treatment of NSCLC reflecting both the continued adoption of *Keytruda* in the first-line setting as monotherapy for patients with metastatic NSCLC whose tumors have high PD-L1 expression, as well as the uptake of *Keytruda* in combination with pemetrexed and carboplatin, a commonly used chemotherapy regimen, for the first-line treatment of metastatic nonsquamous NSCLC with or without PD-L1 expression. Other indications, including melanoma, head and neck cancer, and bladder cancer, also contributed to growth in 2017. Sales growth in international markets reflects positive performance in the melanoma indications, as well as a greater contribution from the treatment of patients with NSCLC as reimbursement is established in additional markets in the first- and second-line settings.

In March 2017, the FDA approved *Keytruda* for the treatment of adult and pediatric patients with cHL refractory to treatment, or who have relapsed after three or more prior lines of therapy. In May 2017, the EC approved *Keytruda* for the treatment of adult patients with relapsed or refractory cHL who have failed autologous stem cell transplant and brentuximab vedotin, or who are transplant-ineligible and have failed brentuximab vedotin.

In May 2017, the FDA approved *Keytruda* in combination with pemetrexed and carboplatin for the first-line treatment of metastatic nonsquamous NSCLC, irrespective of PD-L1 expression. *Keytruda* is the only anti-PD-1 treatment approved in the first-line setting as both monotherapy and combination therapy for appropriate patients with metastatic NSCLC. In October 2016, *Keytruda* was approved by the FDA as monotherapy in the first-line setting for patients with metastatic NSCLC whose tumors have high PD-L1 expression, with no EGFR or ALK genomic tumor aberrations. *Keytruda* as monotherapy is also indicated for the second-line or greater treatment setting for patients with metastatic NSCLC whose tumors express PD-L1, with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving *Keytruda*. Additionally, in January 2017, the EC approved *Keytruda* for the first-line treatment of metastatic NSCLC in adults whose tumors have high PD-L1 expression with no EGFR or ALK positive tumor mutations.

Also in May 2017, the FDA approved *Keytruda* for the treatment of certain patients with locally advanced or metastatic urothelial carcinoma, a type of bladder cancer. In the first-line setting, *Keytruda* is approved for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are ineligible for cisplatin-containing chemotherapy. In the second-line setting, *Keytruda* is approved for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. In September 2017, the EC approved *Keytruda* for use as monotherapy for the treatment of locally advanced or metastatic urothelial carcinoma in adults who have received prior platinum-containing chemotherapy, as well as adults who are not eligible for cisplatin-containing chemotherapy.

Additionally in May 2017, the FDA approved *Keytruda* for a first-of-its-kind indication: the treatment of adult and pediatric patients with previously treated unresectable or metastatic MSI-H or mismatch repair deficient solid tumors. With this unique indication, *Keytruda* is the first cancer therapy approved for use based on a biomarker, regardless of tumor type.

In September 2017, the FDA approved *Keytruda* for the treatment of patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1. In December 2017, Merck announced that the pivotal Phase 3 KEYNOTE-061 trial investigating *Keytruda*, as a second-line treatment for patients with advanced gastric or gastroesophageal junction adenocarcinoma, did not meet its primary endpoint of overall survival (OS) in patients whose tumors expressed PD-L1. Additionally, progression free survival (PFS) in the PD-L1 positive population did not show statistical significance. The safety profile observed in KEYNOTE-061 was consistent with that observed in previously reported studies of *Keytruda*; no new safety signals were identified. The current indication remains unchanged and the Company continues to evaluate *Keytruda* for gastric or gastroesophageal junction adenocarcinoma through KEYNOTE-062, a Phase 3 clinical trial studying *Keytruda* as a monotherapy or in combination with chemotherapy as first-line treatment for patients with PD-L1 positive advanced gastric or gastroesophageal junction cancer, and with KEYNOTE-585, a Phase 3 trial studying *Keytruda* in combination with chemotherapy in a neoadjuvant/adjuvant setting.

In August 2016, Merck announced that the FDA approved *Keytruda* for the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) with disease progression on or after platinum-containing chemotherapy. In July 2017, Merck announced that the pivotal Phase 3 KEYNOTE-040 trial investigating *Keytruda* in previously treated patients with recurrent or metastatic HNSCC did not meet its pre-specified primary endpoint of OS. The safety profile observed in KEYNOTE-040 was consistent with that observed in previously reported studies of *Keytruda*; no new safety signals were identified. The current indication remains unchanged and clinical trials continue, including KEYNOTE-048, a Phase 3 clinical trial of *Keytruda* in the first-line treatment of recurrent or metastatic HNSCC.

As a result of the additional approvals received in 2017 as noted above, *Keytruda* is now approved in the United States and in the EU as monotherapy for the treatment of certain patients with NSCLC, melanoma, cHL and urothelial carcinoma. *Keytruda* is also approved in the United States as monotherapy for the treatment of certain patients with HNSCC, gastric or gastroesophageal junction adenocarcinoma and MSI-H or mismatch repair deficient cancer, and in combination with pemetrexed and carboplatin in certain patients with NSCLC. *Keytruda* is also approved in Japan for the treatment of radically unresectable melanoma, PD-L1-positive unresectable advanced or recurrent NSCLC,

relapsed or refractory cHL, and radically unresectable urothelial carcinoma. The *Keytruda* clinical development program includes studies across a broad range of cancer types (see "Research and Development" below).

In January 2017, Merck entered into a settlement and license agreement to resolve worldwide patent infringement litigation related to *Keytruda* (see Note 11 to the consolidated financial statements). Pursuant to the settlement, the Company will pay royalties of 6.5% on net sales of *Keytruda* in 2017 through 2023; and 2.5% on net sales of *Keytruda* in 2024 through 2026.

Lynparza, an oral PARP inhibitor being developed as part of a collaboration formed in July 2017 with AstraZeneca (see Note 4 to the consolidated financial statements), is currently approved for certain types of ovarian and breast cancer. In January 2018, the FDA approved Lynparza for use in patients with BRCA-mutated, HER2-negative metastatic breast cancer who have been previously treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. As a result of this approval, Merck will make a $70 million milestone payment to AstraZeneca (see Note 4 to the consolidated financial statements). Also in January 2018, the Japanese Ministry of Health, Labour and Welfare approved Lynparza for use as a maintenance therapy in patients for platinum-sensitive relapsed ovarian cancer, regardless of their BRCA mutation status, who responded to their last platinum-based chemotherapy. Lynparza is the first PARP inhibitor to be approved in Japan.

Diversified Brands

Merck's diversified brands include human health pharmaceutical products that are approaching the expiration of their marketing exclusivity or are no longer protected by patents in developed markets, but continue to be a core part of the Company's offering in other markets around the world.

Respiratory

Worldwide sales of *Singulair,* a once-a-day oral medicine for the chronic treatment of asthma and for the relief of symptoms of allergic rhinitis, were $732 million in 2017, a decline of 20% compared with 2016, and were $915 million in 2016, a decrease of 2% compared with 2015. Foreign exchange unfavorably affected global sales performance by 1% in 2017 and favorably affected global sales performance by 2% in 2016. The sales declines were driven by lower volumes in Japan as a result of generic competition. The patents that provided market exclusivity for *Singulair* in Japan expired in 2016. As a result, the Company is experiencing a significant decline in *Singulair* sales in Japan and expects the decline to continue. The Company no longer has market exclusivity for *Singulair* in any major market.

Global sales of *Nasonex*, an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, were $387 million in 2017, a decline of 28% compared with 2016, and were $537 million in 2016, a decline of 37% compared with 2015. Foreign exchange favorably affected global sales performance by 1% in 2017. The Company is experiencing a substantial decline in U.S. *Nasonex* sales as a result of generic competition and expects the decline to continue. The decline in global *Nasonex* sales in 2016 was also driven by lower volumes and pricing in Europe from ongoing generic erosion and lower sales in Venezuela due to reduced operations by the Company in this country.

Global sales of *Dulera* Inhalation Aerosol, a combination medicine for the treatment of asthma, were $287 million in 2017, a decline of 34% compared with 2016, driven by lower sales in the United States reflecting ongoing competitive pricing pressure, as well as lower demand. Worldwide sales of *Dulera* Inhalation Aerosol were $436 million in 2016, a decline of 19% compared with 2015 including a 1% unfavorable effect from foreign exchange. The decline was driven by lower sales in the United Sales reflecting competitive pricing pressure that was partially offset by higher demand.

Vaccines

On December 31, 2016, Merck and Sanofi terminated their equally-owned joint venture, SPMSD, which developed and marketed vaccines in Europe. Accordingly, vaccine sales in 2017 include sales of Merck vaccines in the European markets that were previously part of the SPMSD joint venture, whereas sales in periods prior to 2017 do not. Prior to 2017, vaccine sales in these European markets were sold through the SPMSD joint venture, the results of which are reflected in equity income from affiliates included in *Other (income) expense, net* (see Note 15 to the consolidated financial statements). Supply sales to SPMSD, however, are included in vaccine sales in periods prior to 2017. Incremental vaccine sales resulting from the termination of the SPMSD joint venture in 2017 were approximately $400 million, of which approximately $215 million relate to *Gardasil/Gardasil* 9.

Worldwide sales of *Gardasil/Gardasil* 9, vaccines to help prevent certain cancers and diseases caused by certain types of human papillomavirus (HPV), were $2.3 billion in 2017, growth of 6% compared with 2016. Sales growth was driven primarily by higher sales in Europe resulting from the termination of the SPMSD joint venture noted above, as well as higher demand in Asia Pacific due in part to the launch in China, partially offset by lower sales in the United States. Lower sales in the United States reflect the timing of public sector purchases. In addition, during 2017, the Company made a request to borrow doses of *Gardasil* 9 from the CDC Pediatric Vaccine Stockpile, which the CDC granted. The Company's decision to borrow the doses from the CDC was driven in part by the temporary shutdown resulting from the cyber-attack that occurred in June, as well as by overall higher demand than expected. As a result of the borrowing, the Company reversed the sales related to the borrowed doses and recognized a corresponding liability. The Company subsequently replenished nearly half of the doses borrowed from the stockpile. The net effect of the borrowing and subsequent partial replenishment was a reduction in sales of $125 million in 2017. The Company anticipates it will replenish the remaining borrowed doses in the second half of 2018, which will result in the recognition of sales and a reversal of the remaining liability. Additionally, in October 2016, the FDA approved a 2-dose vaccination regimen for *Gardasil* 9, for use in girls and boys 9 through 14 years of age, and the CDC's Advisory Committee on Immunization Practices (ACIP) voted to recommend the 2-dose vaccination regimen for certain 9 through 14 year olds. The Company is experiencing an impact from the transition from a 3-dose vaccine regimen to a 2-dose vaccination regimen; however, increased patient starts are helping to offset the negative effects of the transition. Merck's sales of *Gardasil/Gardasil* 9 were $2.2 billion in 2016, growth of 14% compared with 2015. Sales growth was driven primarily by higher volumes and pricing in the United States, as well as higher demand in the Asia Pacific region, partially offset by a decline in government tenders in Brazil. The Company is a party to certain third-party license agreements with respect to *Gardasil/Gardasil* 9 (including a cross-license and settlement agreement with GlaxoSmithKline). As a result of these agreements, the Company pays royalties on worldwide *Gardasil/Gardasil* 9 sales of 10% to 18% which vary by country and are included in *Materials and production* costs.

Global sales of *ProQuad*, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, were $528 million in 2017, $495 million in 2016 and $454 million in 2015. The increase in 2017 as compared with 2016 was driven primarily by higher pricing and volumes in the United States, as well as volume growth in international markets, particularly in Europe. Sales growth in 2016 as compared with 2015 was driven primarily by higher demand and pricing in the United States.

Worldwide sales of *M-M-R* II, a vaccine to help protect against measles, mumps and rubella, were $382 million in 2017, $353 million in 2016 and $365 million in 2015. Sales growth in 2017 as compared with 2016 was largely attributable to higher sales in Europe resulting from the termination of the SPMSD joint venture. Sales performance in 2016 as compared with 2015 was driven by higher demand in 2015 resulting from measles outbreaks in the United States.

Global sales of *Varivax,* a vaccine to help prevent chickenpox (varicella), were $767 million in 2017, $792 million in 2016 and $686 million in 2015. The sales decline in 2017 as compared with 2016 was driven primarily by lower volumes in Brazil due to the loss of a government tender, as well as lower sales in the United States reflecting lower demand partially offset by higher pricing. Higher sales in Europe resulting from the termination of the SPMSD joint venture partially offset the decline. Sales growth in 2016 as compared with 2015 was driven primarily by higher sales in the United States reflecting the effects of public sector purchasing and higher pricing that were partially offset by lower demand. Volume growth in Brazil reflecting the timing of government tenders also contributed to the sales increase in 2016 as compared with 2015.

Worldwide sales of *Pneumovax* 23, a vaccine to help prevent pneumococcal disease, were $821 million in 2017, an increase of 28% compared with 2016, driven primarily by higher demand and pricing in the United States, as well as higher sales in Europe resulting from the termination of the SPMSD joint venture. Merck's sales of *Pneumovax* 23 were $641 million in 2016, an increase of 18% compared with 2015, driven primarily by higher volumes and pricing in the United States and higher demand in the Asia Pacific region. Foreign exchange unfavorably affected sales performance by 1% in 2017 and favorably affected sales performance by 1% in 2016.

Global sales of *RotaTeq,* a vaccine to help protect against rotavirus gastroenteritis in infants and children, were $686 million in 2017, an increase of 5% compared with 2016, driven primarily by higher sales in Europe resulting from the termination of the SPMSD joint venture. Merck's sales of *RotaTeq* were $652 million in 2016, an increase of 7% compared with 2015 including a 3% unfavorable effect from foreign exchange. Sales performance was driven

primarily by the effects of public sector purchasing in the United States, as well as volume growth in several international markets.

Worldwide sales of *Zostavax,* a vaccine to help prevent shingles (herpes zoster) in adults 50 years of age and older, were $668 million in 2017, a decline of 2% compared with 2016 including a 1% favorable effect from foreign exchange. The sales decline was driven primarily by lower demand in the United States reflecting the approval of a competitor's vaccine that received a preferential recommendation from the ACIP in October 2017 for the prevention of shingles over *Zostavax*. The Company anticipates this competition will have a material adverse effect on sales of *Zostavax* in future periods. The U.S. sales decline was largely offset by growth in Europe resulting from the termination of the SPMSD joint venture and volume growth in the Asia Pacific region. Merck's sales of *Zostavax* were $685 million in 2016, a decline of 9% compared with 2015 including a 1% unfavorable effect from foreign exchange. The decline was driven primarily by lower volumes in the United States, partially offset by higher pricing in the United States and higher demand in the Asia Pacific region.

Other Segments

The Company's other segments are the Animal Health, Healthcare Services and Alliances segments, which are not material for separate reporting.

Animal Health

Animal Health includes pharmaceutical and vaccine products for the prevention, treatment and control of disease in all major farm and companion animal species. Animal Health sales are affected by competition and the frequent introduction of generic products. Worldwide sales of Animal Health products were $3.9 billion in 2017, $3.5 billion in 2016 and $3.3 billion in 2015. Global sales of Animal Health products grew 11% in 2017 compared with 2016 primarily reflecting higher sales of companion animal products, largely driven by growth in *Bravecto*, a line of products that kill fleas and ticks in dogs and cats for up to 12 weeks, reflecting both growth in the oral formulation and continued uptake in the topical formulation, which was launched in 2016. Animal Health sales growth was also driven by higher sales of ruminant, poultry and swine products. Worldwide sales of Animal Health products increased 4% in 2016 compared with 2015 including a 4% unfavorable effect from foreign exchange. Sales growth reflects volume growth across most species areas, particularly in products for companion animals, driven primarily by higher sales of *Bravecto,* as well as in poultry and swine products.

In March 2017, Merck acquired a controlling interest in Vallée, a leading privately held producer of animal health products in Brazil (see Note 3 to the consolidated financial statements).

Costs, Expenses and Other

($ in millions)		**2017**	**Change**	2016	Change	2015
Materials and production	**$**	**12,775**	**-8 %**	$ 13,891	-7 %	$ 14,934
Marketing and administrative		**9,830**	**1 %**	9,762	-5 %	10,313
Research and development		**10,208**	**1 %**	10,124	51 %	6,704
Restructuring costs		**776**	**19 %**	651	5 %	619
Other (income) expense, net		**12**	**-98 %**	720	-53 %	1,527
	$	**33,601**	**-4 %**	$ 35,148	3 %	$ 34,097

Materials and Production

Materials and production costs were $12.8 billion in 2017, $13.9 billion in 2016 and $14.9 billion in 2015. Costs include expenses for the amortization of intangible assets recorded in connection with business acquisitions which totaled $3.1 billion in 2017, $3.7 billion in 2016 and $4.7 billion in 2015. Costs in 2017, 2016 and 2015 also include intangible asset impairment charges of $58 million, $347 million and $45 million, respectively, related to marketed products and other intangibles recorded in connection with business acquisitions (see Note 8 to the consolidated financial statements). Costs in 2017 also include a $76 million intangible asset impairment charge related to a licensing agreement. The Company may recognize additional non-cash impairment charges in the future related to intangible assets that were measured at fair value and capitalized in connection with business acquisitions and such charges could be material. In addition, expenses for 2015 include $105 million of amortization of purchase accounting adjustments to Cubist's

inventories. Also included in materials and production costs are expenses associated with restructuring activities which amounted to $138 million, $181 million and $361 million in 2017, 2016 and 2015, respectively, primarily reflecting accelerated depreciation and asset write-offs related to the planned sale or closure of manufacturing facilities. Separation costs associated with manufacturing-related headcount reductions have been incurred and are reflected in *Restructuring costs* as discussed below.

Gross margin was 68.2% in 2017 compared with 65.1% in 2016 and 62.2% in 2015. The improvements in gross margin reflect a lower net impact from the amortization of intangible assets, intangible asset impairment charges and restructuring costs as noted above, which reduced gross margin by 8.2 percentage points in 2017, 10.6 percentage points in 2016 and 13.2 percentage points in 2015. The gross margin improvement in 2017 compared with 2016 also reflects the favorable effects of product mix. Manufacturing-related costs associated with the cyber-attack partially offset the gross margin improvement in 2017. The improvement in gross margin in 2016 as compared with 2015 was also driven by lower inventory write-offs and the favorable effects of foreign exchange.

Marketing and Administrative

Marketing and administrative (M&A) expenses were $9.8 billion in 2017, an increase of 1% compared with 2016. Higher administrative costs, including costs associated with the Company operating its vaccines business in the European markets that were previously part of the SPMSD joint venture, remediation costs related to the cyber-attack, and higher promotional expenses related to product launches were partially offset by lower restructuring and acquisition and divestiture-related costs, lower selling expenses and the favorable effect of foreign exchange. M&A expenses were $9.8 billion in 2016, a decline of 5% compared with 2015, driven largely by lower acquisition and divestiture-related costs, the favorable effects of foreign exchange, lower administrative expenses, such as legal defense costs, as well as lower selling costs. Higher promotional spending largely related to product launches and higher restructuring costs partially offset the decline. M&A expenses for 2017, 2016 and 2015 include restructuring costs of $2 million, $95 million and $78 million, respectively, related primarily to accelerated depreciation for facilities to be closed or divested. Separation costs associated with sales force reductions have been incurred and are reflected in *Restructuring costs* as discussed below. M&A expenses also include acquisition and divestiture-related costs of $44 million, $78 million and $436 million in 2017, 2016 and 2015, respectively, consisting of integration, transaction, and certain other costs related to business acquisitions and divestitures. Acquisition and divestiture-related costs in 2015 include costs related to the acquisition of Cubist (see Note 3 to the consolidated financial statements).

Research and Development

Research and development (R&D) expenses were $10.2 billion in 2017, an increase of 1% compared with 2016. The increase was driven primarily by a charge in 2017 related to the formation of a collaboration with AstraZeneca, an unfavorable effect from changes in the estimated fair value measurement of liabilities for contingent consideration and higher clinical development spending, largely offset by lower in-process research and development (IPR&D) impairment charges and lower restructuring costs. R&D expenses were $10.1 billion in 2016 compared with $6.7 billion in 2015. The increase was driven primarily by higher IPR&D impairment charges, increased clinical development spending, higher restructuring and licensing costs, partially offset by a reduction in expenses associated with a decrease in the estimated fair value measurement of liabilities for contingent consideration, as well as by the favorable effects of foreign exchange.

R&D expenses are comprised of the costs directly incurred by Merck Research Laboratories (MRL), the Company's research and development division that focuses on human health-related activities, which were $4.6 billion in 2017, $4.3 billion in 2016 and $4.0 billion in 2015. Also included in R&D expenses are costs incurred by other divisions in support of R&D activities, including depreciation, production and general and administrative, as well as licensing activity, and certain costs from operating segments, including the Pharmaceutical and Animal Health segments, which in the aggregate were $2.7 billion, $2.5 billion and $2.6 billion for 2017, 2016 and 2015, respectively. Additionally, R&D expenses in 2017 include a $2.35 billion aggregate charge related to the formation of a collaboration with AstraZeneca (see Note 4 to the consolidated financial statements). R&D expenses also include IPR&D impairment charges of $483 million, $3.6 billion and $63 million in 2017, 2016 and 2015, respectively (see "Research and Development" below). The Company may recognize additional non-cash impairment charges in the future related to the cancellation or delay of other pipeline programs that were measured at fair value and capitalized in connection with business acquisitions and such charges could be material. In addition, R&D expenses include expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration recorded in connection

with acquisitions. During 2017, the Company recorded charges of $27 million to increase the estimated fair value of liabilities for contingent consideration. During 2016 and 2015, the Company recorded a reduction in expenses of $402 million and $24 million, respectively, to decrease the estimated fair value of liabilities for contingent consideration related to the discontinuation or delay of certain programs (see Note 6 to the consolidated financial statements). R&D expenses in 2017, 2016 and 2015 also reflect $11 million, $142 million and $52 million, respectively, of accelerated depreciation and asset abandonment costs associated with restructuring activities.

Restructuring Costs

The Company incurs substantial costs for restructuring program activities related to Merck's productivity and cost reduction initiatives, as well as in connection with the integration of certain acquired businesses. In 2010 and 2013, the Company commenced actions under global restructuring programs designed to streamline its cost structure. The actions under these programs include the elimination of positions in sales, administrative and headquarters organizations, as well as the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities. The Company also continues to reduce its global real estate footprint and improve the efficiency of its manufacturing and supply network.

Restructuring costs, primarily representing separation and other related costs associated with these restructuring activities, were $776 million, $651 million and $619 million in 2017, 2016 and 2015, respectively. In 2017, 2016 and 2015, separation costs of $552 million, $216 million and $208 million, respectively, were incurred associated with actual headcount reductions, as well as estimated expenses under existing severance programs for headcount reductions that were probable and could be reasonably estimated. Merck eliminated approximately 2,450 positions in 2017, 2,625 positions in 2016 and 3,770 positions in 2015 related to these restructuring activities. Also included in restructuring costs are asset abandonment, shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation plan costs. For segment reporting, restructuring costs are unallocated expenses.

Additional costs associated with the Company's restructuring activities are included in *Materials and production*, *Marketing and administrative* and *Research and development* as discussed above. The Company recorded aggregate pretax costs of $927 million in 2017, $1.1 billion in 2016 and $1.1 billion in 2015 related to restructuring program activities (see Note 5 to the consolidated financial statements). While the Company has substantially completed the actions under the programs, approximately $500 million of additional pretax costs are expected to be incurred in 2018 relating to anticipated employee separations and remaining asset-related costs.

Other (Income) Expense, Net

Other (income) expense, net was $12 million of expense in 2017, $720 million of expense in 2016 and $1.5 billion of expense in 2015. For details on the components of *Other (income) expense, net*, see Note 15 to the consolidated financial statements.

Segment Profits

($ in millions)	**2017**	2016	2015
Pharmaceutical segment profits	**$ 22,586**	$ 22,180	$ 21,658
Other non-reportable segment profits	**1,834**	1,507	1,573
Other	**(17,899)**	(19,028)	(17,830)
Income before taxes	**$ 6,521**	$ 4,659	$ 5,401

Segment profits are comprised of segment sales less standard costs, certain operating expenses directly incurred by the segment, components of equity income or loss from affiliates and certain depreciation and amortization expenses. For internal management reporting presented to the chief operating decision maker, Merck does not allocate materials and production costs, other than standard costs, the majority of research and development expenses or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. Also excluded from the determination of segment profits are acquisition and divestiture-related costs, including the amortization of purchase accounting adjustments, intangible asset impairment charges and changes in the estimated fair value measurement of liabilities for contingent consideration, restructuring costs, and a portion of equity income. Additionally, segment profits do not reflect other expenses from

corporate and manufacturing cost centers and other miscellaneous income or expense. These unallocated items, including a loss on the extinguishment of debt in 2017, a charge related to the settlement of worldwide *Keytruda* patent litigation in 2016, gains on divestitures in 2016 and 2015, as well as a net charge related to the settlement of *Vioxx* shareholder class action litigation and foreign exchange losses related to the devaluation of the Company's net monetary assets in Venezuela in 2015, are reflected in "Other" in the above table. Also included in "Other" are miscellaneous corporate profits (losses), as well as operating profits (losses) related to third-party manufacturing sales.

Pharmaceutical segment profits grew 2% in 2017 compared with 2016 primarily reflecting higher sales and the favorable effects of product mix. Pharmaceutical segment profits grew 2% in 2016 compared with 2015 primarily reflecting higher sales.

Taxes on Income

The effective income tax rates of 62.9% in 2017, 15.4% in 2016 and 17.4% in 2015 reflect the impacts of acquisition and divestiture-related costs, which in 2016 include $3.6 billion of IPR&D impairment charges, as well as restructuring costs and the beneficial impact of foreign earnings. In addition, the effective income tax rate for 2017 includes a provisional net charge of $2.6 billion related to the enactment of U.S. tax legislation known as the Tax Cuts and Jobs Act (TCJA) (see Note 16 to the consolidated financial statements). The effective income tax rate for 2017 also reflects the unfavorable impact of a $2.35 billion aggregate pretax charge recorded in connection with the formation of a collaboration with AstraZeneca for which no tax benefit was recognized, partially offset by the favorable impact of a net benefit of $234 million related to the settlement of certain federal income tax issues (see Note 16 to the consolidated financial statements) and a benefit of $88 million related to the settlement of a state income tax issue. The effective income tax rate for 2015 reflects the favorable impact of a net benefit of $410 million related to the settlement of certain federal income tax issues, the impact of a net charge related to the settlement of *Vioxx* shareholder class action litigation being fully deductible at combined U.S. federal and state tax rates and the favorable impact of tax legislation enacted in the fourth quarter of 2015, as well as the unfavorable effect of non-tax deductible foreign exchange losses related to Venezuela (see Note 15 to the consolidated financial statements).

Net Income and Earnings per Common Share

Net income attributable to Merck & Co., Inc. was $2.4 billion in 2017, $3.9 billion in 2016 and $4.4 billion in 2015. EPS was $0.87 in 2017, $1.41 in 2016 and $1.56 in 2015.

Non-GAAP Income and Non-GAAP EPS

Non-GAAP income and non-GAAP EPS are alternative views of the Company's performance that Merck is providing because management believes this information enhances investors' understanding of the Company's results as it permits investors to understand how management assesses performance. Non-GAAP income and non-GAAP EPS exclude certain items because of the nature of these items and the impact that they have on the analysis of underlying business performance and trends. The excluded items (which should not be considered non-recurring) consist of acquisition and divestiture-related costs, restructuring costs and certain other items. These excluded items are significant components in understanding and assessing financial performance.

Non-GAAP income and non-GAAP EPS are important internal measures for the Company. Senior management receives a monthly analysis of operating results that includes non-GAAP EPS. Management uses these measures internally for planning and forecasting purposes and to measure the performance of the Company along with other metrics. Senior management's annual compensation is derived in part using non-GAAP income and non-GAAP EPS. Since non-GAAP income and non-GAAP EPS are not measures determined in accordance with GAAP, they have no standardized meaning prescribed by GAAP and, therefore, may not be comparable to the calculation of similar measures of other companies. The information on non-GAAP income and non-GAAP EPS should be considered in addition to, but not as a substitute for or superior to, net income and EPS prepared in accordance with generally accepted accounting principles in the United States (GAAP).

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A reconciliation between GAAP financial measures and non-GAAP financial measures is as follows:

($ in millions except per share amounts)	**2017**	2016	2015
Income before taxes as reported under GAAP	**$ 6,521**	$ 4,659	$ 5,401
Increase (decrease) for excluded items:			
Acquisition and divestiture-related costs	**3,760**	7,312	5,398
Restructuring costs	**927**	1,069	1,110
Other items:			
Aggregate charge related to the formation of an oncology collaboration with AstraZeneca	**2,350**	—	—
Charge related to the settlement of worldwide *Keytruda* patent litigation	**—**	625	—
Foreign currency devaluation related to Venezuela	**—**	—	876
Net charge related to the settlement of *Vioxx* shareholder class action litigation	**—**	—	680
Gain on sale of certain migraine clinical development programs	**—**	—	(250)
Gain on divestiture of certain ophthalmic products	**—**	—	(147)
Other	**(16)**	(67)	(34)
Non-GAAP income before taxes	**13,542**	13,598	13,034
Taxes on income as reported under GAAP	**4,103**	718	942
Estimated tax benefit on excluded items [1]	**785**	2,321	1,470
Provisional net tax charge related to the enactment of the TCJA	**(2,625)**	—	—
Net tax benefits from the settlements of certain federal income tax issues	**234**	—	410
Tax benefit related to the settlement of a state income tax issue	**88**	—	—
Non-GAAP taxes on income	**2,585**	**3,039**	**2,822**
Non-GAAP net income	**10,957**	10,559	10,212
Less: Net income attributable to noncontrolling interests	**24**	21	17
Non-GAAP net income attributable to Merck & Co., Inc.	**$ 10,933**	$ 10,538	$ 10,195
EPS assuming dilution as reported under GAAP	**$ 0.87**	$ 1.41	$ 1.56
EPS difference [2]	**3.11**	2.37	2.03
Non-GAAP EPS assuming dilution	**$ 3.98**	$ 3.78	$ 3.59

[1] *The estimated tax impact on the excluded items is determined by applying the statutory rate of the originating territory of the non-GAAP adjustments.*

[2] *Represents the difference between calculated GAAP EPS and calculated non-GAAP EPS, which may be different than the amount calculated by dividing the impact of the excluded items by the weighted-average shares for the applicable year.*

Acquisition and Divestiture-Related Costs

Non-GAAP income and non-GAAP EPS exclude the impact of certain amounts recorded in connection with business acquisitions and divestitures. These amounts include the amortization of intangible assets and amortization of purchase accounting adjustments to inventories, as well as intangible asset impairment charges and expense or income related to changes in the estimated fair value measurement of contingent consideration. Also excluded are integration, transaction, and certain other costs associated with business acquisitions and divestitures.

Restructuring Costs

Non-GAAP income and non-GAAP EPS exclude costs related to restructuring actions (see Note 5 to the consolidated financial statements). These amounts include employee separation costs and accelerated depreciation associated with facilities to be closed or divested. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the asset, based upon the anticipated date the site will be closed or divested or the equipment disposed of, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. Restructuring costs also include asset abandonment, shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation costs.

Certain Other Items

Non-GAAP income and non-GAAP EPS exclude certain other items. These items are adjusted for after evaluating them on an individual basis, considering their quantitative and qualitative aspects, and typically consist of items that are unusual in nature, significant to the results of a particular period or not indicative of future operating results. Excluded from non-GAAP income and non-GAAP EPS in 2017 is an aggregate charge related to the formation of a collaboration with AstraZeneca (see Note 4 to the consolidated financial statements), a provisional net tax charge related to the enactment of the TCJA, a net benefit related to the settlement of certain federal income tax issues and a benefit related to the settlement of a state income tax issue (see Note 16 to the consolidated financial statements). Excluded from non-GAAP income and non-GAAP EPS in 2016 is a charge to settle worldwide patent litigation related to *Keytruda* (see Note 11 to the consolidated financial statements). Excluded from non-GAAP income and non-GAAP EPS in 2015 are foreign exchange losses related to the devaluation of the Company's net monetary assets in Venezuela (see Note 15 to the consolidated financial statements), a net charge related to the previously disclosed settlement of *Vioxx* shareholder class action litigation, a gain on the sale of certain migraine clinical development programs (see Note 3 to the consolidated financial statements), a gain on the divestiture of the Company's remaining ophthalmics business in international markets (see Note 3 to the consolidated financial statements), as well as a net tax benefit related to the settlement of certain federal income tax issues (see Note 16 to the consolidated financial statements).

Research and Development

A chart reflecting the Company's current research pipeline as of February 23, 2018 is set forth in Item 1. "Business — Research and Development" above.

Research and Development Update

The Company currently has several candidates under regulatory review in the United States and internationally.

Keytruda is an approved anti-PD-1 therapy in clinical development for expanded indications in different cancer types.

In December 2017, the FDA accepted for review a supplemental BLA for *Keytruda* for the treatment of adult and pediatric patients with refractory PMBCL, or who have relapsed after two or more prior lines of therapy. The FDA granted Priority Review status with a Prescription Drug User Fee Action (PDUFA), or target action, date of April 3, 2018.

Additionally, *Keytruda* has received Breakthrough Therapy designation from the FDA in combination with axitnib as a first-line treatment for patients with advanced or metastatic renal cell carcinoma; for the treatment of high-risk early-stage triple-negative breast cancer in combination with neoadjuvant chemotherapy; and for the treatment of Merkel cell carcinoma. Also, in January 2018, Merck and Eisai Co., Ltd. (Eisai) announced receipt of Breakthrough Therapy designation from the FDA for Eisai's multiple receptor tyrosine kinase inhibitor Lenvima (lenvatinib) in combination with *Keytruda* for the potential treatment of patients with advanced and/or metastatic renal cell carcinoma. The Lenvima and *Keytruda* combination therapy is being jointly developed by Eisai and Merck. This marks the 12th Breakthrough Therapy designation granted to *Keytruda*. The FDA's Breakthrough Therapy designation is intended to expedite the development and review of a candidate that is planned for use, alone or in combination, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

In January 2018, Merck announced that the pivotal Phase 3 KEYNOTE-189 trial investigating *Keytruda* in combination with pemetrexed (Alimta) and cisplatin or carboplatin, for the first-line treatment of patients with metastatic non-squamous NSCLC, met its dual primary endpoints of OS and PFS. Based on an interim analysis conducted by the independent Data Monitoring Committee, treatment with *Keytruda* in combination with pemetrexed plus platinum chemotherapy resulted in significantly longer OS and PFS than pemetrexed plus platinum chemotherapy alone. Results from KEYNOTE-189 will be presented at an upcoming medical meeting and submitted to regulatory authorities.

In 2017, the FDA placed a full clinical hold on KEYNOTE-183 and KEYNOTE-185 and a partial clinical hold on Cohort 1 of KEYNOTE-023, three combination studies of *Keytruda* with lenalidomide or pomalidomide versus lenalidomide or pomalidomide alone in the blood cancer multiple myeloma. This decision followed a review

of data by the Data Monitoring Committee in which more deaths were observed in the *Keytruda* arms of KEYNOTE-183 and

KEYNOTE-185. The FDA determined that the data available at the time indicated that the risks of *Keytruda* plus pomalidomide or lenalidomide outweighed any potential benefit for patients with multiple myeloma. All patients enrolled in KEYNOTE-183 and KEYNOTE-185 and those in the *Keytruda*/lenalidomide/dexamethasone cohort in KEYNOTE-023 have discontinued investigational treatment with *Keytruda*. This clinical hold does not apply to other studies with *Keytruda*.

The *Keytruda* clinical development program consists of more than 700 clinical trials, including more than 400 trials that combine *Keytruda* with other cancer treatments. These studies encompass more than 30 cancer types including: bladder, colorectal, esophageal, gastric, head and neck, hepatocellular, Hodgkin lymphoma, non-Hodgkin lymphoma, melanoma, nasopharyngeal, NSCLC, ovarian, PMBCL, prostate, renal, small-cell lung and triple-negative breast, many of which are currently in Phase 3 clinical development. Further trials are being planned for other cancers.

MK-8835, ertugliflozin, an investigational oral SGLT-2 inhibitor in development to help improve glycemic control in adults with type 2 diabetes, and two fixed-dose combination products (MK-8835A, ertugliflozin and *Januvia*, and MK-8835B, ertugliflozin and metformin) are under review in the EU. In January 2018, the CHMP of the EMA adopted a positive opinion recommending approval of these medicines. The CHMP positive opinion will be considered by the EC. Ertugliflozin and the two fixed-dose combination products were approved by the FDA in December 2017.

MK-0431J is an investigational fixed-dose combination of sitagliptin and ipragliflozin under review with the Japan Pharmaceuticals and Medical Devices Agency. MK-0431 is being developed for commercialization in Japan in collaboration with Astellas Pharma Inc. (Astellas). Ipragliflozin, an SGLT2 inhibitor, co-developed by Astellas and Kotobuki Pharmaceutical Co., Ltd. (Kotobuki), is approved for use in Japan and is being co-promoted with Merck and Kotobuki.

MK-1439, doravirine, is an investigational, non-nucleoside reverse transcriptase inhibitor for the treatment of HIV-1 infection. In January 2018, Merck announced that the FDA accepted for review two NDAs for doravirine. The NDAs include data for doravirine as a once-daily tablet for use in combination with other antiretroviral agents, and for use of doravirine with lamivudine and tenofovir disoproxil fumarate in a once-daily fixed-dose combination single tablet as a complete regimen (MK-1439A). The PDUFA action date for both applications is October 23, 2018.

V419 is an investigational pediatric hexavalent combination vaccine, DTaP5-IPV-Hib-HepB, under review with the FDA that is being developed and, if approved, will be commercialized through a joint venture between Merck and Sanofi. This vaccine is designed to help protect against six important diseases - diphtheria, tetanus, pertussis (whooping cough), polio (poliovirus types 1, 2, and 3), invasive disease caused by *Haemophilus influenzae* type b (Hib), and hepatitis B. In 2015, the FDA issued a CRL with respect to the BLA for V419. Both companies are working to provide additional data requested by the FDA. V419 is being marketed as *Vaxelis* in the EU.

In addition to the candidates under regulatory review, the Company has several drug candidates in Phase 3 clinical development in addition to the *Keytruda* programs discussed above.

MK-7655A is a combination of relebactam, an investigational beta-lactamase inhibitor, and imipenem/cilastatin (an approved carbapenem antibiotic). The FDA has designated this combination a Qualified Infectious Disease Product with designated Fast Track status for the treatment of hospital-acquired bacterial pneumonia, ventilator-associated bacterial pneumonia, complicated intra-abdominal infections and complicated urinary tract infections.

MK-7339, Lynparza (olaparib), is an oral PARP inhibitor currently approved for certain types of ovarian and breast cancer. In July 2017, Merck and AstraZeneca entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza for multiple cancer types (see Note 4 to the consolidated financial statements).

MK-5618, selumetinib, is an oral, potent, selective inhibitor of MEK, part of the mitogen-activated protein kinase (MAPK) pathway, currently being developed for multiple cancer types. Additionally, in February 2018, the FDA granted Orphan Drug designation for selumetinib for the treatment of neurofibromatosis type 1. The development of selumetinib is part of the global strategic oncology collaboration between Merck and AstraZeneca reference above.

V920 is an investigational rVSV-ZEBOV (Ebola) vaccine candidate being studied in large scale Phase 2/3 clinical trials. In November 2014, Merck and NewLink Genetics announced an exclusive licensing and collaboration

agreement for the investigational Ebola vaccine. In December 2015, Merck announced that the application for Emergency Use Assessment and Listing (EUAL) for V920 was accepted for review by the World Health Organization

(WHO). According to the WHO, the EUAL process is designed to expedite the availability of vaccines needed for public health emergencies such as another outbreak of Ebola. The decision to grant V920 EUAL status will be based on data regarding quality, safety, and efficacy/effectiveness; as well as a risk/benefit analysis for emergency use. While EUAL designation allows for emergency use, the vaccine remains investigational and has not yet been licensed for commercial distribution. In July 2016, Merck announced that the FDA granted V920 Breakthrough Therapy designation, and that the EMA granted the vaccine candidate PRIME (PRIority MEdicines) status. In December 2016, end of study results from the WHO ring vaccination trial were reported in Lancet supporting the July 2015 interim assessment that V920 offers substantial protection against Ebola virus disease, with no reported cases among vaccinated individuals from 10 days after vaccination in both randomized and non-randomized clusters. Results from other ongoing studies to be included in the first regulatory filing are anticipated in the first half of 2018.

MK-1242, vericiguat, is an investigational treatment for heart failure being studied in patients suffering from chronic heart failure. The development of vericiguat is part of a worldwide strategic collaboration between Merck and Bayer (see Note 4 to the consolidated financial statements).

V212 is an inactivated varicella zoster virus vaccine in development for the prevention of herpes zoster. The Company completed a Phase 3 trial in autologous hematopoietic cell transplant patients and another Phase 3 trial in patients with solid tumor malignancies undergoing chemotherapy and hematological malignancies. The study in autologous hematopoietic cell transplant patients met its primary endpoints and Merck presented the results from this study at the American Society for Blood and Marrow Transplantation Meetings in February 2017. The study in patients with solid tumor malignancies undergoing chemotherapy met its primary endpoints, but the primary efficacy endpoint was not met in patients with hematologic malignancies. Merck will present the results from this study at an upcoming scientific meeting. Due to the competitive environment, development of V212 is currently on hold.

MK-7264 is a selective, non-narcotic, orally-administered P2X3-receptor agonist being developed for the treatment of refractory, chronic cough. Merck plans to initiate a Phase 3 clinical trial in the first half of 2018. MK-7264 was originally developed by Afferent Pharmaceuticals (Afferent), which was acquired by the Company in 2016 (see Note 3 to the consolidated financial statements). Upon initiation of the Phase 3 clinical trial, Merck will make a $175 million milestone payment, which was accrued for at estimated fair value at the time of acquisition.

The Company also discontinued certain drug candidates.

In February 2018, Merck announced that it will be stopping protocol 019, also known as the APECS study, a Phase 3 study evaluating verubecestat, MK-8931, an investigational small molecule inhibitor of the beta-site amyloid precursor protein cleaving enzyme 1 (BACE1), in people with prodromal Alzheimer's disease. The decision to stop the study follows a recommendation by the external Data Monitoring Committee (eDMC), which assessed overall benefit/risk during a recent interim safety analysis. The eDMC concluded that it was unlikely that positive benefit/risk could be established if the trial continued. As a result, the Company recorded an IPR&D impairment charge as discussed below.

In 2017, Merck announced that it will not submit applications for regulatory approval for MK-0859, anacetrapib, the Company's investigational cholesteryl ester transfer protein (CETP) inhibitor. The decision followed a thorough review of the clinical profile of anacetrapib, including discussions with external experts.

Also in 2017, Merck made a strategic decision to discontinue the development of the investigational combination regimens MK-3682B (grazoprevir/ruzasvir/uprifosbuvir) and MK-3682C (ruzasvir/uprifosbuvir) for the treatment of chronic HCV infection. This decision was made based on a review of available Phase 2 efficacy data and in consideration of the evolving marketplace and the growing number of treatment options available for patients with chronic HCV infection, including *Zepatier*, which is currently marketed by the Company for the treatment of adult patients with chronic HCV infection. As a result of this decision, the Company recorded an IPR&D impairment charge as discussed below.

The Company maintains a number of long-term exploratory and fundamental research programs in biology and chemistry as well as research programs directed toward product development. The Company's research and development model is designed to increase productivity and improve the probability of success by prioritizing the Company's research and development resources on candidates the Company believes are capable of providing unambiguous, promotable advantages to patients and payers and delivering the maximum value of its approved medicines and vaccines through new indications and new formulations. Merck is pursuing emerging product

opportunities independent of therapeutic area or modality (small molecule, biologics and vaccines) and is building its biologics capabilities. The Company is committed to ensuring that externally sourced programs remain an important component of its pipeline strategy, with a focus on supplementing its internal research with a licensing and external alliance strategy focused on the entire spectrum of collaborations from early research to late-stage compounds, as well as access to new technologies.

The Company also reviews its pipeline to examine candidates that may provide more value through out-licensing. The Company continues to evaluate certain late-stage clinical development and platform technology assets to determine their out-licensing or sale potential.

The Company's clinical pipeline includes candidates in multiple disease areas, including cancer, cardiovascular diseases, diabetes, infectious diseases, neurosciences, obesity, pain, respiratory diseases and vaccines.

Acquired In-Process Research and Development

In connection with business acquisitions, the Company has recorded the fair value of in-process research projects which, at the time of acquisition, had not yet reached technological feasibility. At December 31, 2017, the balance of IPR&D was $1.2 billion.

During 2017, 2016 and 2015, $14 million, $8 million and $280 million, respectively, of IPR&D projects received marketing approval in a major market and the Company began amortizing these assets based on their estimated useful lives.

All of the IPR&D projects that remain in development are subject to the inherent risks and uncertainties in drug development and it is possible that the Company will not be able to successfully develop and complete the IPR&D programs and profitably commercialize the underlying product candidates. The time periods to receive approvals from the FDA and other regulatory agencies are subject to uncertainty. Significant delays in the approval process, or the Company's failure to obtain approval at all, would delay or prevent the Company from realizing revenues from these products. Additionally, if certain of the IPR&D programs fail or are abandoned during development, then the Company will not realize the future cash flows it has estimated and recorded as IPR&D as of the acquisition date, and the Company may also not recover the research and development expenditures made since the acquisition to further develop such programs. If such circumstances were to occur, the Company's future operating results could be adversely affected and the Company may recognize impairment charges and such charges could be material.

In 2017, the Company recorded $483 million of IPR&D impairment charges within *Research and development* expenses. Of this amount, $240 million resulted from a strategic decision to discontinue the development of the investigational combination regimens MK-3682B (grazoprevir/ruzasvir/uprifosbuvir) and MK-3682C (ruzasvir/uprifosbuvir) for the treatment of chronic HCV infection. This decision was made based on a review of available Phase 2 efficacy data and in consideration of the evolving marketplace and the growing number of treatment options available for patients with chronic HCV infection, including *Zepatier*, which is currently marketed by the Company for the treatment of adult patients with chronic HCV infection. As a result of this decision, the Company recorded an IPR&D impairment charge to write-off the remaining intangible asset related to uprifosbuvir. The Company had previously recorded an impairment charge for uprifosbuvir in 2016 as described below. The IPR&D impairment charges in 2017 also include a charge of $226 million to write-off the intangible asset related to verubecestat, an investigational small molecule inhibitor of the beta-site amyloid precursor protein cleaving enzyme 1 (BACE1), resulting from a decision in February 2018 to stop a Phase 3 study evaluating verubecestat in people with prodromal Alzheimer's disease. The decision to stop the study followed a recommendation by the eDMC, which assessed overall benefit/risk during an interim safety analysis. The eDMC concluded that it was unlikely that positive benefit/risk could be established if the trial continued.

During 2016, the Company recorded $3.6 billion of IPR&D impairment charges. Of this amount, $2.9 billion relates to the clinical development program for uprifosbuvir, a nucleotide prodrug that was being evaluated for the treatment of HCV. The Company determined that changes to the product profile, as well as changes to Merck's expectations for pricing and the market opportunity, taken together constituted a triggering event that required the Company to evaluate the uprifosbuvir intangible asset for impairment. Utilizing market participant assumptions, and considering different scenarios, the Company concluded that its best estimate of the fair value of the intangible asset related to uprifosbuvir was $240 million, resulting in the recognition of the pretax impairment charge noted above. The IPR&D impairment charges in 2016 also include charges of $180 million and $143 million related to the discontinuation

of programs obtained in connection with the acquisitions of cCAM Biotherapeutics Ltd. and OncoEthix, respectively, resulting from unfavorable efficacy data. An additional $72 million relates to programs obtained in connection with the SmartCells acquisition following a decision to terminate the lead compound due to a lack of efficacy and to pursue a back-up compound which reduced projected future cash flows. The IPR&D impairment charges in 2016 also include $112 million related to an in-licensed program for house dust mite allergies that, for business reasons, was returned to the licensor. The remaining IPR&D impairment charges in 2016 primarily relate to deprioritized pipeline programs that were deemed to have no alternative use during the period, including a $79 million impairment charge for an investigational candidate for contraception. The discontinuation or delay of certain of these clinical development programs resulted in a reduction of the related liabilities for contingent consideration (see Note 6 to the consolidated financial statements).

During 2015, the Company recorded $63 million of IPR&D impairment charges, of which $50 million related to the surotomycin clinical development program. In 2015, the Company received unfavorable efficacy data from a clinical trial for surotomycin. The evaluation of this data, combined with an assessment of the commercial opportunity for surotomycin, resulted in the discontinuation of the program and the IPR&D impairment charge noted above.

Additional research and development will be required before any of the remaining programs reach technological feasibility. The costs to complete the research projects will depend on whether the projects are brought to their final stages of development and are ultimately submitted to the FDA or other regulatory agencies for approval.

Acquisitions, Research Collaborations and License Agreements

Merck continues to remain focused on pursuing opportunities that have the potential to drive both near- and long-term growth. Certain of the more recent transactions are described below. Merck is actively monitoring the landscape for growth opportunities that meet the Company's strategic criteria.

In February 2018, Merck and Viralytics Limited (Viralytics) announced a definitive agreement pursuant to which Merck will acquire Viralytics, an Australian publicly traded company focused on oncolytic immunotherapy treatments for a range of cancers, for AUD 1.75 per share. The proposed acquisition values the total issued shares in Viralytics at approximately AUD 502 million ($394 million). Upon completion of the transaction, Merck will gain full rights to Cavatax (CVA21), Viralytics's investigational oncolytic immunotherapy. Cavatax is based on Viralytics's proprietary formulation of an oncolytic virus (Coxsackievirus Type A21) that has been shown to preferentially infect and kill cancer cells. Cavatax is currently being evaluated in multiple Phase 1 and Phase 2 clinical trials, both as an intratumoral and intravenous agent, including in combination with *Keytruda*. Under a previous agreement between Merck and Viralytics, a study is investigating the use of the *Keytruda* and Cavatax combination in melanoma, prostate, lung and bladder cancers. The transaction remains subject to a Viralytics's shareholder vote and customary regulatory approvals. Merck anticipates the transaction will close in the second quarter of 2018.

In October 2017, Merck acquired Rigontec. Rigontec is a leader in accessing the retinoic acid-inducible gene I pathway, part of the innate immune system, as a novel and distinct approach in cancer immunotherapy to induce both immediate and long-term anti-tumor immunity. Rigontec's lead candidate, RGT100, is currently in Phase I development evaluating treatment in patients with various tumors. Under the terms of the agreement, Merck made an upfront cash payment of €119 million ($140 million) and may make additional contingent payments of up to €349 million (of which €184 million are related to the achievement of research milestones and regulatory approvals and €165 million are related to the achievement of commercial targets). The transaction was accounted for as an acquisition of an asset and the upfront payment is reflected within *Research and development* expenses in 2017.

In July 2017, Merck and AstraZeneca entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza (olaparib) for multiple cancer types. Lynparza is an oral PARP inhibitor currently approved for certain types of ovarian and breast cancer. The companies are jointly developing and commercializing Lynparza, both as monotherapy and in combination trials with other potential medicines. Independently, Merck and AstraZeneca will develop and commercialize Lynparza in combinations with their respective PD-1 and PD-L1 medicines, *Keytruda* (pembrolizumab) and Imfinzi (durvalumab). The companies will also jointly develop and commercialize AstraZeneca's selumetinib, an oral, potent, selective inhibitor of MEK, part of the mitogen-activated protein kinase (MAPK) pathway, currently being developed for multiple indications including thyroid cancer. Under the terms of the agreement, AstraZeneca and Merck will share the development and commercialization costs

for Lynparza and selumetinib monotherapy and non-PD-L1/PD-1 combination therapy opportunities. Gross profits from Lynparza and selumetinib product sales generated through monotherapies or combination therapies will be shared equally. Merck will fund all development and commercialization costs of *Keytruda* in combination with Lynparza or selumetinib. AstraZeneca will fund all development and commercialization costs of Imfinzi in combination with Lynparza or selumetinib. As part of the agreement, Merck made an upfront payment to AstraZeneca of $1.6 billion and is making payments of $750 million over a multi-year period for certain license options ($250 million was paid in December 2017, $400 million will be paid in 2018 and $100 million will be paid in 2019). The Company recorded an aggregate charge of $2.35 billion in *Research and development* expenses in 2017 related to the upfront payment and future license options payments. In addition, Merck will pay AstraZeneca up to an additional $6.15 billion contingent upon successful achievement of future regulatory and sales-based milestones for total aggregate consideration of up to $8.5 billion.

Capital Expenditures

Capital expenditures were $1.9 billion in 2017, $1.6 billion in 2016 and $1.3 billion in 2015. Expenditures in the United States were $1.2 billion in 2017, $1.0 billion in 2016 and $879 million in 2015. Merck plans to invest approximately $12.0 billion over five years in capital projects including approximately $8.0 billion in the United States.

Depreciation expense was $1.5 billion in 2017, $1.6 billion in 2016 and $1.6 billion in 2015 of which $1.0 billion, $1.0 billion and $1.1 billion, respectively, applied to locations in the United States. Total depreciation expense in 2017, 2016 and 2015 included accelerated depreciation of $60 million, $227 million and $174 million, respectively, associated with restructuring activities (see Note 5 to the consolidated financial statements).

Analysis of Liquidity and Capital Resources

Merck's strong financial profile enables it to fund research and development, focus on external alliances, support in-line products and maximize upcoming launches while providing significant cash returns to shareholders.

Selected Data

($ in millions)	**2017**	2016	2015
Working capital	**$ 6,152**	$ 13,410	$ 10,550
Total debt to total liabilities and equity	**27.8 %**	26.0 %	26.0 %
Cash provided by operations to total debt	**0.3:1**	0.4:1	0.5:1

The decline in working capital in 2017 as compared with 2016 primarily reflects the reclassification of $3.0 billion of notes due in the first half of 2018 from long-term debt to short-term debt, $1.85 billion of upfront and option payments related to the formation of the AstraZeneca collaboration discussed above, as well as $810 million paid to redeem debt in connection with tender offers discussed below.

Cash provided by operating activities was $6.4 billion in 2017, $10.4 billion in 2016 and $12.5 billion in 2015. The decline in cash provided by operating activities in 2017 reflects a $2.8 billion payment related to the settlement of certain federal income tax issues (see Note 16 to the consolidated financial statements), payments of $1.85 billion related to the formation of a collaboration with AstraZeneca (see Note 4 to the consolidated financial statements), and a $625 million payment made by the Company related to the settlement of worldwide *Keytruda* patent litigation (see Note 11 to the consolidated financial statements). Cash provided by operating activities in 2016 reflects a net payment of approximately $680 million to fund the *Vioxx* shareholder class action litigation settlement not covered by insurance proceeds. Cash provided by operating activities continues to be the Company's primary source of funds to finance operating needs, capital expenditures, treasury stock purchases and dividends paid to shareholders.

Cash provided by investing activities was $2.7 billion in 2017 compared with a use of cash in investing activities of $3.2 billion in 2016. The change was driven primarily by lower purchases of securities and other investments, higher proceeds from the sales of securities and other investments and a lower use of cash for the acquisitions of businesses. Cash used in investing activities was $3.2 billion in 2016 compared with $4.8 billion in 2015. The lower use of cash in 2016 was driven primarily by cash used in 2015 for the acquisition of Cubist, as well as lower purchases of securities and other investments in 2016, partially offset by lower proceeds from the sales of securities and other investments in 2016 and the use of cash in 2016 for the acquisitions of Afferent and The StayWell Company LLC.

Cash used in financing activities was $10.0 billion in 2017 compared with $9.0 billion in 2016. The increase in cash used in financing activities was driven primarily by proceeds from the issuance of debt in 2016, as well as higher purchases of treasury stock and lower proceeds from the exercise of stock options in 2017, partially offset by lower payments on debt in 2017. Cash used in financing activities was $9.0 billion in 2016 compared with $5.4 billion in 2015 driven primarily by lower proceeds from the issuance of debt, partially offset by a decrease in short-term borrowings in 2015, lower payments on debt, lower purchases of treasury stock and higher proceeds from the exercise of stock options.

During 2015, the Company recorded charges of $876 million related to the devaluation of its net monetary assets in Venezuela, the large majority of which was cash (see Note 15 to the consolidated financial statements).

At December 31, 2017, the total of worldwide cash and investments was $20.6 billion, including $8.5 billion of cash, cash equivalents and short-term investments, and $12.1 billion of long-term investments. A substantial majority of cash and investments are held by foreign subsidiaries that, prior to the enactment of the TCJA, would have been subject to significant tax payments if such cash and investments were repatriated in the form of dividends. In accordance with the TCJA, the Company has recorded a provisional amount for taxes on unremitted earnings through December 31, 2017 that were previously deemed to be indefinitely reinvested outside of the United States (see Note 16 to the consolidated financial statements). As a result of the TCJA, repatriation of foreign earnings in the future will have little to no incremental U.S. tax consequences.

The Company's contractual obligations as of December 31, 2017 are as follows:

Payments Due by Period

($ in millions)	Total	2018	2019—2020	2021—2022	Thereafter
Purchase obligations [1]	$ 2,226	$ 715	$ 892	$ 478	$ 141
Loans payable and current portion of long-term debt [2]	3,074	3,074	—	—	—
Long-term debt	21,400	—	3,200	4,589	13,611
Interest related to debt obligations	8,206	675	1,200	1,011	5,320
Unrecognized tax benefits [3]	67	67	—	—	—
Transition tax related to the enactment of the TCJA [4]	5,057	545	853	1,194	2,465
Operating leases	852	255	301	158	138
	$ 40,882	$ 5,331	$ 6,446	$ 7,430	$ 21,675

[1] *Includes future inventory purchases the Company has committed to in connection with certain divestitures.*

[2] *In January 2018, $1.0 billion of notes matured and were repaid.*

[3] *As of December 31, 2017, the Company's Consolidated Balance Sheet reflects liabilities for unrecognized tax benefits, interest and penalties of $2.1 billion, including $67 million reflected as a current liability. Due to the high degree of uncertainty regarding the timing of future cash outflows of liabilities for unrecognized tax benefits beyond one year, a reasonable estimate of the period of cash settlement for years beyond 2018 cannot be made.*

[4] *In connection with the enactment of the TCJA, the Company is required to pay a one-time transition tax, which the Company has elected to pay over a period of eight years as permitted under the TCJA (see Note 16 to the consolidated financial statements).*

Purchase obligations are enforceable and legally binding obligations for purchases of goods and services including minimum inventory contracts, research and development and advertising. Amounts reflected for research and development obligations do not include contingent milestone payments related to collaborative arrangements and acquisitions. Contingent milestone payments are not considered contractual obligations as they are contingent upon the successful achievement of developmental, regulatory approval and commercial milestones. At December 31, 2017, the Company has $635 million of accrued milestone payments related to collaborations with Pfizer, Bayer and AstraZeneca (see Note 4 to the consolidated financial statements), as well as in connection with certain licensing arrangements, that are payable in 2018. In addition, at December 31, 2017, the Company has $315 million of current liabilities for contingent consideration related to business acquisitions expected to be paid in 2018 (see Note 6 to the consolidated financial statements). Also excluded from research and development obligations are potential future funding commitments of up to approximately $60 million for investments in research venture capital funds. Loans payable and current portion of long-term debt reflects $73 million of long-dated notes that are subject to repayment at the option of the holders. Required funding obligations for 2018 relating to the Company's pension and other

postretirement benefit plans are not expected to be material. However, the Company currently anticipates contributing

approximately $60 million to its U.S. pension plans, $150 million to its international pension plans and $25 million to its other postretirement benefit plans during 2018.

In November 2017, the Company launched tender offers for certain outstanding notes and debentures. The Company paid $810 million in aggregate consideration (applicable purchase price together with accrued interest) to redeem $585 million principal amount of debt that was validly tendered in connection with the tender offers.

In November 2016, the Company issued €1.0 billion principal amount of senior unsecured notes consisting of €500 million principal amount of 0.50% notes due 2024 and €500 million principal amount of 1.375% notes due 2036. The Company used the net proceeds of the offering of $1.1 billion for general corporate purposes.

The Company has a $6.0 billion, five-year credit facility that matures in June 2022. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

In December 2015, the Company filed a securities registration statement with the U.S. Securities and Exchange Commission (SEC) under the automatic shelf registration process available to "well-known seasoned issuers" which is effective for three years.

In February 2015, Merck issued $8.0 billion aggregate principal amount of senior unsecured notes. The Company used a portion of the net proceeds of the offering of $7.9 billion to repay commercial paper issued to substantially finance the Company's acquisition of Cubist. The remaining net proceeds were used for general corporate purposes, including for repurchases of the Company's common stock, and the repayment of outstanding commercial paper borrowings and debt maturities.

Also in February 2015, the Company redeemed $1.9 billion of legacy Cubist debt acquired in the acquisition (see Note 3 to the consolidated financial statements).

Effective as of November 3, 2009, the Company executed a full and unconditional guarantee of the then existing debt of its subsidiary Merck Sharp & Dohme Corp. (MSD) and MSD executed a full and unconditional guarantee of the then existing debt of the Company (excluding commercial paper), including for payments of principal and interest. These guarantees do not extend to debt issued subsequent to that date.

The Company continues to maintain a conservative financial profile. The Company places its cash and investments in instruments that meet high credit quality standards, as specified in its investment policy guidelines. These guidelines also limit the amount of credit exposure to any one issuer. The Company does not participate in any off-balance sheet arrangements involving unconsolidated subsidiaries that provide financing or potentially expose the Company to unrecorded financial obligations.

In November 2017, the Board of Directors declared a quarterly dividend of $0.48 per share on the Company's common stock that was paid in January 2018. In January 2018, the Board of Directors declared a quarterly dividend of $0.48 per share on the Company's common stock for the second quarter of 2018 payable in April 2018.

In November 2017, Merck's board of directors authorized additional purchases of up to $10 billion of Merck's common stock for its treasury. The treasury stock purchase authorization has no time limit and will be made over time in open-market transactions, block transactions, on or off an exchange, or in privately negotiated transactions. The Company purchased $4.0 billion of its common stock (67 million shares) for its treasury during 2017. As of December 31, 2017, the Company's share repurchase authorization was $11.0 billion, which includes $1.0 billion in authorized repurchases remaining under a program announced in March 2015. The Company purchased $3.4 billion and $4.2 billion of its common stock during 2016 and 2015, respectively, under authorized share repurchase programs.

Financial Instruments Market Risk Disclosures

The Company manages the impact of foreign exchange rate movements and interest rate movements on its earnings, cash flows and fair values of assets and liabilities through operational means and through the use of various financial instruments, including derivative instruments.

A significant portion of the Company's revenues and earnings in foreign affiliates is exposed to changes in foreign exchange rates. The objectives and accounting related to the Company's foreign currency risk management program, as well as its interest rate risk management activities are discussed below.

Foreign Currency Risk Management

The Company has established revenue hedging, balance sheet risk management, and net investment hedging programs to protect against volatility of future foreign currency cash flows and changes in fair value caused by volatility in foreign exchange rates.

The objective of the revenue hedging program is to reduce the variability caused by changes in foreign exchange rates that would affect the U.S. dollar value of future cash flows derived from foreign currency denominated sales, primarily the euro and Japanese yen. To achieve this objective, the Company will hedge a portion of its forecasted foreign currency denominated third-party and intercompany distributor entity sales (forecasted sales) that are expected to occur over its planning cycle, typically no more than two years into the future. The Company will layer in hedges over time, increasing the portion of forecasted sales hedged as it gets closer to the expected date of the forecasted sales. The portion of forecasted sales hedged is based on assessments of cost-benefit profiles that consider natural offsetting exposures, revenue and exchange rate volatilities and correlations, and the cost of hedging instruments. The Company manages its anticipated transaction exposure principally with purchased local currency put options, forward contracts, and purchased collar options.

Because Merck principally sells foreign currency in its revenue hedging program, a uniform weakening of the U.S. dollar would yield the largest overall potential loss in the market value of these hedge instruments. The market value of Merck's hedges would have declined by an estimated $400 million and $538 million at December 31, 2017 and 2016, respectively, from a uniform 10% weakening of the U.S. dollar. The market value was determined using a foreign exchange option pricing model and holding all factors except exchange rates constant. Although not predictive in nature, the Company believes that a 10% threshold reflects reasonably possible near-term changes in Merck's major foreign currency exposures relative to the U.S. dollar. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

The Company manages operating activities and net asset positions at each local subsidiary in order to mitigate the effects of exchange on monetary assets and liabilities. The Company also uses a balance sheet risk management program to mitigate the exposure of net monetary assets that are denominated in a currency other than a subsidiary's functional currency from the effects of volatility in foreign exchange. In these instances, Merck principally utilizes forward exchange contracts to offset the effects of exchange on exposures denominated in developed country currencies, primarily the euro and Japanese yen. For exposures in developing country currencies, the Company will enter into forward contracts to partially offset the effects of exchange on exposures when it is deemed economical to do so based on a cost-benefit analysis that considers the magnitude of the exposure, the volatility of the exchange rate and the cost of the hedging instrument. The cash flows from these contracts are reported as operating activities in the Consolidated Statements of Cash Flows.

A sensitivity analysis to changes in the value of the U.S. dollar on foreign currency denominated derivatives, investments and monetary assets and liabilities indicated that if the U.S. dollar uniformly weakened by 10% against all currency exposures of the Company at December 31, 2017 and 2016, *Income before taxes* would have declined by approximately $92 million and $26 million in 2017 and 2016, respectively. Because the Company was in a net short (payable) position relative to its major foreign currencies after consideration of forward contracts, a uniform weakening of the U.S. dollar will yield the largest overall potential net loss in earnings due to exchange. This measurement assumes that a change in one foreign currency relative to the U.S. dollar would not affect other foreign currencies relative to the U.S. dollar. Although not predictive in nature, the Company believes that a 10% threshold reflects reasonably possible near-term changes in Merck's major foreign currency exposures relative to the U.S. dollar. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

Since January 2010, Venezuela has been designated hyperinflationary and, as a result, local foreign operations are remeasured in U.S. dollars with the impact recorded in results of operations. During 2015, upon evaluation of evolving economic conditions in Venezuela and volatility in the country, combined with a decline in transactions that were settled at the then official (CENCOEX) rate, the Company determined it was unlikely that all outstanding net monetary assets would be settled at the CENCOEX rate. Accordingly, during 2015, the Company recorded charges of $876 million within *Other (income) expense, net* to devalue its net monetary assets in Venezuela to an amount that represented the Company's estimate of the U.S. dollar amount that would ultimately be collected and recorded additional exchange losses of $138 million in the aggregate reflecting the ongoing effect of translating transactions and net monetary assets consistent with these rates.

The Company may also use forward exchange contracts to hedge its net investment in foreign operations against movements in exchange rates. The forward contracts are designated as hedges of the net investment in a foreign operation. The Company hedges a portion of the net investment in certain of its foreign operations and measures ineffectiveness based upon changes in spot foreign exchange rates that are recorded in *Other (income) expense, net*. The effective portion of the unrealized gains or losses on these contracts is recorded in foreign currency translation adjustment within *Other Comprehensive Income* (*OCI*), and remains in *Accumulated Other Comprehensive Income* (*AOCI)* until either the sale or complete or substantially complete liquidation of the subsidiary. The cash flows from these contracts are reported as investing activities in the Consolidated Statement of Cash Flows.

Foreign exchange risk is also managed through the use of foreign currency debt. The Company's senior unsecured euro-denominated notes have been designated as, and are effective as, economic hedges of the net investment in a foreign operation. Accordingly, foreign currency transaction gains or losses due to spot rate fluctuations on the euro-denominated debt instruments are included in foreign currency translation adjustment within *OCI*.

Interest Rate Risk Management

The Company may use interest rate swap contracts on certain investing and borrowing transactions to manage its net exposure to interest rate changes and to reduce its overall cost of borrowing. The Company does not use leveraged swaps and, in general, does not leverage any of its investment activities that would put principal capital at risk.

At December 31, 2017, the Company was a party to 26 pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes as detailed in the table below.

($ in millions)	**2017**		
Debt Instrument	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
1.30% notes due 2018	$ 1,000	4	$ 1,000
5.00% notes due 2019	1,250	3	550
1.85% notes due 2020	1,250	5	1,250
3.875% notes due 2021	1,150	5	1,150
2.40% notes due 2022	1,000	4	1,000
2.35% notes due 2022	1,250	5	1,250

The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in the benchmark London Interbank Offered Rate (LIBOR) swap rate. The fair value changes in the notes attributable to changes in the LIBOR swap rate are recorded in interest expense and offset by the fair value changes in the swap contracts. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

The Company's investment portfolio includes cash equivalents and short-term investments, the market values of which are not significantly affected by changes in interest rates. The market value of the Company's medium- to long-term fixed-rate investments is modestly affected by changes in U.S. interest rates. Changes in medium- to long-term U.S. interest rates have a more significant impact on the market value of the Company's fixed-rate borrowings, which generally have longer maturities. A sensitivity analysis to measure potential changes in the market value of Merck's investments and debt from a change in interest rates indicated that a one percentage point increase in interest rates at both December 31, 2017 and 2016 would have positively affected the net aggregate market value of these instruments by $1.3 billion. A one percentage point decrease at December 31, 2017 and 2016 would have negatively affected the net aggregate market value by $1.5 billion and $1.6 billion, respectively. The fair value of Merck's debt was determined using pricing models reflecting one percentage point shifts in the appropriate yield curves. The fair values of Merck's investments were determined using a combination of pricing and duration models.

Critical Accounting Policies

The Company's consolidated financial statements are prepared in conformity with GAAP and, accordingly, include certain amounts that are based on management's best estimates and judgments. Estimates are used when accounting for amounts recorded in connection with acquisitions, including initial fair value

determinations of assets and liabilities, primarily IPR&D, other intangible assets and contingent consideration, as well as subsequent fair value

measurements. Additionally, estimates are used in determining such items as provisions for sales discounts and returns, depreciable and amortizable lives, recoverability of inventories, including those produced in preparation for product launches, amounts recorded for contingencies, environmental liabilities and other reserves, pension and other postretirement benefit plan assumptions, share-based compensation assumptions, restructuring costs, impairments of long-lived assets (including intangible assets and goodwill) and investments, and taxes on income. Because of the uncertainty inherent in such estimates, actual results may differ from these estimates. Application of the following accounting policies result in accounting estimates having the potential for the most significant impact on the financial statements.

Acquisitions and Dispositions

To determine whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses, the Company makes certain judgments, which include assessment of the inputs, processes, and outputs associated with the acquired set of activities. If the Company determines that substantially all of the fair value of gross assets included in a transaction is concentrated in a single asset (or a group of similar assets), the assets would not represent a business. To be considered a business, the assets in a transaction need to include an input and a substantive process that together significantly contribute to the ability to create outputs.

In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the acquisition at their respective fair values with limited exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are recognized at fair value if fair value can reasonably be estimated. If the acquisition date fair value of an asset acquired or liability assumed that arises from a contingency cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Accordingly, the Company may be required to value assets at fair value measures that do not reflect the Company's intended use of those assets. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in the Company's consolidated financial statements after the date of the acquisition. The fair values of intangible assets, including acquired IPR&D, are determined utilizing information available near the acquisition date based on expectations and assumptions that are deemed reasonable by management. Given the considerable judgment involved in determining fair values, the Company typically obtains assistance from third-party valuation specialists for significant items. Amounts allocated to acquired IPR&D are capitalized and accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, Merck will make a separate determination as to the then useful life of the asset, generally determined by the period in which the substantial majority of the cash flows are expected to be generated, and begin amortization. Certain of the Company's business acquisitions involve the potential for future payment of consideration that is contingent upon the achievement of performance milestones, including product development milestones and royalty payments on future product sales. The fair value of contingent consideration liabilities is determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date, at each reporting period, the contingent consideration liability is remeasured at current fair value with changes (either expense or income) recorded in earnings. Changes in any of the inputs may result in a significantly different fair value adjustment.

The judgments made in determining estimated fair values assigned to assets acquired and liabilities assumed in a business combination, as well as asset lives, can materially affect the Company's results of operations.

The fair values of identifiable intangible assets related to currently marketed products and product rights are primarily determined by using an income approach through which fair value is estimated based on each asset's discounted projected net cash flows. The Company's estimates of market participant net cash flows consider historical and projected pricing, margins and expense levels; the performance of competing products where applicable; relevant industry and therapeutic area growth drivers and factors; current and expected trends in technology and product life cycles; the time and investment that will be required to develop products and technologies; the ability to obtain marketing and regulatory approvals; the ability to manufacture and commercialize the products; the extent and timing of potential

new product introductions by the Company's competitors; and the life of each asset's underlying patent, if any. The net cash flows are then probability-adjusted where appropriate to consider the uncertainties associated with the underlying assumptions, as well as the risk profile of the net cash flows utilized in the valuation. The probability-adjusted future net cash flows of each product are then discounted to present value utilizing an appropriate discount rate.

The fair values of identifiable intangible assets related to IPR&D are also determined using an income approach, through which fair value is estimated based on each asset's probability-adjusted future net cash flows, which reflect the different stages of development of each product and the associated probability of successful completion. The net cash flows are then discounted to present value using an appropriate discount rate.

If the Company determines the transaction will not be accounted for as an acquisition of a business, the transaction will be accounted for as an asset acquisition rather than a business combination and, therefore, no goodwill will be recorded. In an asset acquisition, acquired IPR&D with no alternative future use is charged to expense and contingent consideration is not recognized at the acquisition date.

Revenue Recognition

Revenues from sales of products are recognized when title and risk of loss passes to the customer, typically at time of delivery. Recognition of revenue also requires reasonable assurance of collection of sales proceeds and completion of all performance obligations. Domestically, sales discounts are issued to customers at the point-of-sale, through an intermediary wholesaler (known as chargebacks), or in the form of rebates. Additionally, sales are generally made with a limited right of return under certain conditions. Revenues are recorded net of provisions for sales discounts and returns, which are established at the time of sale. In addition, revenues are recorded net of time value of money discounts for customers for which collection of accounts receivable is expected to be in excess of one year.

The provision for aggregate customer discounts covers chargebacks and rebates. Chargebacks are discounts that occur when a contracted customer purchases directly through an intermediary wholesaler. The contracted customer generally purchases product at its contracted price plus a mark-up from the wholesaler. The wholesaler, in turn, charges the Company back for the difference between the price initially paid by the wholesaler and the contract price paid to the wholesaler by the customer. The provision for chargebacks is based on expected sell-through levels by the Company's wholesale customers to contracted customers, as well as estimated wholesaler inventory levels. Rebates are amounts owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. The provision is based on expected payments, which are driven by patient usage and contract performance by the benefit provider customers.

The Company uses historical customer segment mix, adjusted for other known events, in order to estimate the expected provision. Amounts accrued for aggregate customer discounts are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers and other customers to the amounts accrued. Adjustments are recorded when trends or significant events indicate that a change in the estimated provision is appropriate.

The Company continually monitors its provision for aggregate customer discounts. There were no material adjustments to estimates associated with the aggregate customer discount provision in 2017, 2016 or 2015.

Summarized information about changes in the aggregate customer discount accrual related to U.S. sales is as follows:

($ in millions)	**2017**	2016
Balance January 1	**$ 2,945**	$ 2,798
Current provision	**10,938**	9,831
Adjustments to prior years	**(223)**	(169)
Payments	**(11,109)**	(9,515)
Balance December 31	**$ 2,551**	$ 2,945

Accruals for chargebacks are reflected as a direct reduction to accounts receivable and accruals for rebates as current liabilities. The accrued balances relative to these provisions included in *Accounts receivable* and *Accrued*

and other current liabilities were $198 million and $2.4 billion, respectively, at December 31, 2017 and were $196 million and $2.7 billion, respectively, at December 31, 2016.

The Company maintains a returns policy that allows its U.S. pharmaceutical customers to return product within a specified period prior to and subsequent to the expiration date (generally, three to six months before and 12 months after product expiration). The estimate of the provision for returns is based upon historical experience with actual returns. Additionally, the Company considers factors such as levels of inventory in the distribution channel, product dating and expiration period, whether products have been discontinued, entrance in the market of additional generic competition, changes in formularies or launch of over-the-counter products, among others. The product returns provision for U.S. pharmaceutical sales as a percentage of U.S. net pharmaceutical sales was 2.1% in 2017, 1.4% in 2016 and 1.5% in 2015.

Through its distribution programs with U.S. wholesalers, the Company encourages wholesalers to align purchases with underlying demand and maintain inventories below specified levels. The terms of the programs allow the wholesalers to earn fees upon providing visibility into their inventory levels, as well as by achieving certain performance parameters such as inventory management, customer service levels, reducing shortage claims and reducing product returns. Information provided through the wholesaler distribution programs includes items such as sales trends, inventory on-hand, on-order quantity and product returns.

Wholesalers generally provide only the above mentioned data to the Company, as there is no regulatory requirement to report lot level information to manufacturers, which is the level of information needed to determine the remaining shelf life and original sale date of inventory. Given current wholesaler inventory levels, which are generally less than a month, the Company believes that collection of order lot information across all wholesale customers would have limited use in estimating sales discounts and returns.

Inventories Produced in Preparation for Product Launches

The Company capitalizes inventories produced in preparation for product launches sufficient to support estimated initial market demand. Typically, capitalization of such inventory does not begin until the related product candidates are in Phase 3 clinical trials and are considered to have a high probability of regulatory approval. The Company monitors the status of each respective product within the regulatory approval process; however, the Company generally does not disclose specific timing for regulatory approval. If the Company is aware of any specific risks or contingencies other than the normal regulatory approval process or if there are any specific issues identified during the research process relating to safety, efficacy, manufacturing, marketing or labeling, the related inventory would generally not be capitalized. Expiry dates of the inventory are affected by the stage of completion. The Company manages the levels of inventory at each stage to optimize the shelf life of the inventory in relation to anticipated market demand in order to avoid product expiry issues. For inventories that are capitalized, anticipated future sales and shelf lives support the realization of the inventory value as the inventory shelf life is sufficient to meet initial product launch requirements. Inventories produced in preparation for product launches capitalized at both December 31, 2017 and 2016 were $80 million.

Contingencies and Environmental Liabilities

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property and commercial litigation, as well as certain additional matters (see Note 11 to the consolidated financial statements). The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. For product liability claims, a portion of the overall accrual is actuarially determined and considers such factors as past experience, number of claims reported and estimates of claims incurred but not yet reported. Individually significant contingent losses are accrued when probable and reasonably estimable.

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of December 31, 2017 and 2016 of approximately $160 million and $185 million, respectively, represents the Company's best estimate

of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

The Company and its subsidiaries are parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund, and other federal and state equivalents. When a legitimate claim for contribution is asserted, a liability is initially accrued based upon the estimated transaction costs to manage the site. Accruals are adjusted as site investigations, feasibility studies and related cost assessments of remedial techniques are completed, and as the extent to which other potentially responsible parties who may be jointly and severally liable can be expected to contribute is determined.

The Company is also remediating environmental contamination resulting from past industrial activity at certain of its sites and takes an active role in identifying and accruing for these costs. In the past, Merck performed a worldwide survey to assess all sites for potential contamination resulting from past industrial activities. Where assessment indicated that physical investigation was warranted, such investigation was performed, providing a better evaluation of the need for remedial action. Where such need was identified, remedial action was then initiated. As definitive information became available during the course of investigations and/or remedial efforts at each site, estimates were refined and accruals were established or adjusted accordingly. These estimates and related accruals continue to be refined annually.

The Company believes that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on the Company. Expenditures for remediation and environmental liabilities were $11 million in 2017, and are estimated at $56 million in the aggregate for the years 2018 through 2022. In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $82 million and $83 million at December 31, 2017 and 2016, respectively. These liabilities are undiscounted, do not consider potential recoveries from other parties and will be paid out over the periods of remediation for the applicable sites, which are expected to occur primarily over the next 15 years. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed $63 million in the aggregate. Management also does not believe that these expenditures should result in a material adverse effect on the Company's financial position, results of operations, liquidity or capital resources for any year.

Share-Based Compensation

The Company expenses all share-based payment awards to employees, including grants of stock options, over the requisite service period based on the grant date fair value of the awards. The Company determines the fair value of certain share-based awards using the Black-Scholes option-pricing model which uses both historical and current market data to estimate the fair value. This method incorporates various assumptions such as the risk-free interest rate, expected volatility, expected dividend yield and expected life of the options. Total pretax share-based compensation expense was $312 million in 2017, $300 million in 2016 and $299 million in 2015. At December 31, 2017, there was $469 million of total pretax unrecognized compensation expense related to nonvested stock option, restricted stock unit and performance share unit awards which will be recognized over a weighted average period of 1.9 years. For segment reporting, share-based compensation costs are unallocated expenses.

Pensions and Other Postretirement Benefit Plans

Net periodic benefit cost for pension plans totaled $201 million in 2017, $144 million in 2016 and $277 million in 2015. Net periodic benefit (credit) for other postretirement benefit plans was $(60) million in 2017, $(88) million in 2016 and $(24) million in 2015. Pension and other postretirement benefit plan information for financial reporting purposes is calculated using actuarial assumptions including a discount rate for plan benefit obligations and an expected rate of return on plan assets. The changes in net periodic benefit cost year over year for pension plans are largely attributable to changes in the discount rate affecting net loss amortization. The increase in net periodic benefit (credit) for other postretirement benefit plans in 2017 and 2016 as compared with 2015 is largely attributable to changes in retiree medical benefits approved by the Company in December 2015, partially offset by lower returns on plan assets.

The Company reassesses its benefit plan assumptions on a regular basis. For both the pension and other postretirement benefit plans, the discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due. The discount rates for the Company's U.S. pension and other postretirement benefit plans ranged from 3.20% to 3.80% at December 31, 2017, compared with a range of 3.40% to 4.30% at December 31, 2016.

The expected rate of return for both the pension and other postretirement benefit plans represents the average rate of return to be earned on plan assets over the period the benefits included in the benefit obligation are to be paid. In developing the expected rate of return, the Company considers long-term compound annualized returns of historical market data, current market conditions and actual returns on the Company's plan assets. Using this reference information, the Company develops forward-looking return expectations for each asset category and a weighted-average expected long-term rate of return for a target portfolio allocated across these investment categories. The expected portfolio performance reflects the contribution of active management as appropriate. For 2018, the expected rate of return for the Company's U.S. pension and other postretirement benefit plans will range from 7.70% to 8.30%, compared to a range of 8.00% to 8.75% in 2017. The decrease is primarily due to a modest shift in asset allocation.

The Company has established investment guidelines for its U.S. pension and other postretirement plans to create an asset allocation that is expected to deliver a rate of return sufficient to meet the long-term obligation of each plan, given an acceptable level of risk. The target investment portfolio of the Company's U.S. pension and other postretirement benefit plans is allocated 35% to 55% in U.S. equities, 20% to 35% in international equities, 20% to 35% in fixed-income investments, and up to 5% in cash and other investments. The portfolio's equity weighting is consistent with the long-term nature of the plans' benefit obligations. The expected annual standard deviation of returns of the target portfolio, which approximates 13%, reflects both the equity allocation and the diversification benefits among the asset classes in which the portfolio invests. For non-U.S. pension plans, the targeted investment portfolio varies based on the duration of pension liabilities and local government rules and regulations. Although a significant percentage of plan assets are invested in U.S. equities, concentration risk is mitigated through the use of strategies that are diversified within management guidelines.

Actuarial assumptions are based upon management's best estimates and judgment. A reasonably possible change of plus (minus) 25 basis points in the discount rate assumption, with other assumptions held constant, would have had an estimated $77 million favorable (unfavorable) impact on the Company's net periodic benefit cost in 2017. A reasonably possible change of plus (minus) 25 basis points in the expected rate of return assumption, with other assumptions held constant, would have had an estimated $44 million favorable (unfavorable) impact on Merck's net periodic benefit cost in 2017. Required funding obligations for 2018 relating to the Company's pension and other postretirement benefit plans are not expected to be material. The preceding hypothetical changes in the discount rate and expected rate of return assumptions would not impact the Company's funding requirements.

Net loss amounts, which reflect experience differentials primarily relating to differences between expected and actual returns on plan assets as well as the effects of changes in actuarial assumptions, are recorded as a component of *Accumulated Other Comprehensive Income (AOCI)*. Expected returns for pension plans are based on a calculated market-related value of assets. Under this methodology, asset gains/losses resulting from actual returns that differ from the Company's expected returns are recognized in the market-related value of assets ratably over a five-year period. Also, net loss amounts in *AOCI* in excess of certain thresholds are amortized into net periodic benefit cost over the average remaining service life of employees.

Restructuring Costs

Restructuring costs have been recorded in connection with restructuring programs designed to streamline the Company's cost structure. As a result, the Company has made estimates and judgments regarding its future plans, including future termination benefits and other exit costs to be incurred when the restructuring actions take place. When accruing these costs, the Company will recognize the amount within a range of costs that is the best estimate within the range. When no amount within the range is a better estimate than any other amount, the Company recognizes the minimum amount within the range. In connection with these actions, management also assesses the recoverability of long-lived assets employed in the business. In certain instances, asset lives have been shortened based on changes in the expected useful lives of the affected assets. Severance and other related costs are reflected within *Restructuring*

costs. Asset-related charges are reflected within *Materials and production* costs, *Marketing and administrative* expenses and *Research and development* expenses depending upon the nature of the asset.

Impairments of Long-Lived Assets

The Company assesses changes in economic, regulatory and legal conditions and makes assumptions regarding estimated future cash flows in evaluating the value of the Company's property, plant and equipment, goodwill and other intangible assets.

The Company periodically evaluates whether current facts or circumstances indicate that the carrying values of its long-lived assets to be held and used may not be recoverable. If such circumstances are determined to exist, an estimate of the undiscounted future cash flows of these assets, or appropriate asset groupings, is compared to the carrying value to determine whether an impairment exists. If the asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows approach.

Goodwill represents the excess of the consideration transferred over the fair value of net assets of businesses acquired and is assigned to reporting units. The Company tests its goodwill for impairment on at least an annual basis, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. Some of the factors considered in the assessment include general macroeconomic conditions, conditions specific to the industry and market, cost factors which could have a significant effect on earnings or cash flows, the overall financial performance of the reporting unit, and whether there have been sustained declines in the Company's share price. Additionally, the Company evaluates the extent to which the fair value exceeded the carrying value of the reporting unit at the last date a valuation was performed. If the Company concludes it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a quantitative fair value test is performed.

Other acquired intangible assets (excluding IPR&D) are initially recorded at fair value, assigned an estimated useful life, and are amortized primarily on a straight-line basis over their estimated useful lives. When events or circumstances warrant a review, the Company will assess recoverability from future operations using pretax undiscounted cash flows derived from the lowest appropriate asset groupings. Impairments are recognized in operating results to the extent that the carrying value of the intangible asset exceeds its fair value, which is determined based on the net present value of estimated future cash flows.

IPR&D that the Company acquires through business combinations represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. The amounts are capitalized and accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the project. The Company tests IPR&D for impairment at least annually, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the IPR&D intangible asset is less than its carrying amount. If the Company concludes it is more likely than not that the fair value is less than the carrying amount, a quantitative test that compares the fair value of the IPR&D intangible asset with its carrying value is performed. For impairment testing purposes, the Company may combine separately recorded IPR&D intangible assets into one unit of account based on the relevant facts and circumstances. Generally, the Company will combine IPR&D intangible assets for testing purposes if they operate as a single asset and are essentially inseparable. If the fair value is less than the carrying amount, an impairment loss is recognized within the Company's operating results.

The judgments made in evaluating impairment of long-lived intangibles can materially affect the Company's results of operations.

Impairments of Investments

The Company reviews its investments for impairments based on the determination of whether the decline in market value of the investment below the carrying value is other-than-temporary. The Company considers available evidence in evaluating potential impairments of its investments, including the duration and extent to which fair value is less than cost and, for equity securities, the Company's ability and intent to hold the investments. For debt securities, an other-than-temporary impairment has occurred if the Company does not expect to recover the entire amortized cost basis of the debt security. If the Company does not intend to sell the impaired debt security, and it is not more likely than not it will be required to sell the debt security before the recovery of its amortized cost basis, the amount of the

other-than-temporary impairment recognized in earnings is limited to the portion attributed to credit loss. The remaining portion of the other-than-temporary impairment related to other factors is recognized in *OCI*.

Taxes on Income

The Company's effective tax rate is based on pretax income, statutory tax rates and tax planning opportunities available in the various jurisdictions in which the Company operates. An estimated effective tax rate for a year is applied to the Company's quarterly operating results. In the event that there is a significant unusual or one-time item recognized, or expected to be recognized, in the Company's quarterly operating results, the tax attributable to that item would be separately calculated and recorded at the same time as the unusual or one-time item. The Company considers the resolution of prior year tax matters to be such items. Significant judgment is required in determining the Company's tax provision and in evaluating its tax positions. The recognition and measurement of a tax position is based on management's best judgment given the facts, circumstances and information available at the reporting date. The Company evaluates tax positions to determine whether the benefits of tax positions are more likely than not of being sustained upon audit based on the technical merits of the tax position. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely of being realized upon ultimate settlement in the financial statements. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit in the financial statements. If the more likely than not threshold is not met in the period for which a tax position is taken, the Company may subsequently recognize the benefit of that tax position if the tax matter is effectively settled, the statute of limitations expires, or if the more likely than not threshold is met in a subsequent period (see Note 16 to the consolidated financial statements).

Tax regulations require items to be included in the tax return at different times than the items are reflected in the financial statements. Timing differences create deferred tax assets and liabilities. Deferred tax assets generally represent items that can be used as a tax deduction or credit in the tax return in future years for which the Company has already recorded the tax benefit in the financial statements. The Company establishes valuation allowances for its deferred tax assets when the amount of expected future taxable income is not likely to support the use of the deduction or credit. Deferred tax liabilities generally represent tax expense recognized in the financial statements for which payment has been deferred or expense for which the Company has already taken a deduction on the tax return, but has not yet recognized as expense in the financial statements.

Recently Issued Accounting Standards

For a discussion of recently issued accounting standards, see Note 2 to the consolidated financial statements.

Cautionary Factors That May Affect Future Results

This report and other written reports and oral statements made from time to time by the Company may contain so-called "forward-looking statements," all of which are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially from those set forth in the statements. One can identify these forward-looking statements by their use of words such as "anticipates," "expects," "plans," "will," "estimates," "forecasts," "projects" and other words of similar meaning, or negative variations of any of the foregoing. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address the Company's growth strategy, financial results, product development, product approvals, product potential and development programs. One must carefully consider any such statement and should understand that many factors could cause actual results to differ materially from the Company's forward-looking statements. These factors include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. No forward-looking statement can be guaranteed and actual future results may vary materially.

The Company does not assume the obligation to update any forward-looking statement. One should carefully evaluate such statements in light of factors, including risk factors, described in the Company's filings with the Securities and Exchange Commission, especially on this Form 10-K and Forms 10-Q and 8-K. In Item 1A. "Risk Factors" of this annual report on Form 10-K the Company discusses in more detail various important risk factors that could cause actual results to differ from expected or historic results. The Company notes these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. One should understand that it is not possible to predict or identify

all such factors. Consequently, the reader should not consider any such list to be a complete statement of all potential risks or uncertainties.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

The information required by this Item is incorporated by reference to the discussion under "Financial Instruments Market Risk Disclosures" in Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Item 8. Financial Statements and Supplementary Data.

(a) Financial Statements

The consolidated balance sheet of Merck & Co., Inc. and subsidiaries as of December 31, 2017 and 2016, and the related consolidated statements of income, of comprehensive income, of equity and of cash flows for each of the three years in the period ended December 31, 2017, the notes to consolidated financial statements, and the report dated February 27, 2018 of PricewaterhouseCoopers LLP, independent registered public accounting firm, are as follows:

Consolidated Statement of Income
Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions except per share amounts)

	2017	2016	2015
Sales	**$ 40,122**	$ 39,807	$ 39,498
Costs, Expenses and Other			
Materials and production	**12,775**	13,891	14,934
Marketing and administrative	**9,830**	9,762	10,313
Research and development	**10,208**	10,124	6,704
Restructuring costs	**776**	651	619
Other (income) expense, net	**12**	720	1,527
	33,601	35,148	34,097
Income Before Taxes	**6,521**	4,659	5,401
Taxes on Income	**4,103**	718	942
Net Income	**2,418**	3,941	4,459
Less: Net Income Attributable to Noncontrolling Interests	**24**	21	17
Net Income Attributable to Merck & Co., Inc.	**$ 2,394**	$ 3,920	$ 4,442
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	**$ 0.88**	$ 1.42	$ 1.58
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	**$ 0.87**	$ 1.41	$ 1.56

Consolidated Statement of Comprehensive Income
Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions)

	2017	2016	2015
Net Income Attributable to Merck & Co., Inc.	**$ 2,394**	$ 3,920	$ 4,442
Other Comprehensive Income (Loss) Net of Taxes:			
Net unrealized loss on derivatives, net of reclassifications	**(446)**	(66)	(126)
Net unrealized loss on investments, net of reclassifications	**(58)**	(44)	(70)
Benefit plan net gain (loss) and prior service credit (cost), net of amortization	**419**	(799)	579
Cumulative translation adjustment	**401**	(169)	(208)
	316	(1,078)	175
Comprehensive Income Attributable to Merck & Co., Inc.	**$ 2,710**	$ 2,842	$ 4,617

The accompanying notes are an integral part of these consolidated financial statements.

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Consolidated Balance Sheet
Merck & Co., Inc. and Subsidiaries
December 31
($ in millions except per share amounts)

	2017	2016
Assets		
Current Assets		
Cash and cash equivalents	**$ 6,092**	$ 6,515
Short-term investments	**2,406**	7,826
Accounts receivable (net of allowance for doubtful accounts of $210 in 2017 and $195 in 2016)	**6,873**	7,018
Inventories (excludes inventories of $1,187 in 2017 and $1,117 in 2016 classified in Other assets - see Note 7)	**5,096**	4,866
Other current assets	**4,299**	4,389
Total current assets	**24,766**	30,614
Investments	**12,125**	11,416
Property, Plant and Equipment (at cost)		
Land	**365**	412
Buildings	**11,726**	11,439
Machinery, equipment and office furnishings	**14,649**	14,053
Construction in progress	**2,301**	1,871
	29,041	27,775
Less: accumulated depreciation	**16,602**	15,749
	12,439	12,026
Goodwill	**18,284**	18,162
Other Intangibles, Net	**14,183**	17,305
Other Assets	**6,075**	5,854
	$ 87,872	$ 95,377
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	**$ 3,057**	$ 568
Trade accounts payable	**3,102**	2,807
Accrued and other current liabilities	**10,427**	10,274
Income taxes payable	**708**	2,239
Dividends payable	**1,320**	1,316
Total current liabilities	**18,614**	17,204
Long-Term Debt	**21,353**	24,274
Deferred Income Taxes	**2,219**	5,077
Other Noncurrent Liabilities	**11,117**	8,514
Merck & Co., Inc. Stockholders' Equity		
Common stock, $0.50 par value Authorized - 6,500,000,000 shares Issued - 3,577,103,522 shares in 2017 and 2016	**1,788**	1,788
Other paid-in capital	**39,902**	39,939
Retained earnings	**41,350**	44,133
Accumulated other comprehensive loss	**(4,910)**	(5,226)
	78,130	80,634
Less treasury stock, at cost: 880,491,914 shares in 2017 and 828,372,200 shares in 2016	**43,794**	40,546
Total Merck & Co., Inc. stockholders' equity	**34,336**	40,088

Noncontrolling Interests	**233**	220
Total equity	**34,569**	40,308
	$ 87,872	$ 95,377

The accompanying notes are an integral part of this consolidated financial statement.

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Consolidated Statement of Equity
Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions except per share amounts)

	Common Stock	Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock	Non-controlling Interests	Total
Balance January 1, 2015	$1,788	$ 40,423	$ 46,021	$ (4,323)	$ (35,262)	$ 144	$ 48,791
Net income attributable to Merck & Co., Inc.	—	—	4,442	—	—	—	4,442
Other comprehensive income, net of taxes	—	—	—	175	—	—	175
Cash dividends declared on common stock ($1.81 per share)	—	—	(5,115)	—	—	—	(5,115)
Treasury stock shares purchased	—	—	—	—	(4,186)	—	(4,186)
Changes in noncontrolling ownership interests	—	(20)	—	—	—	(55)	(75)
Net income attributable to noncontrolling interests	—	—	—	—	—	17	17
Distributions attributable to noncontrolling interests	—	—	—	—	—	(15)	(15)
Share-based compensation plans and other	—	(181)	—	—	914	—	733
Balance December 31, 2015	1,788	40,222	45,348	(4,148)	(38,534)	91	44,767
Net income attributable to Merck & Co., Inc.	—	—	3,920	—	—	—	3,920
Other comprehensive loss, net of taxes	—	—	—	(1,078)	—	—	(1,078)
Cash dividends declared on common stock ($1.85 per share)	—	—	(5,135)	—	—	—	(5,135)
Treasury stock shares purchased	—	—	—	—	(3,434)	—	(3,434)
Changes in noncontrolling ownership interests	—	—	—	—	—	124	124
Net income attributable to noncontrolling interests	—	—	—	—	—	21	21
Distributions attributable to noncontrolling interests	—	—	—	—	—	(16)	(16)
Share-based compensation plans and other	—	(283)	—	—	1,422	—	1,139
Balance December 31, 2016	1,788	39,939	44,133	(5,226)	(40,546)	220	40,308
Net income attributable to Merck & Co., Inc.	**—**	**—**	**2,394**	**—**	**—**	**—**	**2,394**
Other comprehensive income, net of taxes	**—**	**—**	**—**	**316**	**—**	**—**	**316**
Cash dividends declared on common stock ($1.89 per share)	**—**	**—**	**(5,177)**	**—**	**—**	**—**	**(5,177)**
Treasury stock shares purchased	**—**	**—**	**—**	**—**	**(4,014)**	**—**	**(4,014)**
Acquisition of Vallée S.A.	**—**	**—**	**—**	**—**	**—**	**7**	**7**
Net income attributable to noncontrolling interests	**—**	**—**	**—**	**—**	**—**	**24**	**24**
Distributions attributable to noncontrolling interests	**—**	**—**	**—**	**—**	**—**	**(18)**	**(18)**
Share-based compensation plans and other	**—**	**(37)**	**—**	**—**	**766**	**—**	**729**
Balance December 31, 2017	**$ 1,788**	**$ 39,902**	**$ 41,350**	**$ (4,910)**	**$ (43,794)**	**$ 233**	**$ 34,569**

The accompanying notes are an integral part of this consolidated financial statement.

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Consolidated Statement of Cash Flows
Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions)

	2017	2016	2015
Cash Flows from Operating Activities			
Net income	**$ 2,418**	$ 3,941	$ 4,459
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	**4,637**	5,441	6,375
Intangible asset impairment charges	**646**	3,948	162
Provisional charge for one-time transition tax related to the enactment of U.S. tax legislation	**5,347**	—	—
Charge for future payments related to AstraZeneca collaboration license options	**500**	—	—
Charge related to the settlement of worldwide *Keytruda* patent litigation	**—**	625	—
Foreign currency devaluation related to Venezuela	**—**	—	876
Net charge related to the settlement of *Vioxx* shareholder class action litigation	**—**	—	680
Equity income from affiliates	**(42)**	(86)	(205)
Dividends and distributions from equity method affiliates	**2**	16	50
Deferred income taxes	**(2,621)**	(1,521)	(764)
Share-based compensation	**312**	300	299
Other	**269**	313	874
Net changes in assets and liabilities:			
Accounts receivable	**297**	(619)	(480)
Inventories	**(145)**	206	805
Trade accounts payable	**254**	278	(37)
Accrued and other current liabilities	**(922)**	(2,018)	(8)
Income taxes payable	**(3,291)**	124	(266)
Noncurrent liabilities	**(123)**	(809)	(277)
Other	**(1,091)**	237	(5)
Net Cash Provided by Operating Activities	**6,447**	10,376	12,538
Cash Flows from Investing Activities			
Capital expenditures	**(1,888)**	(1,614)	(1,283)
Purchases of securities and other investments	**(10,739)**	(15,651)	(16,681)
Proceeds from sales of securities and other investments	**15,664**	14,353	20,413
Acquisition of Cubist Pharmaceuticals, Inc., net of cash acquired	**—**	—	(7,598)
Acquisitions of other businesses, net of cash acquired	**(396)**	(780)	(146)
Dispositions of businesses, net of cash divested	**—**	—	316
Other	**38**	482	221
Net Cash Provided by (Used in) Investing Activities	**2,679**	(3,210)	(4,758)
Cash Flows from Financing Activities			
Net change in short-term borrowings	**(26)**	—	(1,540)
Payments on debt	**(1,103)**	(2,386)	(2,906)
Proceeds from issuance of debt	**—**	1,079	7,938
Purchases of treasury stock	**(4,014)**	(3,434)	(4,186)
Dividends paid to stockholders	**(5,167)**	(5,124)	(5,117)
Proceeds from exercise of stock options	**499**	939	485
Other	**(195)**	(118)	(61)
Net Cash Used in Financing Activities	**(10,006)**	(9,044)	(5,387)
Effect of Exchange Rate Changes on Cash and Cash Equivalents	**457**	(131)	(1,310)
Net (Decrease) Increase in Cash and Cash Equivalents	**(423)**	(2,009)	1,083

Cash and Cash Equivalents at Beginning of Year	**6,515**	8,524	7,441
Cash and Cash Equivalents at End of Year	**$ 6,092**	$ 6,515	$ 8,524

The accompanying notes are an integral part of this consolidated financial statement.

Notes to Consolidated Financial Statements
Merck & Co., Inc. and Subsidiaries
($ in millions except per share amounts)

1. Nature of Operations

Merck & Co., Inc. (Merck or the Company) is a global health care company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies and animal health products. The Company's operations are principally managed on a products basis and include four operating segments, which are the Pharmaceutical, Animal Health, Healthcare Services and Alliances segments. The Pharmaceutical segment is the only reportable segment.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. On December 31, 2016, Merck and Sanofi Pasteur S.A. (Sanofi) terminated their equally-owned joint venture, Sanofi Pasteur MSD (SPMSD), which developed and marketed vaccines in Europe. Beginning in 2017, Merck is recording vaccine sales and incurring costs as a result of operating its vaccines business in the European markets that were previously part of the SPMSD joint venture, which was accounted for as an equity method affiliate.

The Company also has an Animal Health segment that discovers, develops, manufactures and markets animal health products, including vaccines, which the Company sells to veterinarians, distributors and animal producers. The Company's Healthcare Services segment provides services and solutions that focus on engagement, health analytics and clinical services to improve the value of care delivered to patients.

2. Summary of Accounting Policies

Principles of Consolidation — The consolidated financial statements include the accounts of the Company and all of its subsidiaries in which a controlling interest is maintained. Intercompany balances and transactions are eliminated. Controlling interest is determined by majority ownership interest and the absence of substantive third-party participating rights or, in the case of variable interest entities, by majority exposure to expected losses, residual returns or both. For those consolidated subsidiaries where Merck ownership is less than 100%, the outside shareholders' interests are shown as *Noncontrolling interests* in equity. Investments in affiliates over which the Company has significant influence but not a controlling interest, such as interests in entities owned equally by the Company and a third party that are under shared control, are carried on the equity basis.

Acquisitions — In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the acquisition at their respective fair values with limited exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are generally recognized at fair value. If fair value cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Accordingly, the Company may be required to value assets at fair value measures that do not reflect the Company's intended use of those assets. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in the Company's consolidated financial statements after the date of the acquisition. If the Company determines the assets acquired do not meet the definition of a business under the acquisition method of accounting, the transaction will be accounted for as an acquisition of assets rather than a business combination and, therefore, no goodwill will be recorded.

Foreign Currency Translation — The net assets of international subsidiaries where the local currencies have been determined to be the functional currencies are translated into U.S. dollars using current exchange rates. The U.S. dollar effects that arise from translating the net assets of these subsidiaries at changing rates are recorded in the foreign currency translation account, which is included in *Accumulated other comprehensive income (loss)* (*AOCI*) and reflected as a separate component of equity. For those subsidiaries that operate in highly inflationary economies and for those subsidiaries where the U.S. dollar has been determined to be the functional currency, non-monetary foreign currency assets and liabilities are translated using historical rates, while monetary assets and liabilities are translated at current rates, with the U.S. dollar effects of rate changes included in *Other (income) expense, net*.

Cash Equivalents — Cash equivalents are comprised of certain highly liquid investments with original maturities of less than three months.

Inventories — Inventories are valued at the lower of cost or market. The cost of a substantial majority of domestic pharmaceutical and vaccine inventories is determined using the last-in, first-out (LIFO) method for both financial reporting and tax purposes. The cost of all other inventories is determined using the first-in, first-out (FIFO) method. Inventories consist of currently marketed products, as well as certain inventories produced in preparation for product launches that are considered to have a high probability of regulatory approval. In evaluating the recoverability of inventories produced in preparation for product launches, the Company considers the likelihood that revenue will be obtained from the future sale of the related inventory together with the status of the product within the regulatory approval process.

Investments — Investments in marketable debt and equity securities classified as available-for-sale are reported at fair value. Fair values of the Company's investments are determined using quoted market prices in active markets for identical assets or liabilities or quoted prices for similar assets or liabilities or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Changes in fair value that are considered temporary are reported net of tax in *Other Comprehensive Income* (*OCI*). For declines in the fair value of equity securities that are considered other-than-temporary, impairment losses are charged to *Other (income) expense, net*. The Company considers available evidence in evaluating potential impairments of its investments, including the duration and extent to which fair value is less than cost and, for equity securities, the Company's ability and intent to hold the investments. For debt securities, an other-than-temporary impairment has occurred if the Company does not expect to recover the entire amortized cost basis of the debt security. If the Company does not intend to sell the impaired debt security, and it is not more likely than not it will be required to sell the debt security before the recovery of its amortized cost basis, the amount of the other-than-temporary impairment recognized in earnings, recorded in *Other (income) expense, net*, is limited to the portion attributed to credit loss. The remaining portion of the other-than-temporary impairment related to other factors is recognized in *OCI*. Realized gains and losses for both debt and equity securities are included in *Other (income) expense, net*.

Revenue Recognition — Revenues from sales of products are recognized when title and risk of loss passes to the customer, typically upon delivery. Recognition of revenue also requires reasonable assurance of collection of sales proceeds and completion of all performance obligations. Domestically, sales discounts are issued to customers at the point-of-sale, through an intermediary wholesaler (known as chargebacks), or in the form of rebates. Additionally, sales are generally made with a limited right of return under certain conditions. Revenues are recorded net of provisions for sales discounts and returns, which are established at the time of sale. In addition, revenues are recorded net of time value of money discounts if collection of accounts receivable is expected to be in excess of one year. Accruals for chargebacks are reflected as a direct reduction to accounts receivable and accruals for rebates are recorded as current liabilities. The accrued balances relative to the provisions for chargebacks and rebates included in *Accounts receivable* and *Accrued and other current liabilities* were $198 million and $2.4 billion, respectively, at December 31, 2017 and $196 million and $2.7 billion, respectively, at December 31, 2016.

The Company recognizes revenue from the sales of vaccines to the Federal government for placement into vaccine stockpiles in accordance with Securities and Exchange Commission (SEC) Interpretation, *Commission Guidance Regarding Accounting for Sales of Vaccines and BioTerror Countermeasures to the Federal Government for Placement into the Pediatric Vaccine Stockpile or the Strategic National Stockpile*. This interpretation allows companies to recognize revenue for sales of vaccines into U.S. government stockpiles even though these sales might not meet the criteria for revenue recognition under other accounting guidance.

Depreciation — Depreciation is provided over the estimated useful lives of the assets, principally using the straight-line method. For tax purposes, accelerated tax methods are used. The estimated useful lives primarily range from 25 to 45 years for *Buildings*, and from 3 to 15 years for *Machinery, equipment and office furnishings*. Depreciation expense was $1.5 billion in 2017, $1.6 billion in 2016 and $1.6 billion in 2015.

Advertising and Promotion Costs — Advertising and promotion costs are expensed as incurred. The Company recorded advertising and promotion expenses of $2.2 billion, $2.1 billion and $2.1 billion in 2017, 2016 and 2015, respectively.

Software Capitalization — The Company capitalizes certain costs incurred in connection with obtaining or developing internal-use software including external direct costs of material and services, and payroll costs for employees directly involved with the software development. Capitalized software costs are included in *Property, plant and equipment* and amortized beginning when the software project is substantially complete and the asset is ready for its intended use. Capitalized software costs associated with projects that are being amortized over 6 to 10 years (including the Company's on-going multi-year implementation of an enterprise-wide resource planning system) were $449 million and $452 million, net of accumulated amortization at December 31, 2017 and 2016, respectively. All other capitalized software costs are being amortized over periods ranging from 3 to 5 years. Costs incurred during the preliminary project stage and post-implementation stage, as well as maintenance and training costs, are expensed as incurred.

Goodwill — Goodwill represents the excess of the consideration transferred over the fair value of net assets of businesses acquired. Goodwill is assigned to reporting units and evaluated for impairment on at least an annual basis, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If the Company concludes it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a quantitative fair value test is performed.

Acquired Intangibles — Acquired intangibles include products and product rights, tradenames and patents, which are initially recorded at fair value, assigned an estimated useful life, and are amortized primarily on a straight-line basis over their estimated useful lives ranging from 2 to 20 years (see Note 8). The Company periodically evaluates whether current facts or circumstances indicate that the carrying values of its acquired intangibles may not be recoverable. If such circumstances are determined to exist, an estimate of the undiscounted future cash flows of these assets, or appropriate asset groupings, is compared to the carrying value to determine whether an impairment exists. If the asset is determined to be impaired, the loss is measured based on the difference between the carrying value of the intangible asset and its fair value, which is determined based on the net present value of estimated future cash flows.

Acquired In-Process Research and Development — Acquired in-process research and development (IPR&D) that the Company acquires through business combinations represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. The amounts are capitalized and are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, Merck will make a determination as to the then useful life of the intangible asset, generally determined by the period in which the substantial majority of the cash flows are expected to be generated, and begin amortization. The Company tests IPR&D for impairment at least annually, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the IPR&D intangible asset is less than its carrying amount. If the Company concludes it is more likely than not that the fair value is less than the carrying amount, a quantitative test that compares the fair value of the IPR&D intangible asset with its carrying value is performed. If the fair value is less than the carrying amount, an impairment loss is recognized in operating results.

Contingent Consideration — Certain of the Company's business acquisitions involve the potential for future payment of consideration that is contingent upon the achievement of performance milestones, including product development milestones and royalty payments on future product sales. The fair value of contingent consideration liabilities is determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date,

at each reporting period, the contingent consideration liability is remeasured at current fair value with changes (either expense or income) recorded in earnings.

Research and Development — Research and development is expensed as incurred. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Research and development expenses include restructuring costs and IPR&D impairment charges in all periods. In addition, research and development expenses include expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration.

Collaborative Arrangements — Merck has entered into collaborative arrangements that provide the Company with varying rights to develop, produce and market products together with its collaborative partners. Cost reimbursements between the collaborative partners are recognized as incurred and included in *Materials and production* costs, *Marketing and administrative* expenses and *Research and development* expenses based on the underlying nature of the related activities subject to reimbursement. When Merck is the principal on sales transactions with third parties, the Company recognizes sales, materials and production costs and marketing and administrative expenses on a gross basis. The Company records profit sharing amounts received from its collaborative partners as alliance revenue (within *Sales*) and profit sharing amounts it pays to its collaborative partners within *Materials and production* costs. Terms of the collaboration agreements may require the Company to make payments based upon the achievement of certain developmental, regulatory approval or commercial milestones. Upfront and milestone payments payable by Merck to collaborative partners prior to regulatory approval are expensed as incurred and included in *Research and development* expenses. Payments due to collaborative partners upon or subsequent to regulatory approval are capitalized and amortized over the estimated useful life of the corresponding intangible asset to *Materials and production* costs provided that future cash flows support the amounts capitalized. Sales-based milestones payable by Merck to collaborative partners are accrued when probable of being achieved and capitalized, subject to cumulative amortization catch-up. The amortization catch-up is calculated either from the time of the first regulatory approval for indications that were unapproved at the time the collaboration was formed, or from time of the formation of the collaboration for approved products. The related intangible asset that is recognized is amortized to *Materials and production* costs over its remaining useful life, subject to impairment testing.

Share-Based Compensation — The Company expenses all share-based payments to employees over the requisite service period based on the grant-date fair value of the awards.

Restructuring Costs — The Company records liabilities for costs associated with exit or disposal activities in the period in which the liability is incurred. In accordance with existing benefit arrangements, employee termination costs are accrued when the restructuring actions are probable and estimable. When accruing these costs, the Company will recognize the amount within a range of costs that is the best estimate within the range. When no amount within the range is a better estimate than any other amount, the Company recognizes the minimum amount within the range. Costs for one-time termination benefits in which the employee is required to render service until termination in order to receive the benefits are recognized ratably over the future service period.

Contingencies and Legal Defense Costs — The Company records accruals for contingencies and legal defense costs expected to be incurred in connection with a loss contingency when it is probable that a liability has been incurred and the amount can be reasonably estimated.

Taxes on Income — Deferred taxes are recognized for the future tax effects of temporary differences between financial and income tax reporting based on enacted tax laws and rates. The Company evaluates tax positions to determine whether the benefits of tax positions are more likely than not of being sustained upon audit based on the technical merits of the tax position. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely of being realized upon ultimate settlement in the financial statements. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit in the financial statements. The Company recognizes interest and penalties associated with uncertain tax positions as a component of *Taxes on income* in the Consolidated Statement of Income.

Use of Estimates — The consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States (GAAP) and, accordingly, include certain amounts that are based on management's best estimates and judgments. Estimates are used when accounting for amounts recorded in connection with acquisitions, including initial fair value determinations of assets and liabilities, primarily IPR&D, other intangible assets and contingent consideration, as well as subsequent fair value measurements. Additionally, estimates are used in determining such items as provisions for sales discounts and returns, depreciable and amortizable lives, recoverability of inventories, including those produced in preparation for product launches, amounts recorded for contingencies, environmental liabilities and other reserves, pension and other postretirement benefit plan assumptions, share-based compensation assumptions, restructuring costs, impairments of long-lived assets (including intangible assets and goodwill) and investments, and taxes on income. Because of the uncertainty inherent in such estimates, actual results may differ from these estimates.

Reclassifications — Certain reclassifications have been made to prior year amounts to conform to the current year presentation.

Recently Issued Accounting Standards — In May 2014, the Financial Accounting Standards Board (FASB) issued amended accounting guidance on revenue recognition that will be applied to all contracts with customers. The objective of the new guidance is to improve comparability of revenue recognition practices across entities and to provide more useful information to users of financial statements through improved disclosure requirements. The new standard permits two methods of adoption: retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of adopting the guidance being recognized at the date of initial application (modified retrospective method). The new standard will be effective as of January 1, 2018 and will be adopted using the modified retrospective method. The Company anticipates recording a cumulative-effect adjustment upon adoption increasing *Retained earnings* by $5 million in 2018. The adoption of the new guidance will also result in some additional disclosures.

In January 2016, the FASB issued revised guidance for the accounting and reporting of financial instruments. The new guidance requires that equity investments with readily determinable fair values currently classified as available for sale be measured at fair value with changes in fair value recognized in net income. The new guidance also simplifies the impairment testing of equity investments without readily determinable fair values and changes certain disclosure requirements. The new standard will be effective as of January 1, 2018 and will be adopted using a modified retrospective approach. The Company anticipates recording a cumulative-effect adjustment upon adoption increasing *Retained earnings* by $8 million in 2018.

In August 2016, the FASB issued guidance on the classification of certain cash receipts and payments in the statement of cash flows intended to reduce diversity in practice. The new standard is effective as of January 1, 2018 and will be adopted using a retrospective application. The Company does not anticipate any changes to the presentation of its Consolidated Statement of Cash Flows as a result of adopting the new standard.

In October 2016, the FASB issued guidance on the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. Under existing guidance, the recognition of current and deferred income taxes for an intra-entity asset transfer is prohibited until the asset has been sold to a third party. The new guidance will require the recognition of the income tax consequences of an intra-entity transfer of an asset (with the exception of inventory) when the intra-entity transfer occurs. The new standard will be effective as of January 1, 2018 and will be adopted using a modified retrospective approach. The Company anticipates recording a cumulative-effect adjustment upon adoption increasing *Retained earnings* by approximately $60 million in 2018 with a corresponding increase to deferred tax assets, subject to finalization.

In November 2016, the FASB issued guidance requiring that amounts generally described as restricted cash and restricted cash equivalents be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The new standard is effective as of January 1, 2018 and will be adopted using a retrospective application. The adoption of the new guidance will not have a material effect on the Company's Consolidated Statement of Cash Flows.

In March 2017, the FASB amended the guidance related to net periodic benefit cost for defined benefit plans that requires entities to (1) disaggregate the current service cost component from the other components of net benefit cost and present it with other employee compensation costs in the income statement within operations if such a subtotal

is presented; (2) present the other components of net benefit cost separately in the income statement and outside of income from operations; and (3) only capitalize the service cost component when applicable. Entities must use a retrospective transition method to adopt the requirement for separate presentation in the income statement of service costs and other components and a prospective transition method to adopt the requirement to limit the capitalization of benefit costs to the service cost component. The Company will utilize a practical expedient that permits it to use the amounts disclosed in its pension and other postretirement benefit plan note for the prior comparative periods as the estimation basis for applying the retrospective presentation requirements. The new standard is effective as of January 1, 2018. Net periodic benefit cost (credit) other than service cost was approximately $(510) million and $(530) million for the years ended December 31, 2017 and 2016, respectively, (see Note 14). Upon adoption, these amounts will be reclassified to *Other (income) expense, net* from their current classification within *Materials and production* costs, *Marketing and administrative* expenses and *Research and development* costs.

In May 2017, the FASB issued guidance clarifying when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The new standard is effective as of January 1, 2018 and will be applied to future share-based payment award modifications should they occur.

In February 2016, the FASB issued new accounting guidance for the accounting and reporting of leases. The new guidance requires that lessees recognize a right-of-use asset and a lease liability recorded on the balance sheet for each of its leases (other than leases that meet the definition of a short-term lease). Leases will be classified as either operating or finance. Operating leases will result in straight-line expense in the income statement (similar to current operating leases) while finance leases will result in more expense being recognized in the earlier years of the lease term (similar to current capital leases). The new guidance will be effective for interim and annual periods beginning in 2019 and will be adopted using a modified retrospective approach which will require application of the new guidance at the beginning of the earliest comparative period presented. Early adoption is permitted. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In August 2017, the FASB issued new guidance on hedge accounting that is intended to more closely align hedge accounting with companies' risk management strategies, simplify the application of hedge accounting, and increase transparency as to the scope and results of hedging programs. The new guidance makes more financial and nonfinancial hedging strategies eligible for hedge accounting, amends the presentation and disclosure requirements, and changes how companies assess effectiveness. The new guidance is effective for interim and annual periods beginning in 2019 on a modified retrospective basis. Early application is permitted in any interim period. The Company intends to early adopt this guidance as of January 1, 2018 on a modified retrospective basis. The Company anticipates recording a cumulative-effect adjustment upon adoption decreasing *Retained earnings* by $11 million in 2018.The adoption of the new guidance will result in some additional disclosures.

In February 2018, the FASB issued new guidance to address a narrow-scope financial reporting issue that arose as a consequence of the TCJA. Existing guidance requires that deferred tax liabilities and assets be adjusted for a change in tax laws or rates with the effect included in income from continuing operations in the reporting period that includes the enactment date. That guidance is applicable even in situations in which the related income tax effects of items in accumulated other comprehensive income were originally recognized in other comprehensive income (rather than in net income), such as amounts related to benefit plans and hedging activity. As a result, the tax effects of items within accumulated other comprehensive income do not reflect the appropriate tax rate (the difference is referred to as stranded tax effects). The new guidance allows for a reclassification of these amounts to retained earnings thereby eliminating these stranded tax effects. The new guidance is effective for interim and annual periods in 2019. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In June 2016, the FASB issued amended guidance on the accounting for credit losses on financial instruments. The guidance introduces an expected loss model for estimating credit losses, replacing the incurred loss model. The new guidance also changes the impairment model for available-for-sale debt securities, requiring the use of an allowance to record estimated credit losses (and subsequent recoveries). The new guidance is effective for interim and annual periods beginning in 2020, with earlier application permitted in 2019. The new guidance is to be applied on a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings in the beginning of the period of adoption. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In January 2017, the FASB issued guidance that provides for the elimination of Step 2 from the goodwill impairment test. Under the new guidance, impairment charges are recognized to the extent the carrying amount of a reporting unit exceeds its fair value with certain limitations. The new guidance is effective for interim and annual periods in 2020. Early adoption is permitted. The Company does not anticipate that the adoption of the new guidance will have a material effect on its consolidated financial statements.

3. Acquisitions, Divestitures, Research Collaborations and License Agreements

The Company continues to pursue the acquisition of businesses and establishment of external alliances such as research collaborations and licensing agreements to complement its internal research capabilities. These arrangements often include upfront payments, as well as expense reimbursements or payments to the third party, and milestone, royalty or profit share arrangements, contingent upon the occurrence of certain future events linked to the success of the asset in development. The Company also reviews its marketed products and pipeline to examine candidates which may provide more value through out-licensing and, as part of its portfolio assessment process, may also divest certain assets. Pro forma financial information for acquired businesses is not presented if the historical financial results of the acquired entity are not significant when compared with the Company's financial results.

Recently Announced Transaction

In February 2018, Merck and Viralytics Limited (Viralytics) announced a definitive agreement pursuant to which Merck will acquire Viralytics, an Australian publicly traded company focused on oncolytic immunotherapy treatments for a range of cancers, for AUD 1.75 per share. The proposed acquisition values the total issued shares in Viralytics at approximately AUD 502 million ($394 million). Upon completion of the transaction, Merck will gain full rights to Cavatax (CVA21), Viralytics's investigational oncolytic immunotherapy. The transaction remains subject to a Viralytics's shareholder vote and customary regulatory approvals. Merck anticipates the transaction will close in the second quarter of 2018.

2017 Transactions

In October 2017, Merck acquired Rigontec GmbH (Rigontec). Rigontec is a leader in accessing the retinoic acid-inducible gene I pathway, part of the innate immune system, as a novel and distinct approach in cancer immunotherapy to induce both immediate and long-term anti-tumor immunity. Rigontec's lead candidate, RGT100, is currently in Phase I development evaluating treatment in patients with various tumors. Under the terms of the agreement, Merck made an upfront cash payment of €119 million ($140 million) and may make additional contingent payments of up to €349 million (of which €184 million are related to the achievement of research milestones and regulatory approvals and €165 million are related to the achievement of commercial targets). The transaction was accounted for as an acquisition of an asset and the upfront payment is reflected within *Research and development* expenses in 2017.

In July 2017, Merck and AstraZeneca entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza (olaparib) for multiple cancer types (see Note 4).

In March 2017, Merck acquired a controlling interest in Vallée S.A. (Vallée), a leading privately held producer of animal health products in Brazil. Vallée has an extensive portfolio of products spanning parasiticides, anti-infectives and vaccines that include products for livestock, horses, and companion animals. Under the terms of the agreement, Merck acquired 93.5% of the shares of Vallée for $358 million. Of the total purchase price, $176 million was placed into escrow pending resolution of certain contingent items. The transaction was accounted for as an acquisition of a business. Merck recognized intangible assets of $291 million related to currently marketed products, net deferred tax liabilities of $93 million, other net assets of $14 million and noncontrolling interest of $25 million. In addition, the Company recorded liabilities of $37 million for contingencies identified at the acquisition date and corresponding indemnification assets of $37 million, representing the amounts to be reimbursed to Merck if and when the contingent liabilities are paid. The excess of the consideration transferred over the fair value of net assets acquired of $171 million was recorded as goodwill. The goodwill was allocated to the Animal Health segment and is not deductible for tax purposes. The estimated fair values of identifiable intangible assets related to currently marketed products were determined using an income approach. The probability-adjusted future net cash flows of each product were discounted to present value utilizing a discount rate of 15.5%. Actual cash flows are likely to be different than those assumed. The intangible assets related to currently marketed products are being amortized over their estimated useful lives of 15

years. In the fourth quarter of 2017, Merck acquired an additional 4.5% interest in Vallée for $18 million, which reduced noncontrolling interest related to Vallée.

2016 Transactions

In July 2016, Merck acquired Afferent Pharmaceuticals (Afferent), a privately held pharmaceutical company focused on the development of therapeutic candidates targeting the P2X3 receptor for the treatment of common, poorly-managed, neurogenic conditions. Afferent's lead investigational candidate, MK-7264 (formerly AF-219), is a selective, non-narcotic, orally-administered P2X3 antagonist being evaluated for the treatment of refractory, chronic cough. Total consideration transferred of $510 million included cash paid for outstanding Afferent shares of $487 million, as well as share-based compensation payments to settle equity awards attributable to precombination service and cash paid for transaction costs on behalf of Afferent. In addition, former Afferent shareholders are eligible to receive a total of up to an additional $750 million contingent upon the attainment of certain clinical development and commercial milestones for multiple indications and candidates, including MK-7264. This transaction was accounted for as an acquisition of a business. The Company determined the fair value of the contingent consideration was $223 million at the acquisition date utilizing a probability-weighted estimated cash flow stream using an appropriate discount rate dependent on the nature and timing of the milestone payment. Merck recognized an intangible asset for IPR&D of $832 million, net deferred tax liabilities of $258 million, and other net assets of $29 million (primarily consisting of cash acquired). The excess of the consideration transferred over the fair value of net assets acquired of $130 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair value of the identifiable intangible asset related to IPR&D was determined using an income approach. The asset's probability-adjusted future net cash flows were discounted to present value using a discount rate of 11.5%. Actual cash flows are likely to be different than those assumed.

Also in July 2016, Merck, through its wholly owned subsidiary Healthcare Services & Solutions, LLC, acquired a majority ownership interest in The StayWell Company LLC (StayWell), a portfolio company of Vestar Capital Partners (Vestar). StayWell is a health engagement company that helps its clients engage and educate people to improve health and business results. Under the terms of the transaction, Merck paid $150 million for a majority ownership interest. Additionally, Merck provided StayWell with a $150 million intercompany loan to pay down preexisting third-party debt. Merck has an option to buy, and Vestar has an option to require Merck to buy, some or all of Vestar's remaining ownership interest at fair value beginning three years from the acquisition date. This transaction was accounted for as an acquisition of a business. Merck recognized intangible assets of $238 million, deferred tax liabilities of $84 million, other net liabilities of $5 million and noncontrolling interest of $124 million. The excess of the consideration transferred over the fair value of net assets acquired of $275 million was recorded as goodwill and is largely attributable to anticipated synergies expected to arise after the acquisition. The goodwill was allocated to the Healthcare Services segment and is not deductible for tax purposes. The intangible assets recognized primarily relate to customer relationships, which are being amortized over a 10-year useful life, and medical information and solutions content, which are being amortized over a five-year useful life.

In June 2016, Merck and Moderna Therapeutics (Moderna) entered into a strategic collaboration and license agreement to develop and commercialize novel messenger RNA (mRNA)-based personalized cancer vaccines. The development program will entail multiple studies in several types of cancer and include the evaluation of mRNA-based personalized cancer vaccines in combination with Merck's *Keytruda*. Pursuant to the terms of the agreement, Merck made an upfront cash payment to Moderna of $200 million, which was recorded in *Research and development* expenses. Following human proof of concept studies, Merck has the right to elect to make an additional payment to Moderna. If Merck exercises this right, the two companies will then equally share costs and profits under a worldwide collaboration for the development of personalized cancer vaccines. Moderna will have the right to elect to co-promote the personalized cancer vaccines in the United States. The agreement entails exclusivity around combinations with *Keytruda*. Moderna and Merck each have the ability to combine mRNA-based personalized cancer vaccines with other (non-PD-1) agents.

In January 2016, Merck acquired IOmet Pharma Ltd (IOmet), a privately held UK-based drug discovery company focused on the development of innovative medicines for the treatment of cancer, with a particular emphasis on the fields of cancer immunotherapy and cancer metabolism. The acquisition provides Merck with IOmet's preclinical pipeline of IDO (indoleamine-2,3-dioxygenase 1), TDO (tryptophan-2,3-dioxygenase), and dual-acting IDO/TDO inhibitors. The transaction was accounted for as an acquisition of a business. Total purchase consideration in the transaction included a cash payment of $150 million and future additional milestone payments of up to $250 million contingent upon certain clinical and regulatory milestones being achieved. The Company determined the fair value of

the contingent consideration was $94 million at the acquisition date utilizing a probability-weighted estimated cash flow stream adjusted for the expected timing of each payment utilizing a discount rate of 10.5%. Merck recognized intangible assets for IPR&D of $155 million and net deferred tax assets of $32 million. The excess of the consideration transferred over the fair value of net assets acquired of $57 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair values of the identifiable intangible assets related to IPR&D were determined using an income approach. The assets' probability-adjusted future net cash flows were discounted to present value also using a discount rate of 10.5%. Actual cash flows are likely to be different than those assumed. In July 2017, Merck made a $100 million payment as a result of the achievement of a clinical development milestone, which was accrued for at estimated fair value at the time of acquisition as noted above.

2015 Transactions

In December 2015, the Company divested its remaining ophthalmics portfolio in international markets to Mundipharma Ophthalmology Products Limited. Merck received consideration of approximately $170 million and recognized a gain of $147 million recorded in *Other (income) expense, net* in 2015.

In July 2015, Merck acquired cCAM Biotherapeutics Ltd. (cCAM), a privately held biopharmaceutical company focused on the discovery and development of novel cancer immunotherapies. Total purchase consideration in the transaction included an upfront payment of $96 million in cash and potential future additional payments associated with the attainment of certain clinical development, regulatory and commercial milestones. The transaction was accounted for as an acquisition of a business. Merck recognized an intangible asset for IPR&D of $180 million related to CM-24, a monoclonal antibody, as well as a liability for contingent consideration of $105 million, goodwill of $14 million and other net assets of $7 million. During 2016, as a result of unfavorable efficacy data, the Company determined that it would discontinue development of the pipeline program. Accordingly, the Company recorded an IPR&D impairment charge of $180 million related to CM-24 and reversed the related liability for contingent consideration, which had a fair value of $116 million at the time of program discontinuation. Both the IPR&D impairment charge and the income related to the reduction in the liability for contingent consideration were recorded in *Research and development* expenses in 2016.

Also in July 2015, Merck and Allergan plc (Allergan) entered into an agreement pursuant to which Allergan acquired the exclusive worldwide rights to MK-1602 and MK-8031, Merck's investigational small molecule oral calcitonin gene-related peptide (CGRP) receptor antagonists, which are being developed for the treatment and prevention of migraine. Under the terms of the agreement, Allergan acquired these rights for upfront payments of $250 million, of which $125 million was paid in August 2015 upon closing of the transaction and the remaining $125 million was paid in April of 2016. The Company recorded a gain of $250 million within *Other (income) expense, net* in 2015 related to the transaction. Allergan is fully responsible for development of the CGRP programs, as well as manufacturing and commercialization upon approval and launch of the products. Under the agreement, Merck is entitled to receive potential development and commercial milestone payments and royalties at tiered double-digit rates based on commercialization of the programs. During 2016, Merck recognized gains of $100 million within *Other (income) expense, net* resulting from payments by Allergan for the achievement of research and development milestones.

In February 2015, Merck and NGM Biopharmaceuticals, Inc. (NGM), a privately held biotechnology company, entered into a multi-year collaboration to research, discover, develop and commercialize novel biologic therapies across a wide range of therapeutic areas. Under the terms of the agreement, Merck made an upfront payment to NGM of $94 million, which was included in *Research and development* expenses, and purchased a 15% equity stake in NGM for $106 million. Merck committed up to $250 million to fund all of NGM's efforts under the initial five-year term of the collaboration, with the potential for additional funding if certain conditions are met. Prior to Merck initiating a Phase 3 study for a licensed program, NGM may elect to either receive milestone and royalty payments or, in certain cases, to co-fund development and participate in a global cost and revenue share arrangement of up to 50%. The agreement also provides NGM with the option to participate in the co-promotion of any co-funded program in the United States. Merck has the option to extend the research agreement for two additional two-year terms.

In January 2015, Merck acquired Cubist Pharmaceuticals, Inc. (Cubist), a leader in the development of therapies to treat serious infections caused by a broad range of bacteria. Total consideration transferred of $8.3 billion included cash paid for outstanding Cubist shares of $7.8 billion, as well as share-based compensation payments to settle equity awards attributable to precombination service and cash paid for transaction costs on behalf of Cubist. Share-based compensation payments to settle non-vested equity awards attributable to postcombination service were

recognized as transaction expense in 2015. In addition, the Company assumed all of the outstanding convertible debt of Cubist, which had a fair value of approximately $1.9 billion at the acquisition date. Merck redeemed this debt in February 2015. The transaction was accounted for as an acquisition of a business.

The estimated fair value of assets acquired and liabilities assumed from Cubist is as follows:

Estimated fair value at January 21, 2015		
Cash and cash equivalents	$	733
Accounts receivable		123
Inventories		216
Other current assets		55
Property, plant and equipment		151
Identifiable intangible assets:		
Products and product rights (11 year weighted-average useful life)		6,923
IPR&D		50
Other noncurrent assets		184
Current liabilities [(1)]		(233)
Deferred income tax liabilities		(2,519)
Long-term debt		(1,900)
Other noncurrent liabilities [(1)]		(122)
Total identifiable net assets		3,661
Goodwill [(2)]		4,670
Consideration transferred	$	8,331

[(1)] *Included in current liabilities and other noncurrent liabilities is contingent consideration of $73 million and $50 million, respectively.*

[(2)] *The goodwill recognized is largely attributable to anticipated synergies expected to arise after the acquisition and was allocated to the Pharmaceutical segment. The goodwill is not deductible for tax purposes.*

The estimated fair values of identifiable intangible assets related to currently marketed products were determined using an income approach. The Company's estimates of projected net cash flows considered historical and projected pricing, margins and expense levels; the performance of competing products where applicable; relevant industry and therapeutic area growth drivers and factors; current and expected trends in technology and product life cycles; the extent and timing of potential new product introductions by the Company's competitors; and the life of each asset's underlying patent. The net cash flows were probability-adjusted where appropriate to consider the uncertainties associated with the underlying assumptions, as well as the risk profile of the net cash flows utilized in the valuation. The probability-adjusted future net cash flows of each product were then discounted to present value utilizing a discount rate of 8%. Actual cash flows are likely to be different than those assumed.

The Company recorded the fair value of incomplete research project surotomycin (MK-4261) which, at the time of acquisition, had not reached technological feasibility and had no alternative future use. During the second quarter of 2015, the Company received unfavorable efficacy data from a clinical trial for surotomycin. The evaluation of this data, combined with an assessment of the commercial opportunity for surotomycin, resulted in the discontinuation of the program and an IPR&D impairment charge (see Note 8).

In connection with the Cubist acquisition, liabilities were recorded for potential future consideration that is contingent upon the achievement of future sales-based milestones. The fair value of contingent consideration liabilities was determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and a risk-adjusted discount rate of 8% used to present value the probability-weighted cash flows. Changes in the inputs could result in a different fair value measurement.

This transaction closed on January 21, 2015; accordingly, the results of operations of the acquired business have been included in the Company's results of operations beginning after that date. During 2015, the Company incurred

$324 million of transaction costs directly related to the acquisition of Cubist including share-based compensation costs, severance costs, and legal and advisory fees which are reflected in *Marketing and administrative* expenses.

The following unaudited supplemental pro forma data presents consolidated information as if the acquisition of Cubist had been completed on January 1, 2014:

Years Ended December 31		**2015**
Sales	**$**	**39,584**
Net income attributable to Merck & Co., Inc.		**4,640**
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders		**1.65**
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders		**1.63**

The unaudited supplemental pro forma data reflects the historical information of Merck and Cubist adjusted to include additional amortization expense based on the fair value of assets acquired, additional interest expense that would have been incurred on borrowings used to fund the acquisition, transaction costs associated with the acquisition, and the related tax effects of these adjustments. The pro forma data should not be considered indicative of the results that would have occurred if the acquisition had been consummated on January 1, 2014, nor are they indicative of future results.

Remicade/Simponi

In 1998, a subsidiary of Schering-Plough entered into a licensing agreement with Centocor Ortho Biotech Inc. (Centocor), a Johnson & Johnson (J&J) company, to market *Remicade,* which is prescribed for the treatment of inflammatory diseases. In 2005, Schering-Plough's subsidiary exercised an option under its contract with Centocor for license rights to develop and commercialize *Simponi*, a fully human monoclonal antibody. The Company has marketing rights to both products throughout Europe, Russia and Turkey. *Remicade* lost market exclusivity in major European markets in February 2015 and the Company no longer has market exclusivity in any of its marketing territories. The Company continues to have market exclusivity for *Simponi* in all of its marketing territories. All profits derived from Merck's distribution of the two products in these countries are equally divided between Merck and J&J.

4. Collaborative Arrangements

Merck has entered into collaborative arrangements that provide the Company with varying rights to develop, produce and market products together with its collaborative partners. Both parties in these arrangements are active participants and exposed to significant risks and rewards dependent on the commercial success of the activities of the collaboration. Merck's more significant collaborative arrangements are discussed below.

AstraZeneca

In July 2017, Merck and AstraZeneca entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza (olaparib) for multiple cancer types. Lynparza is an oral poly (ADP-ribose) polymerase (PARP) inhibitor currently approved for certain types of ovarian and breast cancer. The companies are jointly developing and commercializing Lynparza, both as monotherapy and in combination trials with other potential medicines. Independently, Merck and AstraZeneca will develop and commercialize Lynparza in combinations with their respective PD-1 and PD-L1 medicines, *Keytruda* (pembrolizumab) and Imfinzi (durvalumab). The companies will also jointly develop and commercialize AstraZeneca's selumetinib, an oral, potent, selective inhibitor of MEK, part of the mitogen-activated protein kinase (MAPK) pathway, currently being developed for multiple indications including thyroid cancer. Under the terms of the agreement, AstraZeneca and Merck will share the development and commercialization costs for Lynparza and selumetinib monotherapy and non-PD-L1/PD-1 combination therapy opportunities.

Gross profits from Lynparza and selumetinib product sales generated through monotherapies or combination therapies will be shared equally. Merck will fund all development and commercialization costs of *Keytruda* in combination with Lynparza or selumetinib. AstraZeneca will fund all development and commercialization costs of Imfinzi in combination with Lynparza or selumetinib. AstraZenca is currently the principal on Lynparza sales transactions. Merck is recording its share of product sales of Lynparza, net of costs of sales and commercialization costs, as alliance revenue within the Pharmaceutical segment and its share of development costs associated with the

collaboration as part of *Research and development* expenses. Reimbursements received from AstraZeneca for research and development expenses are recognized as reductions to *Research and development* costs.

As part of the agreement, Merck made an upfront payment to AstraZeneca of $1.6 billion and is making payments of $750 million over a multi-year period for certain license options ($250 million was paid in December 2017, $400 million will be paid in 2018 and $100 million will be paid in 2019). The Company recorded an aggregate charge of $2.35 billion in *Research and development* expenses in 2017 related to the upfront payment and future license options payments. In addition, Merck will pay AstraZeneca up to an additional $6.15 billion contingent upon successful achievement of future regulatory milestones of $2.05 billion and sales-based milestones of $4.1 billion for total aggregate consideration of up to $8.5 billion.

During the fourth quarter of 2017, based on the performance of Lynparza since the formation of the collaboration, Merck determined it was probable that annual sales of Lynparza in the future would exceed $250 million, which would trigger a $100 million sales-based milestone payment from Merck to AstraZeneca upon achievement of the sales milestone. Accordingly, in the fourth quarter of 2017, Merck recorded a $100 million liability and a corresponding intangible asset and also recognized $4 million of cumulative amortization expense within *Materials and production* costs. The remaining intangible asset will be amortized over its remaining estimated useful life of 11 years, subject to impairment testing. The remaining $4.0 billion of potential future sales-based milestone payments have not yet been accrued as they are not deemed by the Company to be probable at this time.

Also, in January 2018, Lynparza received approval in the United States for the treatment of certain patients with metastatic breast cancer, triggering a $70 million milestone payment from Merck to AstraZeneca. This milestone payment will be capitalized and amortized over the remaining useful life of Lynparza.

Summarized information related to this collaboration is as follows:

Year Ended December 31	**2017**
Alliance revenues (net of commercialization costs)	**$ 20**
Materials and production costs	**4**
Marketing and administrative expenses	**1**
Research and development expenses	**2,419**
Receivables from AstraZeneca	**12**
Payables to AstraZeneca	**643**

Expenses do not include all amounts attributed to activities related to the collaboration, rather only the amounts relating to payments between partners. Amounts in materials and production costs include amortization of related intangible assets.

Bayer AG

In 2014, the Company entered into a worldwide clinical development collaboration with Bayer AG (Bayer) to market and develop soluble guanylate cyclase (sGC) modulators including Bayer's Adempas (riociguat), which is approved to treat pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension. The two companies equally share costs and profits from the collaboration and implemented a joint development and commercialization strategy. The collaboration also includes clinical development of Bayer's vericiguat, which is in Phase 3 trials for worsening heart failure, as well as opt-in rights for other early-stage sGC compounds in development by Bayer. Merck in turn made available its early-stage sGC compounds under similar terms. Under the agreement, Bayer leads commercialization of Adempas in the Americas, while Merck leads commercialization in the rest of the world. For vericiguat and other potential opt-in products, Bayer will lead commercialization in the rest of world and Merck will lead in the Americas. For all products and candidates included in the agreement, both companies will share in development costs and profits on sales and will have the right to co-promote in territories where they are not the lead. In 2016, Merck began promoting and distributing Adempas in Europe. Transition from Bayer in other Merck territories, including Japan, continued in 2017.

In 2016, the Company determined it was probable that annual sales of Adempas would exceed $500 million triggering a $350 million payment from Merck to Bayer. Accordingly, in 2016, the Company recorded a $350 million liability and a corresponding intangible asset and also recognized $50 million of cumulative amortization expense within *Materials and production* costs. The remaining intangible asset is being amortized over its then-

remaining estimated useful life, subject to impairment testing. In 2017, annual sales of Adempas exceeded $500 million triggering the $350 million milestone payment from Merck to Bayer, which will be paid in the first quarter of 2018. There are $775 million of additional potential future sales-based milestone payments that have not yet been accrued as they are not deemed by the Company to be probable at this time.

Summarized information related to this collaboration is as follows:

Years Ended December 31	**2017**	2016	2015
Net product sales recorded by Merck	**$ 149**	$ 88	$ —
Merck's profit share of sales in Bayer's marketing territories	**151**	81	30
Total sales	**300**	169	30
Materials and production costs	**99**	133	67
Marketing and administrative expenses	**27**	26	3
Research and development expenses	**96**	45	3
Receivables from Bayer	**33**	—	
Payables to Bayer	**352**	353	

Expenses do not include all amounts attributed to activities related to the collaboration, rather only the amounts relating to payments between partners. Amounts in materials and production costs include amortization of related intangible assets.

5. Restructuring

The Company incurs substantial costs for restructuring program activities related to Merck's productivity and cost reduction initiatives, as well as in connection with the integration of certain acquired businesses. In 2010 and 2013, the Company commenced actions under global restructuring programs designed to streamline its cost structure. The actions under these programs include the elimination of positions in sales, administrative and headquarters organizations, as well as the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities. The Company also continues to reduce its global real estate footprint and improve the efficiency of its manufacturing and supply network.

The Company recorded total pretax costs of $927 million in 2017, $1.1 billion in 2016 and $1.1 billion in 2015 related to restructuring program activities. Since inception of the programs through December 31, 2017, Merck has recorded total pretax accumulated costs of approximately $13.5 billion and eliminated approximately 43,350 positions comprised of employee separations, as well as the elimination of contractors and vacant positions. The Company estimates that approximately two-thirds of the cumulative pretax costs are cash outlays, primarily related to employee separation expense. Approximately one-third of the cumulative pretax costs are non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested. While the Company has substantially completed the actions under these programs, approximately $500 million of additional pretax costs are expected to be incurred in 2018 relating to anticipated employee separations and remaining asset-related costs.

For segment reporting, restructuring charges are unallocated expenses.

The following table summarizes the charges related to restructuring program activities by type of cost:

	Separation Costs	Accelerated Depreciation	Other	Total
Year Ended December 31, 2017				
Materials and production	**$ —**	**$ 52**	**$ 86**	**$ 138**
Marketing and administrative	**—**	**2**	**—**	**2**
Research and development	**—**	**6**	**5**	**11**
Restructuring costs	**552**	**—**	**224**	**776**
	$ 552	**$ 60**	**$ 315**	**$ 927**
Year Ended December 31, 2016				
Materials and production	$ —	$ 77	$ 104	$ 181
Marketing and administrative	—	8	87	95
Research and development	—	142	—	142
Restructuring costs	216	—	435	651
	$ 216	$ 227	$ 626	$ 1,069
Year Ended December 31, 2015				
Materials and production	$ —	$ 78	$ 283	$ 361
Marketing and administrative	—	59	19	78
Research and development	—	37	15	52
Restructuring costs	208	—	411	619
	$ 208	$ 174	$ 728	$ 1,110

Separation costs are associated with actual headcount reductions, as well as those headcount reductions which were probable and could be reasonably estimated. Positions eliminated under restructuring program activities were approximately 2,450 in 2017, 2,625 in 2016 and 3,770 in 2015.

Accelerated depreciation costs primarily relate to manufacturing, research and administrative facilities and equipment to be sold or closed as part of the programs. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the asset, based upon the anticipated date the site will be closed or divested or the equipment disposed of, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. All of the sites have and will continue to operate up through the respective closure dates and, since future undiscounted cash flows were sufficient to recover the respective book values, Merck is recording accelerated depreciation over the revised useful life of the site assets. Anticipated site closure dates, particularly related to manufacturing locations, have been and may continue to be adjusted to reflect changes resulting from regulatory or other factors.

Other activity in 2017, 2016 and 2015 includes $267 million, $409 million and $550 million, respectively, of asset abandonment, shut-down and other related costs. Additionally, other activity includes certain employee-related costs associated with pension and other postretirement benefit plans (see Note 14) and share-based compensation. Other activity also reflects net pretax losses resulting from sales of facilities and related assets of $6 million in 2017, $151 million in 2016 and $117 million in 2015.

The following table summarizes the charges and spending relating to restructuring program activities:

	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2016	$ 592	$ —	$ 53	$ 645
Expenses	216	227	626	1,069
(Payments) receipts, net	(413)	—	(347)	(760)
Non-cash activity	—	(227)	(186)	(413)
Restructuring reserves December 31, 2016	395	—	146	541
Expenses	**552**	**60**	**315**	**927**
(Payments) receipts, net	**(328)**	**—**	**(394)**	**(722)**
Non-cash activity	**—**	**(60)**	**61**	**1**
Restructuring reserves December 31, 2017 [1]	**$ 619**	**$ —**	**$ 128**	**$ 747**

[1] *The remaining cash outlays are expected to be substantially completed by the end of 2020.*

6. Financial Instruments

Derivative Instruments and Hedging Activities

The Company manages the impact of foreign exchange rate movements and interest rate movements on its earnings, cash flows and fair values of assets and liabilities through operational means and through the use of various financial instruments, including derivative instruments.

A significant portion of the Company's revenues and earnings in foreign affiliates is exposed to changes in foreign exchange rates. The objectives and accounting related to the Company's foreign currency risk management program, as well as its interest rate risk management activities are discussed below.

Foreign Currency Risk Management

The Company has established revenue hedging, balance sheet risk management and net investment hedging programs to protect against volatility of future foreign currency cash flows and changes in fair value caused by volatility in foreign exchange rates.

The objective of the revenue hedging program is to reduce the variability caused by changes in foreign exchange rates that would affect the U.S. dollar value of future cash flows derived from foreign currency denominated sales, primarily the euro and Japanese yen. To achieve this objective, the Company will hedge a portion of its forecasted foreign currency denominated third-party and intercompany distributor entity sales (forecasted sales) that are expected to occur over its planning cycle, typically no more than two years into the future. The Company will layer in hedges over time, increasing the portion of forecasted sales hedged as it gets closer to the expected date of the forecasted sales. The portion of forecasted sales hedged is based on assessments of cost-benefit profiles that consider natural offsetting exposures, revenue and exchange rate volatilities and correlations, and the cost of hedging instruments. The Company manages its anticipated transaction exposure principally with purchased local currency put options, forward contracts, and purchased collar options.

The fair values of these derivative contracts are recorded as either assets (gain positions) or liabilities (loss positions) in the Consolidated Balance Sheet. Changes in the fair value of derivative contracts are recorded each period in either current earnings or *OCI*, depending on whether the derivative is designated as part of a hedge transaction and, if so, the type of hedge transaction. For derivatives that are designated as cash flow hedges, the effective portion of the unrealized gains or losses on these contracts is recorded in *AOCI* and reclassified into *Sales* when the hedged anticipated revenue is recognized. The hedge relationship is highly effective and hedge ineffectiveness has been *de minimis*. For those derivatives which are not designated as cash flow hedges, but serve as economic hedges of forecasted sales, unrealized gains or losses are recorded in *Sales* each period. The cash flows from both designated and non-designated contracts are reported as operating activities in the Consolidated Statement of Cash Flows. The Company does not enter into derivatives for trading or speculative purposes.

The Company manages operating activities and net asset positions at each local subsidiary in order to mitigate the effects of exchange on monetary assets and liabilities. The Company also uses a balance sheet risk management program to mitigate the exposure of net monetary assets that are denominated in a currency other than a subsidiary's

functional currency from the effects of volatility in foreign exchange. In these instances, Merck principally utilizes forward exchange contracts to offset the effects of exchange on exposures denominated in developed country currencies, primarily the euro and Japanese yen. For exposures in developing country currencies, the Company will enter into forward contracts to partially offset the effects of exchange on exposures when it is deemed economical to do so based on a cost-benefit analysis that considers the magnitude of the exposure, the volatility of the exchange rate and the cost of the hedging instrument. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

Monetary assets and liabilities denominated in a currency other than the functional currency of a given subsidiary are remeasured at spot rates in effect on the balance sheet date with the effects of changes in spot rates reported in *Other (income) expense, net*. The forward contracts are not designated as hedges and are marked to market through *Other (income) expense, net*. Accordingly, fair value changes in the forward contracts help mitigate the changes in the value of the remeasured assets and liabilities attributable to changes in foreign currency exchange rates, except to the extent of the spot-forward differences. These differences are not significant due to the short-term nature of the contracts, which typically have average maturities at inception of less than one year.

The Company may also use forward exchange contracts to hedge its net investment in foreign operations against movements in exchange rates. The forward contracts are designated as hedges of the net investment in a foreign operation. The Company hedges a portion of the net investment in certain of its foreign operations and measures ineffectiveness based upon changes in spot foreign exchange rates that are recorded in *Other (income) expense, net*. The effective portion of the unrealized gains or losses on these contracts is recorded in foreign currency translation adjustment within *OCI*, and remains in *AOCI* until either the sale or complete or substantially complete liquidation of the subsidiary. The cash flows from these contracts are reported as investing activities in the Consolidated Statement of Cash Flows.

Foreign exchange risk is also managed through the use of foreign currency debt. The Company's senior unsecured euro-denominated notes have been designated as, and are effective as, economic hedges of the net investment in a foreign operation. Accordingly, foreign currency transaction gains or losses due to spot rate fluctuations on the euro-denominated debt instruments are included in foreign currency translation adjustment within *OCI*. Included in the cumulative translation adjustment are pretax losses of $520 million in 2017, and pretax gains of $193 million in 2016 and $304 million in 2015 from the euro-denominated notes.

Interest Rate Risk Management

The Company may use interest rate swap contracts on certain investing and borrowing transactions to manage its net exposure to interest rate changes and to reduce its overall cost of borrowing. The Company does not use leveraged swaps and, in general, does not leverage any of its investment activities that would put principal capital at risk.

At December 31, 2017, the Company was a party to 26 pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes as detailed in the table below.

	2017		
Debt Instrument	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
1.30% notes due 2018	$ 1,000	4	$ 1,000
5.00% notes due 2019	1,250	3	550
1.85% notes due 2020	1,250	5	1,250
3.875% notes due 2021	1,150	5	1,150
2.40% notes due 2022	1,000	4	1,000
2.35% notes due 2022	1,250	5	1,250

The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in the benchmark London Interbank Offered Rate (LIBOR) swap rate. The fair value changes in the notes attributable to changes in the LIBOR swap rate are recorded in interest expense and offset by the fair value changes in the swap contracts. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

Presented in the table below is the fair value of derivatives on a gross basis segregated between those derivatives that are designated as hedging instruments and those that are not designated as hedging instruments as of December 31:

		2017			2016		
		Fair Value of Derivative			Fair Value of Derivative		
	Balance Sheet Caption	Asset	Liability	U.S. Dollar Notional	Asset	Liability	U.S. Dollar Notional
Derivatives Designated as Hedging Instruments							
Interest rate swap contracts	Other assets	$ 2	$ —	$ 550	$ 20	$ —	$ 2,700
Interest rate swap contracts	Accrued and other current liabilities	—	3	1,000	—	—	—
Interest rate swap contracts	Other noncurrent liabilities	—	52	4,650	—	29	3,500
Foreign exchange contracts	Other current assets	51	—	4,216	616	—	6,063
Foreign exchange contracts	Other assets	38	—	1,936	129	—	2,075
Foreign exchange contracts	Accrued and other current liabilities	—	71	2,014	—	1	48
Foreign exchange contracts	Other noncurrent liabilities	—	1	20	—	1	12
		$ 91	$ 127	$ 14,386	$ 765	$ 31	$ 14,398
Derivatives Not Designated as Hedging Instruments							
Foreign exchange contracts	Other current assets	$ 39	$ —	$ 3,778	$ 230	$ —	$ 8,210
Foreign exchange contracts	Accrued and other current liabilities	—	90	7,431	—	103	2,931
		$ 39	$ 90	$ 11,209	$ 230	$ 103	$ 11,141
		$ 130	$ 217	$ 25,595	$ 995	$ 134	$ 25,539

As noted above, the Company records its derivatives on a gross basis in the Consolidated Balance Sheet. The Company has master netting agreements with several of its financial institution counterparties (see *Concentrations of Credit Risk* below). The following table provides information on the Company's derivative positions subject to these master netting arrangements as if they were presented on a net basis, allowing for the right of offset by counterparty and cash collateral exchanged per the master agreements and related credit support annexes at December 31:

	2017		2016	
	Asset	Liability	Asset	Liability
Gross amounts recognized in the consolidated balance sheet	$ 130	$ 217	$ 995	$ 134
Gross amount subject to offset in master netting arrangements not offset in the consolidated balance sheet	(94)	(94)	(131)	(131)
Cash collateral (received) posted	(3)	—	(529)	—
Net amounts	$ 33	$ 123	$ 335	$ 3

The table below provides information on the location and pretax gain or loss amounts for derivatives that are: (i) designated in a fair value hedging relationship, (ii) designated in a foreign currency cash flow hedging relationship, (iii) designated in a foreign currency net investment hedging relationship and (iv) not designated in a hedging relationship:

Years Ended December 31	**2017**	2016	2015
Derivatives designated in a fair value hedging relationship			
Interest rate swap contracts			
Amount of loss (gain) recognized in *Other (income) expense, net* on derivatives [1]	**$ 43**	$ 28	$ (14)
Amount of (gain) loss recognized in *Other (income) expense, net* on hedged item [1]	**(48)**	(29)	7
Derivatives designated in foreign currency cash flow hedging relationships			
Foreign exchange contracts			
Amount of gain reclassified from *AOCI* to *Sales*	**(138)**	(311)	(724)
Amount of loss (gain) recognized in *OCI* on derivatives	**561**	(210)	(526)
Derivatives designated in foreign currency net investment hedging relationships			
Foreign exchange contracts			
Amount of gain recognized in *Other (income) expense, net* on derivatives [2]	**—**	(1)	(4)
Amount of loss (gain) recognized in *OCI* on derivatives	**—**	2	(10)
Derivatives not designated in a hedging relationship			
Foreign exchange contracts			
Amount of loss (gain) recognized in *Other (income) expense, net* on derivatives [3]	**110**	132	(461)
Amount of gain recognized in *Sales*	**(3)**	—	(1)

[1] *There was $5 million, $1 million and $7 million of ineffectiveness on the hedge during 2017, 2016 and 2015, respectively.*

[2] *There was no ineffectiveness on the hedge. Represents the amount excluded from hedge effectiveness testing.*

[3] *These derivative contracts mitigate changes in the value of remeasured foreign currency denominated monetary assets and liabilities attributable to changes in foreign currency exchange rates.*

At December 31, 2017, the Company estimates $184 million of pretax net unrealized losses on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from *AOCI* to *Sales*. The amount ultimately reclassified to *Sales* may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.

Investments in Debt and Equity Securities

Information on investments in debt and equity securities at December 31 is as follows:

	2017				2016			
	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses
Corporate notes and bonds	**$ 9,806**	**$ 9,837**	**$ 9**	**$ (40)**	$ 10,577	$ 10,601	$ 15	$ (39)
U.S. government and agency securities	**2,042**	**2,059**	**—**	**(17)**	2,232	2,244	1	(13)
Asset-backed securities	**1,542**	**1,548**	**1**	**(7)**	1,376	1,380	1	(5)
Foreign government bonds	**733**	**739**	**—**	**(6)**	519	521	—	(2)
Mortgage-backed securities	**626**	**634**	**1**	**(9)**	796	801	1	(6)
Commercial paper	**159**	**159**	**—**	**—**	4,330	4,330	—	—
Equity securities	**275**	**265**	**16**	**(6)**	349	281	71	(3)
	$ 15,183	**$ 15,241**	**$ 27**	**$ (85)**	$ 20,179	$ 20,158	$ 89	$ (68)

Available-for-sale debt securities included in *Short-term investments* totaled $2.4 billion at December 31, 2017. Of the remaining debt securities, $11.1 billion mature within five years. At December 31, 2017 and 2016, there were no debt securities pledged as collateral.

Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company uses a fair value hierarchy which maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest:

Level 1 — Quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 — Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity. Level 3 assets or liabilities are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as assets or liabilities for which the determination of fair value requires significant judgment or estimation. If the inputs used to measure the financial assets and liabilities fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

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Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

Financial assets and liabilities measured at fair value on a recurring basis at December 31 are summarized below:

	Fair Value Measurements Using				Fair Value Measurements Using			
	Quoted Prices In Active Markets for Identical Assets (Level 1)	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**	**Total**	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
	2017				2016			
Assets								
Investments								
Corporate notes and bonds	**$ —**	**$ 9,678**	**$ —**	**$ 9,678**	$ —	$ 10,389	$ —	$ 10,389
U.S. government and agency securities	**68**	**1,767**	**—**	**1,835**	29	1,890	—	1,919
Asset-backed securities [1]	**—**	**1,476**	**—**	**1,476**	—	1,257	—	1,257
Foreign government bonds	**—**	**732**	**—**	**732**	—	518	—	518
Mortgage-backed securities [1]	**—**	**547**	**—**	**547**	—	628	—	628
Commercial paper	**—**	**159**	**—**	**159**	—	4,330	—	4,330
Equity securities	**104**	**—**	**—**	**104**	201	—	—	201
	172	**14,359**	**—**	**14,531**	230	19,012	—	19,242
Other assets [2]								
U.S. government and agency securities	**—**	**207**	**—**	**207**	—	313	—	313
Corporate notes and bonds	**—**	**128**	**—**	**128**	—	188	—	188
Mortgage-backed securities [1]	**—**	**79**	**—**	**79**	—	168	—	168
Asset-backed securities [1]	**—**	**66**	**—**	**66**	—	119	—	119
Foreign government bonds	**—**	**1**	**—**	**1**	—	1	—	1
Equity securities	**171**	**—**	**—**	**171**	148	—	—	148
	171	**481**	**—**	**652**	148	789	—	937
Derivative assets [3]								
Purchased currency options	**—**	**80**	**—**	**80**	—	644	—	644
Forward exchange contracts	**—**	**48**	**—**	**48**	—	331	—	331
Interest rate swaps	**—**	**2**	**—**	**2**	—	20	—	20
	—	**130**	**—**	**130**	—	995	—	995
Total assets	**$ 343**	**$ 14,970**	**$ —**	**$ 15,313**	$ 378	$ 20,796	$ —	$ 21,174
Liabilities								
Other liabilities								
Contingent consideration	**$ —**	**$ —**	**$ 935**	**$ 935**	$ —	$ —	$ 891	$ 891
Derivative liabilities [2]								
Forward exchange contracts	**—**	**162**	**—**	**162**	—	93	—	93
Interest rate swaps	**—**	**55**	**—**	**55**	—	29	—	29
Written currency options	**—**	**—**	**—**	**—**	—	12	—	12
	—	**217**	**—**	**217**	—	134	—	134
Total liabilities	**$ —**	**$ 217**	**$ 935**	**$ 1,152**	$ —	$ 134	$ 891	$ 1,025

[1] *Primarily all of the asset-backed securities are highly-rated (Standard & Poor's rating of AAA and Moody's Investors Service rating of Aaa), secured primarily by auto loan, credit card and student loan receivables, with weighted-average lives of primarily 5 years or less. Mortgage-backed securities represent AAA-rated securities issued or unconditionally guaranteed as to payment of principal and interest by U.S. government agencies.*

[2] *Investments included in other assets are restricted as to use, primarily for the payment of benefits under employee benefit plans.*

(3) *The fair value determination of derivatives includes the impact of the credit risk of counterparties to the derivatives and the Company's own credit risk, the effects of which were not significant.*

There were no transfers between Level 1 and Level 2 during 2017. As of December 31, 2017, *Cash and cash equivalents* of $6.1 billion include $5.2 billion of cash equivalents (which would be considered Level 2 in the fair value hierarchy).

Contingent Consideration

Summarized information about the changes in liabilities for contingent consideration is as follows:

	2017	2016
Fair value January 1	**$ 891**	$ 590
Changes in estimated fair value [1]	**141**	(407)
Additions	**3**	733
Payments	**(100)**	(25)
Fair value December 31 [2]	**$ 935**	$ 891

[1] *Recorded in* Research and development *expenses,* Materials and production *costs and* Other (income) expense, net. *Includes cumulative translation adjustments.*

[2] *Includes $315 million recorded as a current liability for amounts expected to be paid within the next 12 months.*

The changes in the estimated fair value of contingent consideration in 2017 primarily relate to changes in the liabilities recorded in connection with the termination of the SPMSD joint venture and the clinical progression of a program related to the Afferent acquisition. The changes in the estimated fair value of contingent consideration in 2016 were largely attributable to the reversal of liabilities related to programs obtained in connection with the acquisitions of cCAM, OncoEthix and SmartCells (see Note 8). The additions to contingent consideration reflected in the table above in 2016 relate to the termination of the SPMSD joint venture (see Note 9) and the acquisitions of IOmet and Afferent (see Note 3). The payments of contingent consideration in 2017 relate to the achievement of a clinical milestone in connection with the acquisition of IOmet (see Note 3) and in 2016 relate to the first commercial sale of *Zerbaxa* in the European Union.

Other Fair Value Measurements

Some of the Company's financial instruments, such as cash and cash equivalents, receivables and payables, are reflected in the balance sheet at carrying value, which approximates fair value due to their short-term nature.

The estimated fair value of loans payable and long-term debt (including current portion) at December 31, 2017, was $25.6 billion compared with a carrying value of $24.4 billion and at December 31, 2016, was $25.7 billion compared with a carrying value of $24.8 billion. Fair value was estimated using recent observable market prices and would be considered Level 2 in the fair value hierarchy.

Concentrations of Credit Risk

On an ongoing basis, the Company monitors concentrations of credit risk associated with corporate and government issuers of securities and financial institutions with which it conducts business. Credit exposure limits are established to limit a concentration with any single issuer or institution. Cash and investments are placed in instruments that meet high credit quality standards, as specified in the Company's investment policy guidelines.

The majority of the Company's accounts receivable arise from product sales in the United States and Europe and are primarily due from drug wholesalers and retailers, hospitals, government agencies, managed health care providers and pharmacy benefit managers. The Company monitors the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in their credit profile. The Company also continues to monitor global economic conditions, including the volatility associated with international sovereign economies, and associated impacts on the financial markets and its business. As of December 31, 2017, the Company's total net accounts receivable outstanding for more than one year were approximately $130 million. The Company does not expect to have write-offs or adjustments to accounts receivable which would have a material adverse effect on its financial position, liquidity or results of operations.

The Company's customers with the largest accounts receivable balances are: McKesson Corporation, AmerisourceBergen Corporation, Cardinal Health, Inc. and Zuellig Pharma Ltd. (Asia Pacific), which represented, in aggregate, approximately 40% of total accounts receivable at December 31, 2017. The Company monitors the creditworthiness of its customers to which it grants credit terms in the normal course of business. Bad debts have been minimal. The Company does not normally require collateral or other security to support credit sales.

Derivative financial instruments are executed under International Swaps and Derivatives Association master agreements. The master agreements with several of the Company's financial institution counterparties also include

credit support annexes. These annexes contain provisions that require collateral to be exchanged depending on the value of the derivative assets and liabilities, the Company's credit rating, and the credit rating of the counterparty. As of December 31, 2017 and 2016, the Company had received cash collateral of $3 million and $529 million, respectively, from various counterparties and the obligation to return such collateral is recorded in *Accrued and other current liabilities*. The Company had not advanced any cash collateral to counterparties as of December 31, 2017 or 2016.

7. Inventories

Inventories at December 31 consisted of:

	2017	2016
Finished goods	**$ 1,334**	$ 1,304
Raw materials and work in process	**4,703**	4,222
Supplies	**201**	155
Total (approximates current cost)	**6,238**	5,681
Increase to LIFO costs	**45**	302
	$ 6,283	$ 5,983
Recognized as:		
Inventories	**$ 5,096**	$ 4,866
Other assets	**1,187**	1,117

Inventories valued under the LIFO method comprised approximately $2.2 billion and $2.3 billion of inventories at December 31, 2017 and 2016, respectively. Amounts recognized as *Other assets* are comprised almost entirely of raw materials and work in process inventories. At December 31, 2017 and 2016, these amounts included $1.1 billion and $1.0 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included $80 million at both December 31, 2017 and 2016, of inventories produced in preparation for product launches.

8. Goodwill and Other Intangibles

The following table summarizes goodwill activity by segment:

	Pharmaceutical	All Other	Total
Balance January 1, 2016	$ 15,862	$ 1,861	$ 17,723
Acquisitions	207	275	482
Impairments	—	(47)	(47)
Other [1]	6	(2)	4
Balance December 31, 2016 [2]	16,075	2,087	18,162
Acquisitions	**—**	**177**	**177**
Impairments	**—**	**(38)**	**(38)**
Other [1]	**(9)**	**(8)**	**(17)**
Balance December 31, 2017 [2]	**$ 16,066**	**$ 2,218**	**$ 18,284**

[1] *Other includes cumulative translation adjustments on goodwill balances and certain other adjustments.*

[2] *Accumulated goodwill impairment losses at December 31, 2017 and 2016 were $225 million and $187 million, respectively.*

In 2016, the additions to goodwill in the Pharmaceutical segment resulted primarily from the acquisitions of Afferent and IOmet (see Note 3). The additions to goodwill within other non-reportable segments in 2017 primarily relate to the acquisition of Vallée, which is part of the Animal Health segment (see Note 3), and in 2016 relate to the acquisition of StayWell, which is part of the Healthcare Services segment (see Note 3). The impairments of goodwill within other non-reportable segments in 2017 and 2016 relate to certain businesses within the Healthcare Services segment.

Other intangibles at December 31 consisted of:

	2017			2016		
	Gross Carrying Amount	**Accumulated Amortization**	**Net**	Gross Carrying Amount	Accumulated Amortization	Net
Products and product rights	**$ 46,693**	**$ 34,950**	**$ 11,743**	$ 46,269	$ 31,919	$ 14,350
IPR&D	**1,194**	**—**	**1,194**	1,653	—	1,653
Tradenames	**209**	**97**	**112**	215	89	126
Other	**2,035**	**901**	**1,134**	1,947	771	1,176
	$ 50,131	**$ 35,948**	**$ 14,183**	$ 50,084	$ 32,779	$ 17,305

Acquired intangibles include products and product rights, tradenames and patents, which are initially recorded at fair value, assigned an estimated useful life, and are amortized primarily on a straight-line basis over their estimated useful lives. Some of the Company's more significant acquired intangibles related to marketed products (included in product and product rights above) at December 31, 2017 include *Zerbaxa*, $3.0 billion; *Sivextro*, $879 million; *Zetia*, $756 million; *Implanon/Nexplanon* $529 million; *Dificid*, $478 million; *Gardasil/Gardasil* 9, $468 million; *Vytorin*, $375 million; *Bridion*, $320 million; and *Simponi*, $226 million. The Company recognized an intangible asset related to Adempas as a result of a collaboration with Bayer (see Note 4) that had a carrying value of $894 million at December 31, 2017 reflected in "Other" in the table above.

During 2017, 2016 and 2015, the Company recorded impairment charges related to marketed products and other intangibles of $58 million, $347 million and $45 million, respectively, within *Material and production* costs. During 2017, the Company recorded an intangible asset impairment charge of $47 million related to *Intron A*, a treatment for certain types of cancers. Sales of *Intron A* are being adversely affected by the availability of new therapeutic options. In 2017, sales of *Intron A* in the United States eroded more rapidly than previously anticipated by the Company, which led to changes in the cash flow assumptions for *Intron A*. These revisions to cash flows indicated that the *Intron A* intangible asset value was not fully recoverable on an undiscounted cash flows basis. The Company utilized market participant assumptions to determine its best estimate of the fair value of the intangible asset related to *Intron A* that, when compared with its related carrying value, resulted in the impairment charge noted above. The intangible asset value for *Intron A* at December 31, 2017 was $13 million. The remaining charges in 2017 relate to the impairment of customer relationship, tradename and developed technology intangibles for certain businesses in the Healthcare Services segment. In 2016, the Company lowered its cash flow projections for *Zontivity,* a product for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction or with peripheral arterial disease, following several business decisions that reduced sales expectations for *Zontivity* in the United States and Europe. The Company utilized market participant assumptions and considered several different scenarios to determine the fair value of the intangible asset related to *Zontivity* that, when compared with its related carrying value, resulted in an impairment charge of $252 million. Also during 2016, the Company wrote-off $95 million that had been capitalized in connection with in-licensed products *Grastek* and *Ragwitek*, allergy immunotherapy tablets that, for business reasons, the Company returned to the licensor. The charges in 2015 primarily relate to the impairment of customer relationship and tradename intangibles for certain businesses within in the Healthcare Services segment.

IPR&D that the Company acquires through business combinations represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. Amounts capitalized as IPR&D are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, the Company will make a separate determination as to the then useful life of the asset and begin amortization. During 2017, 2016 and 2015, $14 million, $8 million and $280 million, respectively, of IPR&D was reclassified to products and product rights upon receipt of marketing approval in a major market.

In 2017, the Company recorded $483 million of IPR&D impairment charges within *Research and development* expenses. Of this amount, $240 million resulted from a strategic decision to discontinue the development of the investigational combination regimens MK-3682B (grazoprevir/ruzasvir/uprifosbuvir) and MK-3682C (ruzasvir/uprifosbuvir) for the treatment of chronic hepatitis C virus (HCV) infection. This decision was made based on a review of available Phase 2 efficacy data and in consideration of the evolving marketplace and the growing number of treatment options available for patients with chronic HCV infection, including *Zepatier*, which is currently marketed by the

Company for the treatment of adult patients with chronic HCV infection. As a result of this decision, the Company recorded an IPR&D impairment charge to write-off the remaining intangible asset related to uprifosbuvir. The Company had previously recorded an impairment charge for uprifosbuvir in 2016 as described below. The IPR&D impairment charges in 2017 also include a charge of $226 million to write-off the intangible asset related to verubecestat, an investigational small molecule inhibitor of the beta-site amyloid precursor protein cleaving enzyme 1 (BACE1), resulting from a decision in February 2018 to stop a Phase 3 study evaluating verubecestat in people with prodromal Alzheimer's disease. The decision to stop the study followed a recommendation by the external Data Monitoring Committee (eDMC), which assessed overall benefit/risk during an interim safety analysis. The eDMC concluded that it was unlikely that positive benefit/risk could be established if the trial continued.

During 2016, the Company recorded $3.6 billion of IPR&D impairment charges. Of this amount, $2.9 billion relates to the clinical development program for uprifosbuvir, a nucleotide prodrug that was being evaluated for the treatment of HCV. The Company determined that changes to the product profile, as well as changes to Merck's expectations for pricing and the market opportunity, taken together constituted a triggering event that required the Company to evaluate the uprifosbuvir intangible asset for impairment. Utilizing market participant assumptions, and considering different scenarios, the Company concluded that its best estimate of the fair value of the intangible asset related to uprifosbuvir was $240 million, resulting in the recognition of the pretax impairment charge noted above. The IPR&D impairment charges in 2016 also include charges of $180 million and $143 million related to the discontinuation of programs obtained in connection with the acquisitions of cCAM and OncoEthix, respectively, resulting from unfavorable efficacy data. An additional $72 million relates to programs obtained in connection with the SmartCells acquisition following a decision to terminate the lead compound due to a lack of efficacy and to pursue a back-up compound which reduced projected future cash flows. The IPR&D impairment charges in 2016 also include $112 million related to an in-licensed program for house dust mite allergies that, for business reasons, was returned to the licensor. The remaining IPR&D impairment charges in 2016 primarily relate to deprioritized pipeline programs that were deemed to have no alternative use during the period, including a $79 million impairment charge for an investigational candidate for contraception. The discontinuation or delay of certain of these clinical development programs resulted in a reduction of the related liabilities for contingent consideration (see Note 6).

During 2015, the Company recorded $63 million of IPR&D impairment charges, of which $50 million related to the surotomycin clinical development program. In 2015, the Company received unfavorable efficacy data from a clinical trial for surotomycin. The evaluation of this data, combined with an assessment of the commercial opportunity for surotomycin, resulted in the discontinuation of the program and the IPR&D impairment charge noted above.

All of the IPR&D projects that remain in development are subject to the inherent risks and uncertainties in drug development and it is possible that the Company will not be able to successfully develop and complete the IPR&D programs and profitably commercialize the underlying product candidates.

The Company may recognize additional non-cash impairment charges in the future related to other marketed products or pipeline programs and such charges could be material.

Aggregate amortization expense primarily recorded within *Materials and production* costs was $3.2 billion in 2017, $3.8 billion in 2016 and $4.8 billion in 2015. The estimated aggregate amortization expense for each of the next five years is as follows: 2018, $2.8 billion; 2019, $1.5 billion; 2020, $1.2 billion; 2021, $1.1 billion; 2022, $1.1 billion.

9. Joint Ventures and Other Equity Method Affiliates

Equity income from affiliates reflects the performance of the Company's joint ventures and other equity method affiliates including SPMSD (until termination on December 31, 2016) and certain investment funds. Equity income from affiliates was $42 million in 2017, $86 million in 2016 and $205 million in 2015 and is included in *Other (income) expense, net* (see Note 15).

Investments in affiliates accounted for using the equity method totaled $767 million at December 31, 2017 and $715 million at December 31, 2016.

Sanofi Pasteur MSD

In 1994, Merck and Pasteur Mérieux Connaught (now Sanofi Pasteur S.A.) established an equally-owned joint venture (SPMSD) to market vaccines in Europe and to collaborate in the development of combination vaccines for distribution in Europe. Joint venture vaccine sales were $1.0 billion for 2016 and $923 million for 2015.

On December 31, 2016, Merck and Sanofi Pasteur (Sanofi) terminated SPMSD and ended their joint vaccines operations in Europe. Under the terms of the termination, Merck acquired Sanofi's 50% interest in SPMSD in exchange for consideration of $657 million comprised of cash, as well as future royalties of 11.5% on net sales of all Merck products that were previously sold by the joint venture through December 31, 2024, which the Company determined had a fair value of $416 million on the date of termination. The Company accounted for this transaction as a step acquisition, which required that Merck remeasure its ownership interest (previously accounted for as an equity method investment) to fair value at the acquisition date. Merck in turn sold to Sanofi its intellectual property rights held by SPMSD in exchange for consideration of $596 million comprised of cash and future royalties of 11.5% on net sales of all Sanofi products that were previously sold by the joint venture through December 31, 2024, which the Company determined had a fair value of $302 million on the date of termination. Excluded from this arrangement are potential future sales of *Vaxelis* (a jointly developed investigational pediatric hexavalent combination vaccine that was approved by the European Commission in February 2016). The European marketing rights for *Vaxelis* were transferred to a separate equally-owned joint venture between Sanofi and Merck.

The net impact of the termination of the SPMSD joint venture is as follows:

Products and product rights (8 year useful life)	$	936
Accounts receivable		133
Income taxes payable		(221)
Deferred income tax liabilities		(147)
Other, net		47
Net assets acquired		748
Consideration payable to Sanofi, net		(392)
Derecognition of Merck's previously held equity investment in SPMSD		(183)
Increase in net assets		173
Merck's share of restructuring costs related to the termination		(77)
Net gain on termination of SPMSD joint venture [(1)]	$	96

[(1)] *Recorded in* Other (income) expense, net.

The estimated fair values of identifiable intangible assets related to products and product rights were determined using an income approach through which fair value is estimated based on market participant expectations of each asset's projected net cash flows. The projected net cash flows were then discounted to present value utilizing a discount rate of 11.5%. Actual cash flows are likely to be different than those assumed. Of the amount recorded for products and product rights, $468 million related to *Gardasil/Gardasil* 9.

The fair value of liabilities for contingent consideration related to Merck's future royalty payments to Sanofi of $416 million (reflected in the consideration payable to Sanofi, net, in the table above) was determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows and a risk-adjusted discount rate of 8% used to present value the cash flows. Changes in the inputs could result in a different fair value measurement.

Based on an existing accounting policy election, Merck did not record the $302 million estimated fair value of contingent future royalties to be received from Sanofi on the sale of Sanofi products, but rather is recognizing such amounts as sales occur and the royalties are earned.

The Company incurred $24 million of transaction costs related to the termination of SPMSD included in *Marketing and administrative* expenses in 2016.

Pro forma financial information for this transaction has not been presented as the results are not significant when compared with the Company's financial results.

AstraZeneca LP

In 1982, Merck entered into an agreement with Astra AB (Astra) to develop and market Astra products under a royalty-bearing license. In 1993, Merck's total sales of Astra products reached a level that triggered the first step in the establishment of a joint venture business carried on by Astra Merck Inc. (AMI), in which Merck and Astra each owned a 50% share. This joint venture, formed in 1994, developed and marketed most of Astra's new prescription medicines in the United States. In 1998, Merck and Astra completed a restructuring of the ownership and operations of the joint venture whereby Merck acquired Astra's interest in AMI, renamed KBI Inc. (KBI), and contributed KBI's operating assets to a new U.S. limited partnership, Astra Pharmaceuticals L.P. (the Partnership), in exchange for a 1% limited partner interest. Astra contributed the net assets of its wholly owned subsidiary, Astra USA, Inc., to the Partnership in exchange for a 99% general partner interest. The Partnership, renamed AstraZeneca LP (AZLP) upon Astra's 1999 merger with Zeneca Group Plc, became the exclusive distributor of the products for which KBI retained rights. Merck earned revenue based on sales of KBI products and earned certain Partnership returns from AZLP.

On June 30, 2014, AstraZeneca exercised its option to purchase Merck's interest in KBI (and redeem Merck's remaining interest in AZLP). A portion of the exercise price, which is subject to a true-up in 2018 based on actual sales of Nexium and Prilosec from closing in 2014 to June 2018, was deferred and recognized as income as the contingency was eliminated as sales occurred. Once the deferred income amount was fully recognized, in 2016, the Company began recognizing income and a corresponding receivable for amounts that will be due to Merck from AstraZeneca based on the sales performance of Nexium and Prilosec subject to the true-up in June 2018. The Company recognized income of $232 million, $98 million and $182 million in 2017, 2016 and 2015, respectively, in *Other (income) expense, net* related to these amounts. The receivable from AstraZeneca was $325 million at December 31, 2017.

10. Loans Payable, Long-Term Debt and Other Commitments

Loans payable at December 31, 2017 included $3.0 billion of notes due in 2018 and $73 million of long-dated notes that are subject to repayment at the option of the holder. Loans payable at December 31, 2016 included $300 million of notes due in 2017, $267 million of long-dated notes that are subject to repayment at the option of the holders. The weighted-average interest rate of commercial paper borrowings was 0.85% and 0.40% for the years ended December 31, 2017 and 2016, respectively.

Long-term debt at December 31 consisted of:

	2017	2016
2.75% notes due 2025	**$ 2,488**	$ 2,487
3.70% notes due 2045	**1,973**	1,972
2.80% notes due 2023	**1,744**	1,743
5.00% notes due 2019	**1,260**	1,273
4.15% notes due 2043	**1,237**	1,236
1.85% notes due 2020	**1,232**	1,238
2.35% notes due 2022	**1,220**	1,228
1.125% euro-denominated notes due 2021	**1,185**	1,035
1.875% euro-denominated notes due 2026	**1,178**	1,028
3.875% notes due 2021	**1,140**	1,152
2.40% notes due 2022	**993**	1,003
6.50% notes due 2033	**729**	806
Floating-rate notes due 2020	**699**	698
0.50% euro-denominated notes due 2024	**591**	516
1.375% euro-denominated notes due 2036	**587**	512
2.50% euro-denominated notes due 2034	**585**	511
3.60% notes due 2042	**489**	489
6.55% notes due 2037	**415**	594
5.75% notes due 2036	**338**	369
5.95% debentures due 2028	**306**	355
5.85% notes due 2039	**270**	415
6.40% debentures due 2028	**250**	325
6.30% debentures due 2026	**135**	152
Floating-rate borrowing due 2018	**—**	999
1.10% notes due 2018	**—**	999
1.30% notes due 2018	**—**	985
Other	**309**	154
	$ 21,353	$ 24,274

Other (as presented in the table above) includes $300 million and $147 million at December 31, 2017 and 2016, respectively, of borrowings at variable rates that resulted in effective interest rates of 1.42% and 0.89% for 2017 and 2016, respectively.

With the exception of the 6.30% debentures due 2026, the notes listed in the table above are redeemable in whole or in part, at Merck's option at any time, at varying redemption prices.

In November 2017, the Company launched tender offers for certain outstanding notes and debentures. The Company paid $810 million in aggregate consideration (applicable purchase price together with accrued interest) to redeem $585 million principal amount of debt that was validly tendered in connection with the tender offers and recognized a loss on extinguishment of debt of $191 million in 2017.

Effective as of November 3, 2009, the Company executed a full and unconditional guarantee of the then existing debt of its subsidiary Merck Sharp & Dohme Corp. (MSD) and MSD executed a full and unconditional guarantee of the then existing debt of the Company (excluding commercial paper), including for payments of principal and interest. These guarantees do not extend to debt issued subsequent to that date.

Certain of the Company's borrowings require that Merck comply with financial covenants including a requirement that the Total Debt to Capitalization Ratio (as defined in the applicable agreements) not exceed 60%. At December 31, 2017, the Company was in compliance with these covenants.

The aggregate maturities of long-term debt for each of the next five years are as follows: 2018, $3.0 billion; 2019, $1.3 billion; 2020, $1.9 billion; 2021, $2.3 billion; 2022, $2.2 billion.

The Company has a $6.0 billion, five-year credit facility that matures in June 2022. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

Rental expense under operating leases, net of sublease income, was $327 million in 2017, $292 million in 2016 and $303 million in 2015. The minimum aggregate rental commitments under noncancellable leases are as follows: 2018, $255 million; 2019, $175 million; 2020, $126 million; 2021, $90 million; 2022, $68 million and thereafter, $138 million. The Company has no significant capital leases.

11. Contingencies and Environmental Liabilities

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property, and commercial litigation, as well as certain additional matters including governmental and environmental matters. In the opinion of the Company, it is unlikely that the resolution of these matters will be material to the Company's financial position, results of operations or cash flows.

Given the nature of the litigation discussed below and the complexities involved in these matters, the Company is unable to reasonably estimate a possible loss or range of possible loss for such matters until the Company knows, among other factors, (i) what claims, if any, will survive dispositive motion practice, (ii) the extent of the claims, including the size of any potential class, particularly when damages are not specified or are indeterminate, (iii) how the discovery process will affect the litigation, (iv) the settlement posture of the other parties to the litigation and (v) any other factors that may have a material effect on the litigation.

The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. For product liability claims, a portion of the overall accrual is actuarially determined and considers such factors as past experience, number of claims reported and estimates of claims incurred but not yet reported. Individually significant contingent losses are accrued when probable and reasonably estimable. Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable.

The Company's decision to obtain insurance coverage is dependent on market conditions, including cost and availability, existing at the time such decisions are made. The Company has evaluated its risks and has determined that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and, as such, has no insurance for most product liabilities effective August 1, 2004.

Product Liability Litigation

Fosamax

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Fosamax* (*Fosamax* Litigation). As of December 31, 2017, approximately 4,085 cases are filed and pending against Merck in either federal or state court. In approximately 15 of these actions, plaintiffs allege, among other things, that they have suffered osteonecrosis of the jaw (ONJ), generally subsequent to invasive dental procedures, such as tooth extraction or dental implants and/or delayed healing, in association with the use of *Fosamax*. In addition, plaintiffs in approximately 4,070 of these actions generally allege that they sustained femur fractures and/or other bone injuries (Femur Fractures) in association with the use of *Fosamax*.

Cases Alleging ONJ and/or Other Jaw Related Injuries

In August 2006, the Judicial Panel on Multidistrict Litigation (JPML) ordered that certain *Fosamax* product liability cases pending in federal courts nationwide should be transferred and consolidated into one multidistrict litigation (*Fosamax* ONJ MDL) for coordinated pre-trial proceedings.

In December 2013, Merck reached an agreement in principle with the Plaintiffs' Steering Committee (PSC) in the *Fosamax* ONJ MDL to resolve pending ONJ cases not on appeal in the *Fosamax* ONJ MDL and in the state courts for an aggregate amount of $27.7 million. Merck and the PSC subsequently formalized the terms of this agreement

in a Master Settlement Agreement (ONJ Master Settlement Agreement) that was executed in April 2014 and included over 1,200 plaintiffs. In July 2014, Merck elected to proceed with the ONJ Master Settlement Agreement at a reduced funding level of $27.3 million since the participation level was approximately 95%. Merck has fully funded the ONJ Master Settlement Agreement and the escrow agent under the agreement has been making settlement payments to qualifying plaintiffs. The ONJ Master Settlement Agreement has no effect on the cases alleging Femur Fractures discussed below.

Discovery is currently ongoing in some of the approximately 15 remaining ONJ cases that are pending in various federal and state courts and the Company intends to defend against these lawsuits.

Cases Alleging Femur Fractures

In March 2011, Merck submitted a Motion to Transfer to the JPML seeking to have all federal cases alleging Femur Fractures consolidated into one multidistrict litigation for coordinated pre-trial proceedings. The Motion to Transfer was granted in May 2011, and all federal cases involving allegations of Femur Fracture have been or will be transferred to a multidistrict litigation in the District of New Jersey (Femur Fracture MDL). In the only bellwether case tried to date in the Femur Fracture MDL, *Glynn v. Merck*, the jury returned a verdict in Merck's favor. In addition, in June 2013, the Femur Fracture MDL court granted Merck's motion for judgment as a matter of law in the *Glynn* case and held that the plaintiff's failure to warn claim was preempted by federal law. The *Glynn* decision was not appealed by plaintiff.

In August 2013, the Femur Fracture MDL court entered an order requiring plaintiffs in the Femur Fracture MDL to show cause why those cases asserting claims for a femur fracture injury that took place prior to September 14, 2010, should not be dismissed based on the court's preemption decision in the *Glynn* case. Pursuant to the show cause order, in March 2014, the Femur Fracture MDL court dismissed with prejudice approximately 650 cases on preemption grounds. Plaintiffs in approximately 515 of those cases appealed that decision to the U.S. Court of Appeals for the Third Circuit (Third Circuit). The Femur Fracture MDL court also dismissed without prejudice another approximately 510 cases pending plaintiffs' appeal of the preemption ruling to the Third Circuit. On March 22, 2017, the Third Circuit issued a decision reversing the Femur Fracture MDL court's preemption ruling and remanding the appealed cases back to the Femur Fracture MDL court. On April 5, 2017, Merck filed a petition seeking a rehearing on the Third Circuit's March 22, 2017 decision, which was denied on April 24, 2017. Merck filed a petition for a writ of certiorari to the U.S. Supreme Court on August 22, 2017, seeking review of the Third Circuit's decision. On December 4, 2017, the Supreme Court invited the Solicitor General to file a brief in the case expressing the views of the United States.

In addition, in June 2014, the Femur Fracture MDL court granted Merck summary judgment in the *Gaynor v. Merck* case and found that Merck's updates in January 2011 to the *Fosamax* label regarding atypical femur fractures were adequate as a matter of law and that Merck adequately communicated those changes. The plaintiffs in *Gaynor* did not appeal the Femur Fracture MDL court's findings with respect to the adequacy of the 2011 label change but did appeal the dismissal of their case based on preemption grounds, and the Third Circuit subsequently reversed that dismissal in its March 22, 2017 decision. In August 2014, Merck filed a motion requesting that the Femur Fracture MDL court enter a further order requiring all plaintiffs in the Femur Fracture MDL who claim that the 2011 *Fosamax* label is inadequate and the proximate cause of their alleged injuries to show cause why their cases should not be dismissed based on the court's preemption decision and its ruling in the *Gaynor* case. In November 2014, the court granted Merck's motion and entered the requested show cause order. No plaintiffs responded to or appealed the November 2014 show cause order.

As of December 31, 2017, approximately 530 cases were pending in the Femur Fracture MDL following the reinstatement of the cases that had been on appeal to the Third Circuit. The 510 cases dismissed without prejudice that were also pending the final resolution of the aforementioned appeal have not yet been reinstated.

As of December 31, 2017, approximately 2,750 cases alleging Femur Fractures have been filed in New Jersey state court and are pending before Judge James Hyland in Middlesex County. The parties selected an initial group of 30 cases to be reviewed through fact discovery. Two additional groups of 50 cases each to be reviewed through fact discovery were selected in November 2013 and March 2014, respectively. A further group of 25 cases to be reviewed through fact discovery was selected by Merck in July 2015, and Merck has continued to select additional cases to be reviewed through fact discovery during 2016 and 2017.

As of December 31, 2017, approximately 280 cases alleging Femur Fractures have been filed and are pending in California state court. All of the Femur Fracture cases filed in California state court have been coordinated before a single judge in Orange County, California. In March 2014, the court directed that a group of 10 discovery pool cases be reviewed through fact discovery and subsequently scheduled the *Galper v. Merck* case, which plaintiffs selected, as the first trial. The *Galper* trial began in February 2015 and the jury returned a verdict in Merck's favor in April 2015, and plaintiff appealed that verdict to the California appellate court. Oral argument on plaintiff's appeal in *Galper* was held in November 2016 and, on April 24, 2017, the California appellate court issued a decision affirming the lower court's judgment in favor of Merck. The next Femur Fracture trial in California that was scheduled to begin in April 2016 was stayed at plaintiffs' request and a new trial date has not been set.

Additionally, there are five Femur Fracture cases pending in other state courts.

Discovery is ongoing in the Femur Fracture MDL and in state courts where Femur Fracture cases are pending and the Company intends to defend against these lawsuits.

Januvia/Janumet

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Januvia* and/or *Janumet*. As of December 31, 2017, Merck is aware of approximately 1,235 product user claims alleging generally that use of *Januvia* and/or *Janumet* caused the development of pancreatic cancer and other injuries. These complaints were filed in several different state and federal courts.

Most of the claims were filed in a consolidated multidistrict litigation proceeding in the U.S. District Court for the Southern District of California called "In re Incretin-Based Therapies Products Liability Litigation" (MDL). The MDL includes federal lawsuits alleging pancreatic cancer due to use of the following medicines: *Januvia, Janumet*, Byetta and Victoza, the latter two of which are products manufactured by other pharmaceutical companies. The majority of claims not filed in the MDL were filed in the Superior Court of California, County of Los Angeles (California State Court).

In November 2015, the MDL and California State Court - in separate opinions - granted summary judgment to defendants on grounds of preemption. Of the approximately 1,235 product user claims, these rulings resulted in the dismissal of approximately 1,100 product user claims.

Plaintiffs appealed the MDL and California State Court preemption rulings. On November 28, 2017, the U.S. Court of Appeals for the Ninth Circuit (Ninth Circuit) reversed the trial court's ruling in the MDL and remanded for further proceedings. The Ninth Circuit did not address the substance of defendants' preemption argument but instead ruled that the district court made various errors during discovery. Jurisdiction returned to U.S. District Court for the Southern District of California on January 2, 2018. The preemption appeal in the California state court litigation has been fully briefed, but the court has not yet scheduled oral argument.

As of December 31, 2017, seven product users have claims pending against Merck in state courts other than California state court, including four active product user claims pending in Illinois state court. On June 30, 2017, the Illinois trial court denied Merck's motion for summary judgment on grounds of preemption. Merck sought permission to appeal that order on an interlocutory basis and was granted a stay of proceedings in the trial court. On September 19, 2017, an intermediate appellate court in Illinois denied Merck's petition for interlocutory review. On October 20, 2017, Merck filed a petition with the Illinois Supreme Court, seeking leave to appeal the appellate court's denial. The Illinois Supreme Court denied Merck's petition for certiorari review and, instead, directed the appellate court to answer the certified question. As a result, proceedings in the trial court remain stayed and trials for certain of the product users in Illinois have been delayed.

In addition to the claims noted above, the Company has agreed to toll the statute of limitations for approximately 50 additional claims. The Company intends to continue defending against these lawsuits.

Propecia/Proscar

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Propecia* and/or *Proscar*. As of December 31, 2017, approximately 775 lawsuits have been filed by plaintiffs who allege that they have experienced persistent sexual side effects following cessation of treatment with *Propecia* and/or *Proscar*. Approximately 20 of the plaintiffs also allege that *Propecia* or *Proscar* has caused or can cause prostate cancer,

testicular cancer or male breast cancer. The lawsuits have been filed in various federal courts and in state court in New Jersey. The federal lawsuits have been consolidated for pretrial purposes in a federal multidistrict litigation before Judge Brian Cogan of the Eastern District of New York. The matters pending in state court in New Jersey have been consolidated before Judge Hyland in Middlesex County. In addition, there is one matter pending in state court in California, one matter pending in state court in Ohio, and one matter on appeal in the Massachusetts Supreme Judicial Court. The Company intends to defend against these lawsuits.

Governmental Proceedings

As previously disclosed, the Company has learned that the Prosecution Office of Milan, Italy is investigating interactions between the Company's Italian subsidiary, certain employees of the subsidiary and certain Italian health care providers. The Company understands that this is part of a larger investigation involving engagements between various health care companies and those health care providers. The Company is cooperating with the investigation.

As previously disclosed, the United Kingdom (UK) Competition and Markets Authority (CMA) issued a Statement of Objections against the Company and MSD Sharp & Dohme Limited (MSD UK) on May 23, 2017. In the Statement of Objections, the CMA alleges that MSD UK abused a dominant position through a discount program for *Remicade* over the period from March 2015 to February 2016. The Company and MSD UK are contesting the CMA's allegations.

As previously disclosed, the Company has received an investigative subpoena from the California Insurance Commissioner's Fraud Bureau (Bureau) seeking information from January 1, 2007 to the present related to the pricing and promotion of *Cubicin*. The Bureau is investigating whether Cubist Pharmaceuticals, Inc., which the Company acquired in 2015, unlawfully induced the presentation of false claims for *Cubicin* to private insurers under the California Insurance Code False Claims Act. The Company is cooperating with the investigation.

As previously disclosed, the Company has received a civil investigative demand from the U.S. Attorney's Office for the Southern District of New York that requests information relating to the Company's contracts with, services from and payments to pharmacy benefit managers with respect to *Maxalt* and Levitra from January 1, 2006 to the present. The Company is cooperating with the investigation.

As previously disclosed, the Company has received a subpoena from the Office of Inspector General of the U.S. Department of Health and Human Services on behalf of the U.S. Attorney's Office for the District of Maryland and the Civil Division of the U.S. Department of Justice that requests information relating to the Company's marketing of *Singulair* and *Dulera* Inhalation Aerosol and certain of its other marketing activities from January 1, 2006 to the present. The Company is cooperating with the investigation.

As previously disclosed, the Company's subsidiaries in China have received and may continue to receive inquiries regarding their operations from various Chinese governmental agencies. Some of these inquiries may be related to matters involving other multinational pharmaceutical companies, as well as Chinese entities doing business with such companies. The Company's policy is to cooperate with these authorities and to provide responses as appropriate.

As previously disclosed, from time to time, the Company receives inquiries and is the subject of preliminary investigation activities from competition and other governmental authorities in markets outside the United States. These authorities may include regulators, administrative authorities, and law enforcement and other similar officials, and these preliminary investigation activities may include site visits, formal or informal requests or demands for documents or materials, inquiries or interviews and similar matters. Certain of these preliminary inquiries or activities may lead to the commencement of formal proceedings. Should those proceedings be determined adversely to the Company, monetary fines and/or remedial undertakings may be required.

Commercial and Other Litigation

K-DUR Antitrust Litigation

In June 1997 and January 1998, Schering-Plough Corporation (Schering-Plough) settled patent litigation with Upsher-Smith, Inc. (Upsher-Smith) and ESI Lederle, Inc. (Lederle), respectively, relating to generic versions of Schering-Plough's long-acting potassium chloride product supplement used by cardiac patients, for which Lederle and Upsher-Smith had filed abbreviated New DrugApplications (NDA). Putative class and non-class action suits were then

filed on behalf of direct and indirect purchasers of K-DUR against Schering-Plough, Upsher-Smith and Lederle and were consolidated in a multidistrict litigation in the U.S. District Court for the District of New Jersey. In February 2016, the court denied the Company's motion for summary judgment relating to all of the direct purchasers' claims concerning the settlement with Upsher-Smith and granted the Company's motion for summary judgment relating to all of the direct purchasers' claims concerning the settlement with Lederle.

As previously disclosed, in February 2017, Merck and Upsher-Smith reached a settlement in principle with the class of direct purchasers and the opt-outs to the class. Merck will contribute approximately $80 million in the aggregate towards the overall settlement. On April 5, 2017, the claims of the opt-outs were dismissed with prejudice pursuant to a written settlement agreement with those parties. On May 15, 2017, Merck and the class executed a settlement agreement, which received preliminary approval from the court on May 23, 2017. On October 5, 2017, the court entered a Final Judgment and Order of Dismissal approving the settlement agreement with the direct purchaser class and dismissing the claims of the class with prejudice.

Zetia *Antitrust Litigation*

In May 2010, Schering Corporation (Schering) and MSP Singapore Company LLC (MSP) settled patent litigation with Glenmark Pharmaceuticals Inc., USA, and Glenmark Pharmaceuticals Ltd. (together, Glenmark) relating to a generic version of *Zetia*, a pharmaceutical product containing ezetimibe used by patients with high cholesterol, for which Glenmark had filed an abbreviated NDA. In January and February 2018, putative class action suits were filed on behalf of direct and indirect purchasers of *Zetia* against Merck, MSD, Schering-Plough, Schering, MSP, and Glenmark in the U.S. District Courts for the Eastern District of Virginia and the Eastern District of New York. These suits claim violations of federal and state antitrust laws, as well as other state statutory and common law causes of action. These suits seek unspecified damages.

Sales Force Litigation

As previously disclosed, in May 2013, Ms. Kelli Smith filed a complaint against the Company in the U.S. District Court for the District of New Jersey on behalf of herself and a putative class of female sales representatives and a putative sub-class of female sales representatives with children, claiming (a) discriminatory policies and practices in selection, promotion and advancement, (b) disparate pay, (c) differential treatment, (d) hostile work environment and (e) retaliation under federal and state discrimination laws. Plaintiffs sought and were granted leave to file an amended complaint. In January 2014, plaintiffs filed an amended complaint adding four additional named plaintiffs. In October 2014, the court denied the Company's motion to dismiss or strike the class claims as premature. In September 2015, plaintiffs filed additional motions, including a motion for conditional certification under the Equal Pay Act; a motion to amend the pleadings seeking to add ERISA and constructive discharge claims and a Company subsidiary as a named defendant; and a motion for equitable relief. Merck filed papers in opposition to the motions. On April 27, 2016, the court granted plaintiff's motion for conditional certification but denied plaintiffs' motions to extend the liability period for their Equal Pay Act claims back to June 2009. As a result, the liability period will date back to April 2012, at the earliest. On April 29, 2016, the Magistrate Judge granted plaintiffs' request to amend the complaint to add the following: (i) a Company subsidiary as a corporate defendant; (ii) an ERISA claim and (iii) an individual constructive discharge claim for one of the named plaintiffs. Approximately 700 individuals have opted-in to this action; the opt-in period has closed. On August 1, 2017, plaintiffs filed their motion for class certification. This motion seeks to certify a Title VII pay discrimination class and also seeks final collective action certification of plaintiffs' Equal Pay Act claim. The parties are currently engaged in motion practice before the court.

Qui Tam Litigation

As previously disclosed, on June 21, 2012, the U.S. District Court for the Eastern District of Pennsylvania unsealed a complaint that has been filed against the Company under the federal False Claims Act by two former employees alleging, among other things, that the Company defrauded the U.S. government by falsifying data in connection with a clinical study conducted on the mumps component of the Company's *M-M-R* II vaccine. The complaint alleges the fraud took place between 1999 and 2001. The U.S. government had the right to participate in and take over the prosecution of this lawsuit, but notified the court that it declined to exercise that right. The two former employees are pursuing the lawsuit without the involvement of the U.S. government. In addition, as previously disclosed, two putative class action lawsuits on behalf of direct purchasers of the *M-M-R* II vaccine, which charge that the Company misrepresented the efficacy of the *M-M-R* II vaccine in violation of federal antitrust laws and various state consumer protection laws, are pending in the Eastern District of Pennsylvania. In September 2014, the court denied Merck's motion to dismiss the False Claims Act suit and granted in part and denied in part its motion to dismiss the then-pending

antitrust suit. As a result, both the False Claims Act suit and the antitrust suits have proceeded into discovery. The Company intends to defend against these lawsuits.

Merck KGaA Litigation

In January 2016, to protect its long-established brand rights in the United States, the Company filed a lawsuit against Merck KGaA, Darmstadt, Germany (KGaA), operating as the EMD Group in the United States, alleging it improperly uses the name "Merck" in the United States. KGaA has filed suit against the Company in France, the UK, Germany, Switzerland, Mexico, and India alleging breach of the parties' co-existence agreement, unfair competition and/or trademark infringement. In December 2015, the Paris Court of First Instance issued a judgment finding that certain activities by the Company directed towards France did not constitute trademark infringement and unfair competition while other activities were found to infringe. The Company and KGaA appealed the decision, and the appeal was heard in May 2017. In June 2017, the French appeals court held that certain of the activities by the Company directed to France constituted unfair competition or trademark infringement and no further appeal was pursued. In January 2016, the UK High Court issued a judgment finding that the Company had breached the co-existence agreement and infringed KGaA's trademark rights as a result of certain activities directed towards the UK based on use of the word MERCK on promotional and information activity. As noted in the UK decision, this finding was not based on the Company's use of the sign MERCK in connection with the sale of products or any material pharmaceutical business transacted in the UK. The Company and KGaA have both appealed this decision, and the appeal was heard in June 2017. In November 2017, the UK Court of Appeals affirmed the decision on the co-existence agreement and remitted for re-hearing issues of trade mark infringement, validity and the relief to which KGaA would be entitled.

Patent Litigation

From time to time, generic manufacturers of pharmaceutical products file abbreviated NDAs with the FDA seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned by the Company. To protect its patent rights, the Company may file patent infringement lawsuits against such generic companies. Certain products of the Company currently involved in such patent infringement litigation in the United States include *Noxafil* and *NuvaRing*. Similar lawsuits defending the Company's patent rights may exist in other countries. The Company intends to vigorously defend its patents, which it believes are valid, against infringement by companies attempting to market products prior to the expiration of such patents. As with any litigation, there can be no assurance of the outcomes, which, if adverse, could result in significantly shortened periods of exclusivity for these products and, with respect to products acquired through acquisitions, potentially significant intangible asset impairment charges.

Noxafil — In August 2015, the Company filed a lawsuit against Actavis Laboratories Fl, Inc. (Actavis) in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Noxafil*. In October 2017, the district court held the patent valid and infringed. Actavis has appealed this decision. In March 2016, the Company filed a lawsuit against Roxane Laboratories, Inc. (Roxane) in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Noxafil*. In October 2017, the parties reached a settlement whereby Roxane can launch its generic version upon expiry of the patent, or earlier under certain conditions. In February 2016, the Company filed a lawsuit against Par Sterile Products LLC, Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc. and Par Pharmaceutical Holdings, Inc. (collectively, Par) in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Noxafil* injection. In October 2016, the parties reached a settlement whereby Par can launch its generic version in January 2023, or earlier under certain conditions.

Nasonex — *Nasonex* lost market exclusivity in the United States in 2016. Prior to that, in April 2015, the Company filed a patent infringement lawsuit against Apotex Inc. and Apotex Corp. (Apotex) in respect of Apotex's marketed product that the Company believed was infringing. In January 2018, the Company and Apotex settled this matter with Apotex agreeing to pay the Company $115 million plus certain other consideration.

NuvaRing — In December 2013, the Company filed a lawsuit against a subsidiary of Allergan plc in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of *NuvaRing*. The trial in this matter was held in January 2016. In August 2016, the district court ruled that the patent was invalid and the Company appealed this decision. In October 2017, the appellate court reversed the district court decision and found the patent to be valid. The case was remanded and the district court enjoined the defendant

from marketing its generic version of *NuvaRing* until the patent expires. In September 2015, the Company filed a lawsuit against Teva Pharma in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of *NuvaRing*. Based on its ruling in the Allergan plc matter, the district court dismissed the Company's lawsuit in December 2016. Following the appellate reversal in the Allergan plc matter, the defendant has agreed to be enjoined from marketing its generic version of *NuvaRing* until the patent expires.

Anti-PD-1 Antibody Patent Oppositions and Litigation

As previously disclosed, Ono Pharmaceutical Co. (Ono) has a European patent (EP 1 537 878) ('878) that broadly claims the use of an anti-PD-1 antibody, such as the Company's immunotherapy, *Keytruda*, for the treatment of cancer. Ono has previously licensed its commercial rights to an anti-PD-1 antibody to Bristol-Myers Squibb (BMS) in certain markets. BMS and Ono also own European Patent EP 2 161 336 ('336) that, as granted, broadly claimed anti-PD-1 antibodies that could include *Keytruda*.

As previously disclosed, the Company and BMS and Ono were engaged in worldwide litigation, including in the United States, over the validity and infringement of the '878 patent, the '336 patent and their equivalents.

In January 2017, the Company announced that it had entered into a settlement and license agreement with BMS and Ono resolving the worldwide patent infringement litigation related to the use of an anti-PD-1 antibody for the treatment of cancer, such as *Keytruda*. Under the settlement and license agreement, the Company made a one-time payment of $625 million (which was recorded as an expense in the Company's 2016 financial results) to BMS and will pay royalties on the worldwide sales of *Keytruda* for a non-exclusive license to market *Keytruda* in any market in which it is approved. For global net sales of *Keytruda*, the Company will pay royalties of 6.5% of net sales occurring from January 1, 2017 through and including December 31, 2023; and 2.5% of net sales occurring from January 1, 2024 through and including December 31, 2026. The parties also agreed to dismiss all claims worldwide in the relevant legal proceedings.

In October 2015, PDL Biopharma (PDL) filed a lawsuit in the United States against the Company alleging that the manufacture of *Keytruda* infringed US Patent No. 5,693,761 ('761 patent), which expired in December 2014. This patent claims platform technology used in the creation and manufacture of recombinant antibodies and PDL is seeking damages for pre-expiry infringement of the '761 patent. In April 2017, the parties reached a settlement pursuant to which, in exchange for a lump sum, PDL dismissed its lawsuit with prejudice and granted the Company a fully paid-up non-exclusive license to the '761 patent.

In July 2016, the Company filed a declaratory judgment action in the United States against Genentech and City of Hope seeking a ruling that US Patent No. 7,923,221 (Cabilly III patent), which claims platform technology used in the creation and manufacture of recombinant antibodies, is invalid and that *Keytruda* and bezlotoxumab do not infringe the Cabilly III patent. In July 2016, the Company also filed a petition in the USPTO for *Inter Partes* Review (IPR) of certain claims of US Patent No. 6,331,415 (Cabilly II patent), which claims platform technology used in the creation and manufacture of recombinant antibodies and is also owned by Genentech and City of Hope, as being invalid. In December 2016, the USPTO denied the petition but allowed the Company to join an IPR filed previously by another party. In May 2017, the parties reached a settlement pursuant to which the Company dismissed its lawsuit with prejudice and moved to terminate the IPR and Genentech and City of Hope granted the Company a fully paid-up non-exclusive license to the Cabilly II and Cabilly III patent.

Gilead Patent Litigation and Opposition

In August 2013, Gilead Sciences, Inc. (Gilead) filed a lawsuit in the U.S. District Court for the Northern District of California seeking a declaration that two Company patents were invalid and not infringed by the sale of their two sofosbuvir containing products, Solvadi and Harvoni. The Company filed a counterclaim that the sale of these products did infringe these two patents and sought a reasonable royalty for the past, present and future sales of these products. In March 2016, at the conclusion of a jury trial, the patents were found to be not invalid and infringed. The jury awarded the Company $200 million as a royalty for sales of these products up to December 2015. After the conclusion of the jury trial, the court held a bench trial on the equitable defenses raised by Gilead. In June 2016, the court found for Gilead and determined that Merck could not collect the jury award and that the patents were unenforceable with respect to Gilead. The Company appealed the court's decision. Gilead also asked the court to overturn the jury's decision on validity. The court held a hearing on Gilead's motion in August 2016, and the court subsequently rejected

Gilead's request, which Gilead appealed. A hearing on the combined appeals for this case was held on February 4, 2018. The Company will pay 20%, net of legal fees, of damages or royalties, if any, that it receives to Ionis Pharmaceuticals, Inc.

The Company, through its Idenix Pharmaceuticals, Inc. subsidiary, has pending litigation against Gilead in the United States, the UK, Norway, Canada, Germany, France, and Australia based on different patent estates that would also be infringed by Gilead's sales of these two products. Gilead opposed the European patent at the European Patent Office (EPO). Trial in the United States was held in December 2016 and the jury returned a verdict for the Company, awarding damages of $2.54 billion. The Company submitted post-trial motions, including on the issues of enhanced damages and future royalties. Gilead submitted post-trial motions for judgment as a matter of law. A hearing on the motions was held in September 2017. Also, in September 2017, the court denied the Company's motion on enhanced damages, granted its motion on prejudgment interest and deferred its motion on future royalties. In February 2018, the court granted Gilead's motion for judgment as a matter of law and found the patent was invalid for a lack of enablement. The Company will appeal this decision. In Australia, the Company was initially unsuccessful and the Full Federal Court affirmed the lower court decision. The Company has sought leave to appeal to the High Court of Australia for further review. In Canada, the Company was initially unsuccessful and the Federal Court of Appeals affirmed the lower court decision The Company sought leave to the Supreme Court of Canada for further review. In the UK and Norway, the patent was held invalid and no further appeal was filed. The EPO opposition division revoked the European patent, and the Company appealed this decision. The cases in France and Germany have been stayed pending the final decision of the EPO.

Other Litigation

There are various other pending legal proceedings involving the Company, principally product liability and intellectual property lawsuits. While it is not feasible to predict the outcome of such proceedings, in the opinion of the Company, either the likelihood of loss is remote or any reasonably possible loss associated with the resolution of such proceedings is not expected to be material to the Company's financial position, results of operations or cash flows either individually or in the aggregate.

Legal Defense Reserves

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of December 31, 2017 and December 31, 2016 of approximately $160 million and $185 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

Environmental Matters

As previously disclosed, Merck's facilities in Oss, the Netherlands, were inspected by the Province of Brabant (Province) pursuant to the Dutch Hazards of Major Accidents Decree and the sites' environmental permits. The Province issued penalties for alleged violations of regulations governing preventing and managing accidents with hazardous substances, and the government also issued a fine for alleged environmental violations at one of the Oss facilities, which together totaled $235 thousand. The Company was subsequently advised that a criminal investigation had been initiated based upon certain of the issues that formed the basis of the administrative enforcement action by the Province. The Company intends to defend itself against any enforcement action that may result from this investigation.

In May 2015, the Environmental Protection Agency (EPA) conducted an air compliance evaluation of the Company's pharmaceutical manufacturing facility in Elkton, Virginia. As a result of the investigation, the Company was issued a Notice of Noncompliance and Show Cause Notification relating to certain federally enforceable requirements applicable to the Elkton facility. The Company has been advised by the EPA that enforcement action is no longer being pursued.

The Company and its subsidiaries are parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund, and other federal and state equivalents. These proceedings seek to require the operators of hazardous waste disposal facilities, transporters of waste to the sites and generators of hazardous waste disposed of at the sites to clean up the sites or to reimburse the government for cleanup costs. The Company has been made a party to these proceedings as an alleged generator of waste disposed of at the sites. In each case, the government alleges that the defendants are jointly and severally liable for the cleanup costs. Although joint and several liability is alleged, these proceedings are frequently resolved so that the allocation of cleanup costs among the parties more nearly reflects the relative contributions of the parties to the site situation. The Company's potential liability varies greatly from site to site. For some sites the potential liability is *de minimis* and for others the final costs of cleanup have not yet been determined. While it is not feasible to predict the outcome of many of these proceedings brought by federal or state agencies or private litigants, in the opinion of the Company, such proceedings should not ultimately result in any liability which would have a material adverse effect on the financial position, results of operations, liquidity or capital resources of the Company. The Company has taken an active role in identifying and accruing for these costs and such amounts do not include any reduction for anticipated recoveries of cleanup costs from former site owners or operators or other recalcitrant potentially responsible parties.

In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $82 million and $83 million at December 31, 2017 and 2016, respectively. These liabilities are undiscounted, do not consider potential recoveries from other parties and will be paid out over the periods of remediation for the applicable sites, which are expected to occur primarily over the next 15 years. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed $63 million in the aggregate. Management also does not believe that these expenditures should result in a material adverse effect on the Company's financial position, results of operations, liquidity or capital resources for any year.

12. Equity

The Merck certificate of incorporation authorizes 6,500,000,000 shares of common stock and 20,000,000 shares of preferred stock.

Capital Stock

A summary of common stock and treasury stock transactions (shares in millions) is as follows:

	2017		2016		2015	
	Common Stock	**Treasury Stock**	Common Stock	Treasury Stock	Common Stock	Treasury Stock
Balance January 1	**3,577**	**828**	3,577	796	3,577	739
Purchases of treasury stock	**—**	**67**	—	60	—	75
Issuances [(1)]	**—**	**(15)**	—	(28)	—	(18)
Balance December 31	**3,577**	**880**	3,577	828	3,577	796

[(1)] *Issuances primarily reflect activity under share-based compensation plans.*

13. Share-Based Compensation Plans

The Company has share-based compensation plans under which the Company grants restricted stock units (RSUs) and performance share units (PSUs) to certain management level employees. In addition, employees and non-employee directors may be granted options to purchase shares of Company common stock at the fair market value at the time of grant. These plans were approved by the Company's shareholders.

At December 31, 2017, 118 million shares collectively were authorized for future grants under the Company's share-based compensation plans. These awards are settled primarily with treasury shares.

Employee stock options are granted to purchase shares of Company stock at the fair market value at the time of grant. These awards generally vest one-third each year over a three-year period, with a contractual term of 7-10 years. RSUs are stock awards that are granted to employees and entitle the holder to shares of common stock as the awards vest. The fair value of the stock option and RSU awards is determined and fixed on the grant date based on the Company's stock price. PSUs are stock awards where the ultimate number of shares issued will be contingent on the Company's performance against a pre-set objective or set of objectives. The fair value of each PSU is determined on the date of grant based on the Company's stock price. For RSUs and PSUs, dividends declared during the vesting period are payable to the employees only upon vesting. Over the PSU performance period, the number of shares of stock that are expected to be issued will be adjusted based on the probability of achievement of a performance target and final compensation expense will be recognized based on the ultimate number of shares issued. RSU and PSU distributions will be in shares of Company stock after the end of the vesting or performance period, subject to the terms applicable to such awards. PSU awards generally vest after three years. Prior to 2018, RSU awards generally vested after three years; beginning with awards granted in 2018, RSU awards will vest one-third each year over a three-year period.

Total pretax share-based compensation cost recorded in 2017, 2016 and 2015 was $312 million, $300 million and $299 million, respectively, with related income tax benefits of $57 million, $92 million and $93 million, respectively.

The Company uses the Black-Scholes option pricing model for determining the fair value of option grants. In applying this model, the Company uses both historical data and current market data to estimate the fair value of its options. The Black-Scholes model requires several assumptions including expected dividend yield, risk-free interest rate, volatility, and term of the options. The expected dividend yield is based on historical patterns of dividend payments. The risk-free rate is based on the rate at grant date of zero-coupon U.S. Treasury Notes with a term equal to the expected term of the option. Expected volatility is estimated using a blend of historical and implied volatility. The historical component is based on historical monthly price changes. The implied volatility is obtained from market data on the Company's traded options. The expected life represents the amount of time that options granted are expected to be outstanding, based on historical and forecasted exercise behavior.

The weighted average exercise price of options granted in 2017, 2016 and 2015 was $63.88, $54.63 and $59.73 per option, respectively. The weighted average fair value of options granted in 2017, 2016 and 2015 was $7.04, $5.89 and $6.46 per option, respectively, and were determined using the following assumptions:

Years Ended December 31	**2017**	2016	2015
Expected dividend yield	**3.6 %**	3.8 %	4.1 %
Risk-free interest rate	**2.0 %**	1.4 %	1.7 %
Expected volatility	**17.8 %**	19.6 %	19.9 %
Expected life (years)	**6.1**	6.2	6.2

Summarized information relative to stock option plan activity (options in thousands) is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2017	45,091	$ 44.47		
Granted	**4,232**	**63.88**		
Exercised	**(11,512)**	**43.38**		
Forfeited	**(1,537)**	**51.78**		
Outstanding December 31, 2017	**36,274**	**$ 46.77**	**4.89**	**$ 397**
Exercisable December 31, 2017	**26,778**	**$ 42.54**	**3.64**	**$ 384**

Additional information pertaining to stock option plans is provided in the table below:

Years Ended December 31	**2017**	2016	2015
Total intrinsic value of stock options exercised	**$ 236**	$ 444	$ 332
Fair value of stock options vested	**30**	28	30
Cash received from the exercise of stock options	**499**	939	485

A summary of nonvested RSU and PSU activity (shares in thousands) is as follows:

	RSUs		PSUs	
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested January 1, 2017	13,266	$ 57.19	1,744	$ 59.24
Granted	**5,014**	**63.85**	**1,008**	**63.62**
Vested	**(3,795)**	**58.13**	**(833)**	**62.71**
Forfeited	**(876)**	**58.22**	**(51)**	**60.24**
Nonvested December 31, 2017	**13,609**	**$ 59.32**	**1,868**	**$ 60.03**

At December 31, 2017, there was $469 million of total pretax unrecognized compensation expense related to nonvested stock options, RSU and PSU awards which will be recognized over a weighted average period of 1.9 years. For segment reporting, share-based compensation costs are unallocated expenses.

14. Pension and Other Postretirement Benefit Plans

The Company has defined benefit pension plans covering eligible employees in the United States and in certain of its international subsidiaries. In addition, the Company provides medical benefits, principally to its eligible U.S. retirees and their dependents, through its other postretirement benefit plans. The Company uses December 31 as the year-end measurement date for all of its pension plans and other postretirement benefit plans.

Net Periodic Benefit Cost

The net periodic benefit cost (credit) for pension and other postretirement benefit plans consisted of the following components:

	Pension Benefits								
	U.S.			International			Other Postretirement Benefits		
Years Ended December 31	**2017**	2016	2015	**2017**	2016	2015	**2017**	2016	2015
Service cost	**$ 312**	$ 282	$ 307	**$ 252**	$ 238	$ 251	**$ 57**	$ 54	$ 80
Interest cost	**454**	456	434	**172**	204	206	**81**	82	110
Expected return on plan assets	**(862)**	(831)	(819)	**(393)**	(382)	(379)	**(78)**	(107)	(143)
Amortization of unrecognized prior service cost	**(53)**	(55)	(56)	**(11)**	(11)	(14)	**(98)**	(106)	(64)
Net loss amortization	**180**	119	214	**98**	87	118	**1**	3	5
Termination benefits	**44**	23	22	**4**	4	1	**8**	4	7
Curtailments	**3**	5	(12)	**(4)**	(1)	(9)	**(31)**	(18)	(19)
Settlements	**—**	—	1	**5**	6	12	**—**	—	—
Net periodic benefit cost (credit)	**$ 78**	$ (1)	$ 91	**$ 123**	$ 145	$ 186	**$ (60)**	$ (88)	$ (24)

The changes in net periodic benefit cost (credit) year over year for pension plans are largely attributable to changes in the discount rate affecting net loss amortization. The increase in net periodic benefit credit for other postretirement benefit plans in 2017 and 2016 as compared with 2015 is largely attributable to changes in retiree medical benefits approved by the Company in December 2015, partially offset by lower returns on plan assets.

In connection with restructuring actions (see Note 5), termination charges were recorded in 2017, 2016 and 2015 on pension and other postretirement benefit plans related to expanded eligibility for certain employees exiting Merck. Also, in connection with these restructuring activities, curtailments were recorded on pension and other postretirement benefit plans and settlements were recorded on certain U.S. and international pension plans as reflected in the table above.

Obligations and Funded Status

Summarized information about the changes in plan assets and benefit obligations, the funded status and the amounts recorded at December 31 is as follows:

	Pension Benefits				Other Postretirement Benefits	
	U.S.		International			
	2017	2016	**2017**	2016	**2017**	2016
Fair value of plan assets January 1	**$ 9,766**	$ 9,266	**$ 7,794**	$ 7,204	**$ 1,019**	$ 1,913
Actual return on plan assets	**1,723**	941	**677**	898	**161**	138
Company contributions, net	**58**	63	**226**	424	**(4)**	68
Effects of exchange rate changes	**—**	—	**843**	(546)	**—**	—
Benefits paid	**(651)**	(504)	**(198)**	(193)	**(62)**	(108)
Settlements	**—**	—	**(17)**	(21)	**—**	—
Assets no longer restricted to the payment of postretirement benefits [1]	**—**	—	**—**	—	**—**	(992)
Other	**—**	—	**14**	28	**—**	—
Fair value of plan assets December 31	**$ 10,896**	$ 9,766	**$ 9,339**	$ 7,794	**$ 1,114**	$ 1,019
Benefit obligation January 1	**$ 10,849**	$ 9,723	**$ 8,372**	$ 7,733	**$ 1,922**	$ 1,810
Service cost	**312**	282	**252**	238	**57**	54
Interest cost	**454**	456	**172**	204	**81**	82
Actuarial losses (gains) [2]	**881**	854	**(7)**	938	**(87)**	77
Benefits paid	**(651)**	(504)	**(198)**	(193)	**(62)**	(108)
Effects of exchange rate changes	**—**	—	**916**	(576)	**3**	2
Plan amendments	**—**	—	**(22)**	—	**—**	—
Curtailments	**15**	15	**(3)**	(15)	**—**	1
Termination benefits	**44**	23	**4**	4	**8**	4
Settlements	**—**	—	**(17)**	(21)	**—**	—
Other	**—**	—	**14**	60	**—**	—
Benefit obligation December 31	**$ 11,904**	$ 10,849	**$ 9,483**	$ 8,372	**$ 1,922**	$ 1,922
Funded status December 31	**$ (1,008)**	$ (1,083)	**$ (144)**	$ (578)	**$ (808)**	$ (903)
Recognized as:						
Other assets	**$ —**	$ —	**$ 828**	$ 451	**$ —**	$ —
Accrued and other current liabilities	**(59)**	(50)	**(17)**	(7)	**(11)**	(11)
Other noncurrent liabilities	**(949)**	(1,033)	**(955)**	(1,022)	**(797)**	(892)

[1] *As a result of certain allowable administrative actions that occurred in June 2016, $992 million of plan assets previously restricted for the payment of other postretirement benefits became available to fund certain other health and welfare benefits.*

[2] *Actuarial losses in 2017 and 2016 primarily reflect changes in discount rates.*

At December 31, 2017 and 2016, the accumulated benefit obligation was $20.5 billion and $18.4 billion, respectively, for all pension plans, of which $11.5 billion and $10.5 billion, respectively, related to U.S. pension plans.

Information related to the funded status of selected pension plans at December 31 is as follows:

	U.S.		International	
	2017	2016	**2017**	2016
Pension plans with a projected benefit obligation in excess of plan assets				
Projected benefit obligation	**$ 11,904**	$ 10,849	**$ 3,323**	$ 5,486
Fair value of plan assets	**10,896**	9,766	**2,352**	4,457
Pension plans with an accumulated benefit obligation in excess of plan assets				
Accumulated benefit obligation	**$ 676**	$ 9,807	**$ 2,120**	$ 2,692
Fair value of plan assets	**—**	9,057	**1,346**	1,898

Plan Assets

Entities are required to use a fair value hierarchy which maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest:

Level 1 — Quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 — Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity. The Level 3 assets are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as instruments for which the determination of fair value requires significant judgment or estimation. At December 31, 2017 and 2016, $488 million and $435 million, respectively, or approximately 2% of the Company's pension investments were categorized as Level 3 assets.

If the inputs used to measure the financial assets fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

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The fair values of the Company's pension plan assets at December 31 by asset category are as follows:

	Fair Value Measurements Using				Fair Value Measurements Using			
	Quoted Prices In Active Markets for Identical Assets (Level 1)	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**	**Total**	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
	2017				2016			
U.S. Pension Plans								
Assets								
Cash and cash equivalents	**$ 6**	**$ —**	**$ —**	**$ 6**	$ 2	$ 2	$ —	$ 4
Investment funds								
Developed markets equities	**390**	**—**	**—**	**390**	521	—	—	521
Emerging markets equities	**138**	**—**	**—**	**138**	104	—	—	104
Equity securities								
Developed markets	**2,743**	**—**	**—**	**2,743**	2,521	—	—	2,521
Fixed income securities								
Government and agency obligations	**—**	**757**	**—**	**757**	—	475	—	475
Corporate obligations	**—**	**900**	**—**	**900**	—	660	—	660
Mortgage and asset-backed securities	**—**	**240**	**—**	**240**	—	239	—	239
Other investments	**—**	**—**	**15**	**15**	—	—	18	18
Net assets in fair value hierarchy	**$ 3,277**	**$ 1,897**	**$ 15**	**$ 5,189**	$ 3,148	$ 1,376	$ 18	$ 4,542
Investments measured at NAV [1]				**5,707**				5,224
Plan assets at fair value				**$ 10,896**				$ 9,766
International Pension Plans								
Assets								
Cash and cash equivalents	**$ 54**	**$ 19**	**$ —**	**$ 73**	$ 42	$ 11	$ —	$ 53
Investment funds								
Developed markets equities	**562**	**3,326**	**—**	**3,888**	187	2,846	—	3,033
Emerging markets equities	**62**	**176**	**—**	**238**	24	148	—	172
Government and agency obligations	**249**	**2,095**	**—**	**2,344**	123	1,904	—	2,027
Corporate obligations	**5**	**329**	**—**	**334**	2	282	—	284
Fixed income obligations	**7**	**4**	**—**	**11**	6	3	—	9
Real estate [2]	**—**	**1**	**2**	**3**	—	3	4	7
Equity securities								
Developed markets	**660**	**—**	**—**	**660**	565	—	—	565
Fixed income securities								
Government and agency obligations	**2**	**266**	**—**	**268**	2	235	—	237
Corporate obligations	**1**	**118**	**—**	**119**	—	92	—	92
Mortgage and asset-backed securities	**—**	**55**	**—**	**55**	—	50	—	50
Other investments								
Insurance contracts [3]	**—**	**67**	**470**	**537**	—	59	412	471
Other	**—**	**6**	**1**	**7**	1	4	1	6
Net assets in fair value hierarchy	**$ 1,602**	**$ 6,462**	**$ 473**	**$ 8,537**	$ 952	$ 5,637	$ 417	$ 7,006
Investments measured at NAV [1]				**802**				788
Plan assets at fair value				**$ 9,339**				$ 7,794

(1) *Certain investments that were measured at net asset value (NAV) per share or its equivalent as a practical expedient have not been classified in the fair value hierarchy. The fair value amounts presented in this table are intended to permit reconciliation of the fair value hierarchy to the fair value of plan assets at December 31, 2017 and 2016.*

(2) *The plans' Level 3 investments in real estate funds are generally valued by market appraisals of the underlying investments in the funds.*

(3) *The plans' Level 3 investments in insurance contracts are generally valued using a crediting rate that approximates market returns and invest in underlying securities whose market values are unobservable and determined using pricing models, discounted cash flow methodologies, or similar techniques.*

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The table below provides a summary of the changes in fair value, including transfers in and/or out, of all financial assets measured at fair value using significant unobservable inputs (Level 3) for the Company's pension plan assets:

	2017				2016			
	Insurance Contracts	**Real Estate**	**Other**	**Total**	Insurance Contracts	Real Estate	Other	Total
U.S. Pension Plans								
Balance January 1	**$ —**	**$ —**	**$ 18**	**$ 18**	$ —	$ —	$ 23	$ 23
Actual return on plan assets:								
Relating to assets still held at December 31	**—**	**—**	**(2)**	**(2)**	—	—	(3)	(3)
Relating to assets sold during the year	**—**	**—**	**4**	**4**	—	—	4	4
Purchases and sales, net	**—**	**—**	**(5)**	**(5)**	—	—	(6)	(6)
Balance December 31	**$ —**	**$ —**	**$ 15**	**$ 15**	$ —	$ —	$ 18	$ 18
International Pension Plans								
Balance January 1	**$ 412**	**$ 4**	**$ 1**	**$ 417**	$ 393	$ 5	$ 2	$ 400
Actual return on plan assets:								
Relating to assets still held at December 31	**52**	**—**	**—**	**52**	(9)	1	—	(8)
Purchases and sales, net	**5**	**(2)**	**—**	**3**	2	(2)	(1)	(1)
Transfers into Level 3	**1**	**—**	**—**	**1**	26	—	—	26
Balance December 31	**$ 470**	**$ 2**	**$ 1**	**$ 473**	**$ 412**	**$ 4**	**$ 1**	**$ 417**

The fair values of the Company's other postretirement benefit plan assets at December 31 by asset category are as follows:

	Fair Value Measurements Using				Fair Value Measurements Using			
	Quoted Prices In Active Markets for Identical Assets (Level 1)	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**	**Total**	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
		2017				2016		
Assets								
Cash and cash equivalents	**$ 97**	**$ —**	**$ —**	**$ 97**	$ 125	$ —	$ —	$ 125
Investment funds								
Developed markets equities	**37**	**—**	**—**	**37**	48	—	—	48
Emerging markets equities	**13**	**—**	**—**	**13**	10	—	—	10
Government and agency obligations	**1**	**—**	**—**	**1**	1	—	—	1
Equity securities								
Developed markets	**256**	**—**	**—**	**256**	231	—	—	231
Fixed income securities								
Government and agency obligations	**—**	**71**	**—**	**71**	—	43	—	43
Corporate obligations	**—**	**84**	**—**	**84**	—	60	—	60
Mortgage and asset-backed securities	**—**	**23**	**—**	**23**	—	22	—	22
Net assets in fair value hierarchy	**$ 404**	**$ 178**	**$ —**	**$ 582**	$ 415	$ 125	$ —	$ 540
Investments measured at NAV [1]				**532**				479
Plan assets at fair value				**$ 1,114**				$ 1,019

[1] *Certain investments that were measured at net asset value (NAV) per share or its equivalent as a practical expedient have not been classified in the fair value hierarchy. The fair value amounts presented in this table are intended to permit reconciliation of the fair value hierarchy to the fair value of plan assets at December 31, 2017 and 2016.*

The Company has established investment guidelines for its U.S. pension and other postretirement plans to create an asset allocation that is expected to deliver a rate of return sufficient to meet the long-term obligation of each

plan, given an acceptable level of risk. The target investment portfolio of the Company's U.S. pension and other postretirement benefit plans is allocated 35% to 55% in U.S. equities, 20% to 35% in international equities, 20% to 35% in fixed-income investments, and up to 5% in cash and other investments. The portfolio's equity weighting is consistent with the long-term nature of the plans' benefit obligations. The expected annual standard deviation of returns of the target portfolio, which approximates 13%, reflects both the equity allocation and the diversification benefits among the asset classes in which the portfolio invests. For international pension plans, the targeted investment portfolio varies based on the duration of pension liabilities and local government rules and regulations. Although a significant percentage of plan assets are invested in U.S. equities, concentration risk is mitigated through the use of strategies that are diversified within management guidelines.

Expected Contributions

Expected contributions during 2018 are approximately $60 million for U.S. pension plans, approximately $150 million for international pension plans and approximately $25 million for other postretirement benefit plans.

Expected Benefit Payments

Expected benefit payments are as follows:

	U.S. Pension Benefits	International Pension Benefits	Other Postretirement Benefits
2018	$ 609	$ 222	$ 96
2019	638	205	101
2020	650	217	104
2021	663	225	109
2022	683	243	113
2023 — 2027	3,760	1,326	623

Expected benefit payments are based on the same assumptions used to measure the benefit obligations and include estimated future employee service.

Amounts Recognized in Other Comprehensive Income

Net loss amounts reflect experience differentials primarily relating to differences between expected and actual returns on plan assets as well as the effects of changes in actuarial assumptions. Net loss amounts in excess of certain thresholds are amortized into net periodic benefit cost over the average remaining service life of employees. The following amounts were reflected as components of *OCI*:

	Pension Plans						Other Postretirement Benefit Plans		
	U.S.			International					
Years Ended December 31	**2017**	2016	2015	**2017**	2016	2015	**2017**	2016	2015
Net (loss) gain arising during the period	**$ (19)**	$ (743)	$ 73	**$ 309**	$ (380)	$ (66)	**$ 170**	$ (45)	$ 209
Prior service (cost) credit arising during the period	**(13)**	(10)	(13)	**22**	(2)	(4)	**(31)**	(19)	511
	$ (32)	$ (753)	$ 60	**$ 331**	$ (382)	$ (70)	**$ 139**	$ (64)	$ 720
Net loss amortization included in benefit cost	**$ 180**	$ 119	$ 214	**$ 98**	$ 87	$ 118	**$ 1**	$ 3	$ 5
Prior service (credit) cost amortization included in benefit cost	**(53)**	(55)	(56)	**(11)**	(11)	(14)	**(98)**	(106)	(64)
	$ 127	$ 64	$ 158	**$ 87**	$ 76	$ 104	**$ (97)**	$ (103)	$ (59)

The estimated net loss (gain) and prior service cost (credit) amounts that will be amortized from *AOCI* into net periodic benefit cost during 2018 are $314 million and $(64) million, respectively, for pension plans (of which $230 million and $(51) million, respectively, relates to U.S. pension plans) and $1 million and $(84) million, respectively, for other postretirement benefit plans.

Actuarial Assumptions

The Company reassesses its benefit plan assumptions on a regular basis. The weighted average assumptions used in determining U.S. pension and other postretirement benefit plan and international pension plan information are as follows:

	U.S. Pension and Other Postretirement Benefit Plans			International Pension Plans		
December 31	**2017**	2016	2015	**2017**	2016	2015
Net periodic benefit cost						
Discount rate	**4.30 %**	4.70 %	4.20 %	**2.20 %**	2.80 %	2.70 %
Expected rate of return on plan assets	**8.70 %**	8.60 %	8.50 %	**5.10 %**	5.60 %	5.70 %
Salary growth rate	**4.30 %**	4.30 %	4.40 %	**2.90 %**	2.90 %	2.90 %
Benefit obligation						
Discount rate	**3.70 %**	4.30 %	4.80 %	**2.10 %**	2.20 %	2.80 %
Salary growth rate	**4.30 %**	4.30 %	4.30 %	**2.90 %**	2.90 %	2.90 %

For both the pension and other postretirement benefit plans, the discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due. The expected rate of return for both the pension and other postretirement benefit plans represents the average rate of return to be earned on plan assets over the period the benefits included in the benefit obligation are to be paid and is determined on a plan basis. The expected rate of return within each plan is developed considering long-term historical returns data, current market conditions, and actual returns on the plan assets. Using this reference information, the long-term return expectations for each asset category and a weighted average expected return for each plan's target portfolio is developed, according to the allocation among those investment categories. The expected portfolio performance reflects the contribution of active management as appropriate. For 2018, the expected rate of return for the Company's U.S. pension and other postretirement benefit plans will range from 7.70% to 8.30%, as compared to a range of 8.00% to 8.75% in 2017. The decrease is primarily due to a modest shift in asset allocation. The increase in the weighted-average expected return on U.S. pension and other postretirement benefit plan assets from 2015 to 2017 is due to the relative weighting of the referenced plans' assets.

The health care cost trend rate assumptions for other postretirement benefit plans are as follows:

December 31	**2017**	2016
Health care cost trend rate assumed for next year	**7.2 %**	7.4 %
Rate to which the cost trend rate is assumed to decline	**4.5 %**	4.5 %
Year that the trend rate reaches the ultimate trend rate	**2032**	2032

A one percentage point change in the health care cost trend rate would have had the following effects:

	One Percentage Point	
	Increase	Decrease
Effect on total service and interest cost components	**$ 13**	**$ (11)**
Effect on benefit obligation	**125**	**(104)**

Savings Plans

The Company also maintains defined contribution savings plans in the United States. The Company matches a percentage of each employee's contributions consistent with the provisions of the plan for which the employee is eligible. Total employer contributions to these plans in 2017, 2016 and 2015 were $131 million, $126 million and $125 million, respectively.

15. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

Years Ended December 31	**2017**	2016	2015
Interest income	**$ (385)**	$ (328)	$ (289)
Interest expense	**754**	693	672
Exchange (gains) losses	**(11)**	174	1,277
Equity income from affiliates	**(42)**	(86)	(205)
Other, net	**(304)**	267	72
	$ 12	$ 720	$ 1,527

The exchange losses in 2015 were related primarily to the Venezuelan Bolívar. During 2015, upon evaluation of evolving economic conditions in Venezuela and volatility in the country, combined with a decline in transactions that were settled at the then official (CENCOEX) rate, the Company determined it was unlikely that all outstanding net monetary assets would be settled at the CENCOEX rate. Accordingly, during 2015, the Company recorded charges of $876 million to devalue its net monetary assets in Venezuela to amounts that represented the Company's estimate of the U.S. dollar amount that would ultimately be collected and recorded additional exchange losses of $138 million in the aggregate during 2015 reflecting the ongoing effect of translating transactions and net monetary assets consistent with these rates. Since January 2010, Venezuela has been designated hyperinflationary and, as a result, local foreign operations are remeasured in U.S. dollars with the impact recorded in results of operations.

The decline in equity income from affiliates in 2017 as compared with 2016 was driven primarily by the termination of the SPMSD joint venture on December 31, 2016, partially offset by higher equity income from certain research investment funds. The decline in equity income from affiliates in 2016 as compared with 2015 was driven primarily by lower equity income from certain research investment funds.

Other, net (as presented in the table above) in 2017 includes gains of $291 million on the sale of equity investments, income of $232 million related to AstraZeneca's option exercise (see Note 9), and a $191 million loss on extinguishment of debt (see Note 10).

Other, net in 2016 includes a charge of $625 million to settle worldwide patent litigation related to *Keytruda* (see Note 11), a gain of $117 million related to the settlement of other patent litigation, gains of $100 million resulting from the receipt of milestone payments for out-licensed migraine clinical development programs (see Note 3) and $98 million of income related to AstraZeneca's option exercise.

Other, net in 2015 includes a $680 million net charge related to the settlement of *Vioxx* shareholder class action litigation (which was paid in 2016) and an expense of $78 million for a contribution of investments in equity securities to the Merck Foundation, partially offset by a $250 million gain on the sale of certain migraine clinical development programs (see Note 3), a $147 million gain on the divestiture of Merck's remaining ophthalmics business in international markets (see Note 3), and the recognition of $182 million of income related to AstraZeneca's option exercise.

Interest paid was $723 million in 2017, $686 million in 2016 and $653 million in 2015.

16. Taxes on Income

A reconciliation between the effective tax rate and the U.S. statutory rate is as follows:

	2017		2016		2015	
	Amount	**Tax Rate**	Amount	Tax Rate	Amount	Tax Rate
U.S. statutory rate applied to income before taxes	**$ 2,282**	**35.0 %**	$ 1,631	35.0 %	$ 1,890	35.0 %
Differential arising from:						
Provisional impact of the TCJA	**2,625**	**40.3**	—	—	—	—
Impact of purchase accounting adjustments, including amortization	**713**	**10.9**	623	13.4	797	14.8
Valuation allowances	**632**	**9.7**	(5)	(0.1)	39	0.7
Restructuring	**142**	**2.2**	145	3.1	167	3.1
State taxes	**77**	**1.2**	173	3.7	159	2.9
U.S. health care reform legislation	**74**	**1.1**	68	1.4	66	1.2
Foreign currency devaluation related to Venezuela	**—**	**—**	—	—	321	5.9
Foreign earnings	**(1,725)**	**(26.5)**	(1,646)	(35.3)	(2,144)	(39.7)
Tax settlements	**(356)**	**(5.5)**	—	—	(417)	(7.7)
Unremitted foreign earnings	**—**	**—**	(30)	(0.6)	260	4.8
Other [(1)]	**(361)**	**(5.5)**	(241)	(5.2)	(196)	(3.6)
	$ 4,103	**62.9 %**	$ 718	15.4 %	$ 942	17.4 %

[(1)] *Other includes the tax effect of contingency reserves, research credits, losses on foreign subsidiaries and miscellaneous items.*

The Company's 2017 effective tax rate reflects a provisional impact of 40.3% for the Tax Cuts and Jobs Act (TCJA), which was enacted on December 22, 2017. Among other provisions, the TCJA reduces the U.S. federal corporate statutory tax rate from 35% to 21% effective January 1, 2018, requires companies to pay a one-time transition tax on undistributed earnings of certain foreign subsidiaries, and creates new taxes on certain foreign sourced earnings.

The Company has reflected the impact of the TCJA in its financial statements as described below. However, application of certain provisions of the TCJA remains subject to further interpretation and in these instances the Company has made a reasonable estimate of the effects of the TCJA.

The one-time transition tax is based on the Company's post-1986 undistributed earnings and profits (E&P). For a substantial portion of these undistributed E&P, the Company had not previously provided deferred taxes as these earnings were deemed by Merck to be retained indefinitely by subsidiary companies for reinvestment. The Company recorded a provisional amount for its one-time transition tax liability of $5.3 billion. Merck has not yet finalized its calculation of the total post-1986 undistributed E&P for these foreign subsidiaries. The transition tax is based in part on the amount of undistributed E&P held in cash and other specified assets; therefore, this amount may change when the Company finalizes its calculation of post-1986 undistributed foreign E&P and finalizes the amounts held in cash or other specified assets. This provisional amount was reduced by the reversal of $2.0 billion of deferred taxes that were previously recorded in connection with the merger of Schering-Plough Corporation in 2009 for certain undistributed foreign E&P. The Company anticipates that it will be able to utilize certain foreign tax credits to partially reduce the transition tax payment, resulting in a net transition tax payment of $5.1 billion. As permitted under the TCJA, the Company has elected to pay the one-time transition tax over a period of eight years. The current portion of the transition tax liability of $545 million is included as reduction to prepaid income taxes included in *Other Current Assets* and the remainder of $4.5 billion is included in *Other Noncurrent Liabilities*. As a result of the TCJA, the Company has made a determination it is no longer indefinitely reinvested with respect to its undistributed earnings from foreign subsidiaries and has provided a deferred tax liability for withholding tax that would apply.

The Company remeasured its deferred tax assets and liabilities at the new federal statutory tax rate of 21%, which resulted in a provisional deferred tax benefit of $779 million. The deferred tax benefit calculation remains subject to certain clarifications, particularly related to executive compensation and benefits.

Beginning in 2018, the TCJA includes a tax on "global intangible low-taxed income" (GILTI) as defined in the TCJA. The Company is allowed to make an accounting policy election to account for the tax effects of the GILTI tax either in the income tax provision in future periods as the tax arises, or as a component of deferred taxes on the related investments in foreign subsidiaries. The Company is currently evaluating the GILTI provisions of the TCJA and the implications on its tax provision and has not finalized the accounting policy election; therefore, the Company has not recorded deferred taxes for GILTI as of December 31, 2017.

The foreign earnings tax rate differentials in the tax rate reconciliation above primarily reflect the impacts of operations in jurisdictions with different tax rates than the United States, particularly Ireland and Switzerland, as well as Singapore and Puerto Rico which operate under tax incentive grants (which begin to expire in 2022), where the earnings had been indefinitely reinvested, thereby yielding a favorable impact on the effective tax rate as compared with the 35% U.S. statutory rate. The foreign earnings tax rate differentials do not include the impact of intangible asset impairment charges, amortization of purchase accounting adjustments or restructuring costs. These items are presented separately as they each represent a significant, separately disclosed pretax cost or charge, and a substantial portion of each of these items relates to jurisdictions with lower tax rates than the United States. Therefore, the impact of recording these expense items in lower tax rate jurisdictions is an unfavorable impact on the effective tax rate as compared to the 35% U.S. statutory rate.

The Company's 2015 effective tax rate reflects the impact of the Protecting Americans From Tax Hikes Act, which was signed into law on December 18, 2015, extending the research credit permanently and the controlled foreign corporation look-through provisions for five years.

Income before taxes consisted of:

Years Ended December 31	**2017**	2016	2015
Domestic	**$ 3,483**	$ 518	$ 2,247
Foreign	**3,038**	4,141	3,154
	$ 6,521	$ 4,659	$ 5,401

Taxes on income consisted of:

Years Ended December 31	**2017**	2016	2015
Current provision			
Federal	**$ 5,585**	$ 1,166	$ 732
Foreign	**1,229**	916	844
State	**(90)**	157	130
	6,724	2,239	1,706
Deferred provision			
Federal	**(2,958)**	(1,255)	(552)
Foreign	**75**	(225)	(163)
State	**262**	(41)	(49)
	(2,621)	(1,521)	(764)
	$ 4,103	$ 718	$ 942

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Deferred income taxes at December 31 consisted of:

	2017		2016	
	Assets	**Liabilities**	Assets	Liabilities
Intangibles	**$ 307**	**$ 2,435**	$ 86	$ 3,854
Inventory related	**29**	**499**	30	660
Accelerated depreciation	**28**	**642**	28	927
Unremitted foreign earnings	**—**	**33**	—	2,044
Pensions and other postretirement benefits	**498**	**192**	727	109
Compensation related	**314**	**—**	438	—
Unrecognized tax benefits	**156**	**—**	383	—
Net operating losses and other tax credit carryforwards	**654**	**—**	437	—
Other	**1,088**	**19**	1,248	46
Subtotal	**3,074**	**3,820**	3,377	7,640
Valuation allowance	**(900)**		(268)	
Total deferred taxes	**$ 2,174**	**$ 3,820**	$ 3,109	$ 7,640
Net deferred income taxes		**$ 1,646**		$ 4,531
Recognized as:				
Other assets	**$ 573**		$ 546	
Deferred income taxes		**$ 2,219**		$ 5,077

The Company has net operating loss (NOL) carryforwards in several jurisdictions. As of December 31, 2017, $630 million of deferred taxes on NOL carryforwards relate to foreign jurisdictions. Valuation allowances of $900 million have been established on these foreign NOL carryforwards and other foreign deferred tax assets. In addition, the Company has $24 million of deferred tax assets relating to various U.S. tax credit carryforwards and NOL carryforwards, all of which are expected to be fully utilized prior to expiry.

Income taxes paid in 2017, 2016 and 2015 were $4.9 billion, $1.8 billion and $1.8 billion, respectively. Tax benefits relating to stock option exercises were $73 million in 2017, $147 million in 2016 and $109 million in 2015.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	2017	2016	2015
Balance January 1	**$ 3,494**	$ 3,448	$ 3,534
Additions related to current year positions	**146**	196	198
Additions related to prior year positions	**520**	75	53
Reductions for tax positions of prior years [(1)]	**(1,038)**	(90)	(59)
Settlements [(1)]	**(1,388)**	(92)	(184)
Lapse of statute of limitations	**(11)**	(43)	(94)
Balance December 31	**$ 1,723**	$ 3,494	$ 3,448

[(1)] *Amounts reflect the settlements with the IRS as discussed below.*

If the Company were to recognize the unrecognized tax benefits of $1.7 billion at December 31, 2017, the income tax provision would reflect a favorable net impact of $1.6 billion.

The Company is under examination by numerous tax authorities in various jurisdictions globally. The Company believes that it is reasonably possible that the total amount of unrecognized tax benefits as of December 31, 2017 could decrease by up to approximately $165 million in the next 12 months as a result of various audit closures, settlements or the expiration of the statute of limitations. The ultimate finalization of the Company's examinations with relevant taxing authorities can include formal administrative and legal proceedings, which could have a significant impact on the timing of the reversal of unrecognized tax benefits. The Company believes that its reserves for uncertain tax positions are adequate to cover existing risks or exposures.

Expenses for interest and penalties associated with uncertain tax positions amounted to $183 million in 2017, $134 million in 2016 and $102 million in 2015. These amounts reflect the beneficial impacts of various tax

settlements, including those discussed below. Liabilities for accrued interest and penalties were $341 million and $886 million as of December 31, 2017 and 2016, respectively.

In 2017, the Internal Revenue Service (IRS) concluded its examinations of Merck's 2006-2011 U.S. federal income tax returns. As a result, the Company was required to make a payment of approximately $2.8 billion. The Company's reserves for unrecognized tax benefits for the years under examination exceeded the adjustments relating to this examination period and therefore the Company recorded a net $234 million tax benefit in 2017. This net benefit reflects reductions in reserves for unrecognized tax benefits for tax positions relating to the years that were under examination, partially offset by additional reserves for tax positions not previously reserved for, as well as adjustments to reserves for unrecognized tax benefits relating to years which remain open to examination that are affected by this settlement.

Although the IRS's examination of the Company's 2002-2005 federal tax returns was concluded prior to 2015, one issue relating to a refund claim remained open. During 2015, this issue was resolved and the Company received a refund of approximately $715 million, which exceeded the receivable previously recorded by the Company, resulting in a tax benefit of $410 million.

The IRS is currently conducting examinations of the Company's tax returns for the years 2012 through 2014. In addition, various state and foreign tax examinations are in progress. For most of its other significant tax jurisdictions (both U.S. state and foreign), the Company's income tax returns are open for examination for the period 2003 through 2017.

17. Earnings per Share

The calculations of earnings per share (shares in millions) are as follows:

Years Ended December 31	**2017**	2016	2015
Net income attributable to Merck & Co., Inc.	**$ 2,394**	$ 3,920	$ 4,442
Average common shares outstanding	**2,730**	2,766	2,816
Common shares issuable [(1)]	**18**	21	25
Average common shares outstanding assuming dilution	**2,748**	2,787	2,841
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	**$ 0.88**	$ 1.42	$ 1.58
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	**$ 0.87**	$ 1.41	$ 1.56

[(1)] *Issuable primarily under share-based compensation plans.*

In 2017, 2016 and 2015, 5 million, 13 million and 9 million, respectively, of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

18. Other Comprehensive Income (Loss)

Changes in *AOCI* by component are as follows:

	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance January 1, 2015, net of taxes	$ 530	$ 111	$ (2,986)	$ (1,978)	$ (4,323)
Other comprehensive income (loss) before reclassification adjustments, pretax	526	(9)	710	(158)	1,069
Tax	(177)	(13)	(272)	(28)	(490)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	349	(22)	438	(186)	579
Reclassification adjustments, pretax	(731) (1)	(73) (2)	203 (3)	(22)	(623)
Tax	256	25	(62)	—	219
Reclassification adjustments, net of taxes	(475)	(48)	141	(22)	(404)
Other comprehensive income (loss), net of taxes	(126)	(70)	579	(208)	175
Balance December 31, 2015, net of taxes	404	41	(2,407)	(2,186)	(4,148)
Other comprehensive income (loss) before reclassification adjustments, pretax	210	(38)	(1,199)	(150)	(1,177)
Tax	(72)	16	363	(19)	288
Other comprehensive income (loss) before reclassification adjustments, net of taxes	138	(22)	(836)	(169)	(889)
Reclassification adjustments, pretax	(314) (1)	(31) (2)	37 (3)	—	(308)
Tax	110	9	—	—	119
Reclassification adjustments, net of taxes	(204)	(22)	37	—	(189)
Other comprehensive income (loss), net of taxes	(66)	(44)	(799)	(169)	(1,078)
Balance December 31, 2016, net of taxes	338	(3)	(3,206) (4)	(2,355)	(5,226)
Other comprehensive income (loss) before reclassification adjustments, pretax	**(561)**	**212**	**438**	**235**	**324**
Tax	**207**	**(35)**	**(106)**	**166**	**232**
Other comprehensive income (loss) before reclassification adjustments, net of taxes	**(354)**	**177**	**332**	**401**	**556**
Reclassification adjustments, pretax	**(141) (1)**	**(291) (2)**	**117 (3)**	**—**	**(315)**
Tax	**49**	**56**	**(30)**	**—**	**75**
Reclassification adjustments, net of taxes	**(92)**	**(235)**	**87**	**—**	**(240)**
Other comprehensive income (loss), net of taxes	**(446)**	**(58)**	**419**	**401**	**316**
Balance December 31, 2017, net of taxes	**$ (108)**	**$ (61)**	**$ (2,787) (4)**	**$ (1,954)**	**$ (4,910)**

(1) Relates to foreign currency cash flow hedges that were reclassified from AOCI *to* Sales.

(2) Represents net realized (gains) losses on the sales of available-for-sale investments that were reclassified from AOCI *to* Other (income) expense, net.

(3) Includes net amortization of prior service cost and actuarial gains and losses included in net periodic benefit cost (see Note 14).

(4) Includes pension plan net loss of $3.5 billion and $3.9 billion at December 31, 2017 and 2016, respectively, and other postretirement benefit plan net (gain) loss of $(16) million and $115 million at December 31, 2017 and 2016, respectively, as well as pension plan prior service credit of $326 million and $361 million at December 31, 2017 and 2016, respectively, and other postretirement benefit plan prior service credit of $383 million and $466 million at December 31, 2017 and 2016, respectively.

19. Segment Reporting

The Company's operations are principally managed on a products basis and include four operating segments, which are the Pharmaceutical, Animal Health, Healthcare Services and Alliances segments. The Pharmaceutical segment is the only reportable segment.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. A large component of pediatric and adolescent vaccine sales are made to the U.S. Centers for Disease Control and Prevention Vaccines for Children program, which is funded by the U.S. government. Additionally, the Company sells vaccines to the Federal government for placement into vaccine stockpiles. Sales of vaccines in most major European markets were marketed through the Company's SPMSD joint venture until its termination on December 31, 2016 (see Note 9).

The Company also has an Animal Health segment that discovers, develops, manufactures and markets animal health products, including vaccines, which the Company sells to veterinarians, distributors and animal producers. The Company's Healthcare Services segment provides services and solutions that focus on engagement, health analytics and clinical services to improve the value of care delivered to patients.

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Sales of the Company's products were as follows:

Years Ended December 31	**2017**			2016			2015		
	U.S.	**Int'l**	**Total**	U.S.	Int'l	Total	U.S.	Int'l	Total
Primary Care and Women's Health									
Cardiovascular									
Zetia	**$ 352**	**$ 992**	**$ 1,344**	$ 1,588	$ 972	$ 2,560	$ 1,612	$ 914	$ 2,526
Vytorin	**124**	**627**	**751**	473	668	1,141	479	771	1,251
Atozet	**—**	**225**	**225**	1	146	146	2	34	36
Adempas	**—**	**300**	**300**	—	169	169	—	30	30
Diabetes									
Januvia	**2,153**	**1,584**	**3,737**	2,286	1,622	3,908	2,263	1,601	3,863
Janumet	**863**	**1,296**	**2,158**	984	1,217	2,201	976	1,175	2,151
General Medicine and Women's Health									
NuvaRing	**564**	**197**	**761**	576	202	777	515	216	732
Implanon/Nexplanon	**496**	**191**	**686**	420	186	606	367	221	588
Follistim AQ	**123**	**174**	**298**	157	197	355	160	223	383
Hospital and Specialty									
Hepatitis									
Zepatier	**771**	**888**	**1,660**	488	67	555	—	—	—
HIV									
Isentress/Isentress HD	**565**	**639**	**1,204**	721	666	1,387	797	714	1,511
Hospital Acute Care									
Bridion	**239**	**465**	**704**	77	405	482	—	353	353
Noxafil	**309**	**327**	**636**	284	312	595	212	275	487
Invanz	**361**	**241**	**602**	329	233	561	322	247	569
Cancidas	**20**	**402**	**422**	25	533	558	24	548	573
Cubicin [(1)]	**189**	**193**	**382**	906	181	1,087	1,030	97	1,127
Primaxin	**10**	**270**	**280**	4	293	297	8	305	313
Immunology									
Remicade	**—**	**837**	**837**	—	1,268	1,268	—	1,794	1,794
Simponi	**—**	**819**	**819**	—	766	766	—	690	690
Oncology									
Keytruda	**2,309**	**1,500**	**3,809**	792	610	1,402	393	173	566
Emend	**342**	**213**	**556**	356	193	549	326	209	535
Temodar	**16**	**256**	**271**	15	268	283	7	306	312
Diversified Brands									
Respiratory									
Singulair	**40**	**692**	**732**	40	874	915	39	892	931
Nasonex	**54**	**333**	**387**	184	352	537	449	409	858
Dulera	**261**	**26**	**287**	412	24	436	515	21	536
Other									
Cozaar/Hyzaar	**18**	**466**	**484**	16	494	511	30	637	667
Arcoxia	**—**	**363**	**363**	—	450	450	—	471	471
Fosamax	**6**	**235**	**241**	5	279	284	12	347	359
Vaccines [(2)]									
Gardasil/Gardasil 9	**1,565**	**743**	**2,308**	1,780	393	2,173	1,520	388	1,908
ProQuad/M-M-R II/Varivax	**1,374**	**303**	**1,676**	1,362	279	1,640	1,290	214	1,505
Pneumovax 23	**581**	**240**	**821**	447	193	641	378	164	542

RotaTeq	**481**	**204**	**686**	482	169	652	447	163	610
Zostavax	**422**	**246**	**668**	518	168	685	592	157	749
Other pharmaceutical *(3)*	**1,246**	**3,049**	**4,295**	1,345	3,228	4,574	1,473	3,785	5,256
Total Pharmaceutical segment sales	**15,854**	**19,536**	**35,390**	17,073	18,077	35,151	16,238	18,544	34,782
Other segment sales *(4)*	**1,486**	**2,785**	**4,272**	1,374	2,489	3,862	1,213	2,454	3,667
Total segment sales	**17,340**	**22,321**	**39,662**	18,447	20,566	39,013	17,451	20,998	38,449
Other (5)	**84**	**377**	**460**	31	763	794	68	981	1,049
	$ 17,424	**$ 22,698**	**$ 40,122**	$ 18,478	$ 21,329	$ 39,807	$ 17,519	$ 21,979	$ 39,498

U.S. plus international may not equal total due to rounding.

(1) Sales of Cubicin *in 2015 represent sales subsequent to the Cubist acquisition date.*

(2) On December 31, 2016, Merck and Sanofi terminated their equally-owned joint venture, SPMSD, which marketed vaccines in most major European markets (see Note 9). Accordingly, vaccine sales in 2017 include sales in the European markets that were previously part of SPMSD. Amounts for 2016 and 2015 do not include sales of vaccines sold through SPMSD, the results of which are reflected in equity income from affiliates included in Other (income) expense, net. *Amounts for 2016 and 2015 do, however, include supply sales to SPMSD.*

(3) Other pharmaceutical primarily reflects sales of other human health pharmaceutical products, including products within the franchises not listed separately.

(4) Represents the non-reportable segments of Animal Health, Healthcare Services and Alliances.

(5) Other is primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, as well as third-party manufacturing sales. Other in 2017 and 2016 also includes $85 million and $170 million, respectively, related to the sale of the marketing rights to certain products.

Consolidated revenues by geographic area where derived are as follows:

Years Ended December 31	**2017**	2016	2015
United States	**$ 17,424**	$ 18,478	$ 17,519
Europe, Middle East and Africa	**11,478**	10,953	10,677
Asia Pacific	**4,337**	3,918	3,825
Japan	**3,122**	2,846	2,673
Latin America	**2,339**	2,155	2,825
Other	**1,422**	1,457	1,979
	$ 40,122	$ 39,807	$ 39,498

A reconciliation of total segment profits to consolidated *Income before taxes* is as follows:

Years Ended December 31	**2017**	2016	2015
Segment profits:			
Pharmaceutical segment	**$ 22,586**	$ 22,180	$ 21,658
Other segments	**1,834**	1,507	1,573
Total segment profits	**24,420**	23,687	23,231
Other profits	**26**	481	810
Unallocated:			
Interest income	**385**	328	289
Interest expense	**(754)**	(693)	(672)
Equity income from affiliates	**49**	(19)	135
Depreciation and amortization	**(1,378)**	(1,585)	(1,573)
Research and development	**(9,355)**	(9,084)	(5,871)
Amortization of purchase accounting adjustments	**(3,056)**	(3,692)	(4,816)
Restructuring costs	**(776)**	(651)	(619)
Loss on extinguishment of debt	**(191)**	—	—
Gain on sale of certain migraine clinical development programs	**—**	100	250
Charge related to the settlement of worldwide *Keytruda* patent litigation	**—**	(625)	—
Gain on divestiture of certain ophthalmic products	**—**	—	147
Foreign currency devaluation related to Venezuela	**—**	—	(876)
Net charge related to the settlement of *Vioxx* shareholder class action litigation	**—**	—	(680)
Other unallocated, net	**(2,849)**	(3,588)	(4,354)
	$ 6,521	$ 4,659	$ 5,401

Segment profits are comprised of segment sales less standard costs and certain operating expenses directly incurred by the segments. For internal management reporting presented to the chief operating decision maker, Merck does not allocate materials and production costs, other than standard costs, the majority of research and development expenses or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. In addition, costs related to restructuring activities, as well as the amortization of purchase accounting adjustments are not allocated to segments.

Other profits are primarily comprised of miscellaneous corporate profits, as well as operating profits related to third-party manufacturing sales.

Other unallocated, net includes expenses from corporate and manufacturing cost centers, goodwill and other intangible asset impairment charges, gains or losses on sales of businesses, expense or income related to changes in the estimated fair value of contingent consideration, and other miscellaneous income or expense items.

Equity income from affiliates and depreciation and amortization included in segment profits is as follows:

	Pharmaceutical	All Other	Total
Year Ended December 31, 2017			
Included in segment profits:			
Equity income from affiliates	**$ (7)**	**$ —**	**$ (7)**
Depreciation and amortization	**(125)**	**(87)**	**(212)**
Year Ended December 31, 2016			
Included in segment profits:			
Equity income from affiliates	$ 105	$ —	$ 105
Depreciation and amortization	(160)	(23)	(183)
Year Ended December 31, 2015			
Included in segment profits:			
Equity income from affiliates	$ 70	$ —	$ 70
Depreciation and amortization	(82)	(18)	(100)

Property, plant and equipment, net by geographic area where located is as follows:

December 31	**2017**	2016	2015
United States	**$ 8,070**	$ 8,114	$ 8,467
Europe, Middle East and Africa	**3,151**	2,732	2,844
Asia Pacific	**782**	775	842
Latin America	**271**	234	182
Japan	**158**	164	164
Other	**7**	7	8
	$ 12,439	$ 12,026	$ 12,507

The Company does not disaggregate assets on a products and services basis for internal management reporting and, therefore, such information is not presented.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Merck & Co., Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Merck & Co., Inc. and its subsidiaries as of December 31, 2017 and 2016, and the related consolidated statements of income, comprehensive income, equity and cash flows for each of the three years in the period ended December 31, 2017, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2017, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2017 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail,

accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 27, 2018

We have served as the Company's auditor since 2002

(b) Supplementary Data

Selected quarterly financial data for 2017 and 2016 are contained in the Condensed Interim Financial Data table below.

Condensed Interim Financial Data (Unaudited)

($ in millions except per share amounts)	4th Q [1]	3rd Q [2]	2nd Q	1st Q
2017 [3]				
Sales	**$ 10,433**	**$ 10,325**	**$ 9,930**	**$ 9,434**
Materials and production	**3,406**	**3,274**	**3,080**	**3,015**
Marketing and administrative	**2,580**	**2,401**	**2,438**	**2,411**
Research and development	**2,281**	**4,383**	**1,749**	**1,796**
Restructuring costs	**306**	**153**	**166**	**151**
Other (income) expense, net	**(19)**	**(86)**	**58**	**58**
Income before taxes	**1,879**	**200**	**2,439**	**2,003**
Net (loss) income attributable to Merck & Co., Inc.	**(1,046)**	**(56)**	**1,946**	**1,551**
Basic (loss) earnings per common share attributable to Merck & Co., Inc. common shareholders	**$ (0.39)**	**$ (0.02)**	**$ 0.71**	**$ 0.56**
(Loss) earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	**$ (0.39)**	**$ (0.02)**	**$ 0.71**	**$ 0.56**
2016 [3]				
Sales	$ 10,115	$ 10,536	$ 9,844	$ 9,312
Materials and production	3,332	3,409	3,578	3,572
Marketing and administrative	2,593	2,393	2,458	2,318
Research and development	4,650	1,664	2,151	1,659
Restructuring costs	265	161	134	91
Other (income) expense, net	631	22	19	48
(Loss) income before taxes	(1,356)	2,887	1,504	1,624
Net (loss) income attributable to Merck & Co., Inc.	(594)	2,184	1,205	1,125
Basic (loss) earnings per common share attributable to Merck & Co., Inc. common shareholders	$ (0.22)	$ 0.79	$ 0.44	$ 0.41
(Loss) earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	$ (0.22)	$ 0.78	$ 0.43	$ 0.40

[1] *Amounts for 2017 include a provisional net tax charge related to the enactment of U.S. tax legislation (see Note 16). Amounts for 2016 include a charge to settle worldwide patent litigation related to Keytruda (see Note 11).*

[2] *Amounts for 2017 include an aggregate charge related to the formation of a collaboration with AstraZeneca (see Note 4).*

[3] *Amounts for 2017 and 2016 reflect acquisition and divestiture-related costs (see Note 8) and the impact of restructuring actions (see Note 5).*

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures. Based on their evaluation, as of the end of the period covered by this Form 10-K, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Act)) are effective. For the period covered by this report, there have been no changes in internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Act. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control — Integrated Framework* issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2017. PricewaterhouseCoopers LLP, an independent registered public accounting firm, has performed its own assessment of the effectiveness of the Company's internal control over financial reporting and its attestation report is included in this Form 10-K filing.

Management's Report

Management's Responsibility for Financial Statements

Responsibility for the integrity and objectivity of the Company's financial statements rests with management. The financial statements report on management's stewardship of Company assets. These statements are prepared in conformity with generally accepted accounting principles and, accordingly, include amounts that are based on management's best estimates and judgments. Nonfinancial information included in the Annual Report on Form 10-K has also been prepared by management and is consistent with the financial statements.

To assure that financial information is reliable and assets are safeguarded, management maintains an effective system of internal controls and procedures, important elements of which include: careful selection, training and development of operating and financial managers; an organization that provides appropriate division of responsibility; and communications aimed at assuring that Company policies and procedures are understood throughout the organization. A staff of internal auditors regularly monitors the adequacy and application of internal controls on a worldwide basis.

To ensure that personnel continue to understand the system of internal controls and procedures, and policies concerning good and prudent business practices, annually all employees of the Company are required to complete Code of Conduct training, which includes financial stewardship. This training reinforces the importance and understanding of internal controls by reviewing key corporate policies, procedures and systems. In addition, the Company has compliance programs, including an ethical business practices program to reinforce the Company's long-standing commitment to high ethical standards in the conduct of its business.

The financial statements and other financial information included in the Annual Report on Form 10-K fairly present, in all material respects, the Company's financial condition, results of operations and cash flows. Our formal certification to the Securities and Exchange Commission is included in this Form 10-K filing.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control — Integrated Framework* issued

in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2017.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2017, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

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Kenneth C. Frazier
Chairman, President and Chief Executive Officer

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Robert M. Davis
Executive Vice President, Chief Financial Officer & Global Services

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The required information on directors and nominees is incorporated by reference from the discussion under Proposal 1. Election of Directors of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 22, 2018. Information on executive officers is set forth in Part I of this document on page 32.

The required information on compliance with Section 16(a) of the Securities Exchange Act of 1934 is incorporated by reference from the discussion under the heading "Section 16(a) Beneficial Ownership Reporting Compliance" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 22, 2018.

The Company has a Code of Conduct — *Our Values and Standards* applicable to all employees, including the principal executive officer, principal financial officer, principal accounting officer and Controller. The Code of Conduct is available on the Company's website at *www.merck.com/about/code_of_conduct.pdf*. The Company intends to disclose future amendments to certain provisions of the Code of Conduct, and waivers of the Code of Conduct granted to executive officers and directors, if any, on the website within four business days following the date of any amendment or waiver. Every Merck employee is responsible for adhering to business practices that are in accordance with the law and with ethical principles that reflect the highest standards of corporate and individual behavior. A printed copy will be sent, without charge, to any shareholder who requests it by writing to the Chief Ethics and Compliance Officer of Merck & Co., Inc., 2000 Galloping Hill Road, Kenilworth, NJ 07033.

The required information on the identification of the audit committee and the audit committee financial expert is incorporated by reference from the discussion under the heading "Board Meetings and Committees" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 22, 2018.

Item 11. Executive Compensation.

The information required on executive compensation is incorporated by reference from the discussion under the headings "Compensation Discussion and Analysis", "Summary Compensation Table", "All Other Compensation" table, "Grants of Plan-Based Awards" table, "Outstanding Equity Awards" table, "Option Exercises and Stock Vested" table, "Pension Benefits" table, "Nonqualified Deferred Compensation" table, Potential Payments Upon Termination or a Change in Control, including the discussion under the subheadings "Separation" and "Change in Control", as well as all footnote information to the various tables, of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 22, 2018.

The required information on director compensation is incorporated by reference from the discussion under the heading "Director Compensation" and related "Director Compensation" table and "Schedule of Director Fees" table of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 22, 2018.

The required information under the headings "Compensation and Benefits Committee Interlocks and Insider Participation" and "Compensation and Benefits Committee Report" is incorporated by reference from the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 22, 2018.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information with respect to security ownership of certain beneficial owners and management is incorporated by reference from the discussion under the heading "Stock Ownership Information" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 22, 2018.

Equity Compensation Plan Information

The following table summarizes information about the options, warrants and rights and other equity compensation under the Company's equity compensation plans as of the close of business on December 31, 2017. The table does not include information about tax qualified plans such as the Merck U.S. Savings Plan.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders[1]	36,274,481[2]	$ 46.77	117,820,468
Equity compensation plans not approved by security holders	—	—	—
Total	36,274,481	$ 46.77	117,820,468

(1) *Includes options to purchase shares of Company Common Stock and other rights under the following shareholder-approved plans: the Merck Sharp & Dohme 2004, 2007 and 2010 Incentive Stock Plans, the Merck & Co., Inc. 2006 and 2010 Non-Employee Directors Stock Option Plans, and the Merck & Co., Inc. Schering-Plough 2002 and 2006 Stock Incentive Plans.*

(2) *Excludes approximately 13,608,641 shares of restricted stock units and 1,867,526 performance share units (assuming maximum payouts) under the Merck Sharp & Dohme 2004, 2007 and 2010 Incentive Stock Plans. Also excludes 245,038 shares of phantom stock deferred under the MSD Employee Deferral Program and 551,358 shares of phantom stock deferred under the Merck & Co., Inc. Plan for Deferred Payment of Directors' Compensation.*

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The required information on transactions with related persons is incorporated by reference from the discussion under the heading "Related Person Transactions" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 22, 2018.

The required information on director independence is incorporated by reference from the discussion under the heading "Independence of Directors" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 22, 2018.

Item 14. Principal Accountant Fees and Services.

The information required for this item is incorporated by reference from the discussion under Proposal 4. Ratification of Appointment of Independent Registered Public Accounting Firm for 2018 beginning with the caption "Pre-Approval Policy for Services of Independent Registered Public Accounting Firm" through "Fees for Services Provided by Independent Registered Public Accounting Firm" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 22, 2018.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this Form 10-K

1. Financial Statements

Consolidated statement of income for the years ended December 31, 2017, 2016 and 2015

Consolidated statement of comprehensive income for the years ended December 31, 2017, 2016 and 2015

Consolidated balance sheet as of December 31, 2017 and 2016

Consolidated statement of equity for the years ended December 31, 2017, 2016 and 2015

Consolidated statement of cash flows for the years ended December 31, 2017, 2016 and 2015

Notes to consolidated financial statements

Report of PricewaterhouseCoopers LLP, independent registered public accounting firm

2. Financial Statement Schedules

Schedules are omitted because they are either not required or not applicable.

Financial statements of affiliates carried on the equity basis have been omitted because, considered individually or in the aggregate, such affiliates do not constitute a significant subsidiary.

3. Exhibits

Exhibit Number		Description
3.1	—	Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) — Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
3.2	—	By-Laws of Merck & Co., Inc. (effective July 22, 2015) — Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed July 28, 2015 (No. 1-6571)
4.1	—	Indenture, dated as of April 1, 1991, between Merck Sharp & Dohme Corp. (f/k/a Schering Corporation) and U.S. Bank Trust National Association (as successor to Morgan Guaranty Trust Company of New York), as Trustee (the 1991 Indenture) — Incorporated by reference to Exhibit 4 to MSD's Registration Statement on Form S-3 (No. 33-39349)
4.2	—	First Supplemental Indenture to the 1991 Indenture, dated as of October 1, 1997 — Incorporated by reference to Exhibit 4(b) to MSD's Registration Statement on Form S-3 filed September 25, 1997 (No. 333-36383)
4.3	—	Second Supplemental Indenture to the 1991 Indenture, dated November 3, 2009 — Incorporated by reference to Exhibit 4.3 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No.1-6571)
4.4	—	Third Supplemental Indenture to the 1991 Indenture, dated May 1, 2012 — Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the period ended March 31, 2012 (No. 1-6571)
4.5	—	Indenture, dated November 26, 2003, between Merck & Co., Inc. (f/k/a Schering-Plough Corporation) and The Bank of New York as Trustee (the 2003 Indenture) — Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed November 28, 2003 (No. 1-6571)
4.6	—	Second Supplemental Indenture to the 2003 Indenture (including Form of Note), dated November 26, 2003 — Incorporated by reference to Exhibit 4.3 to Schering-Plough's Current Report on Form 8-K filed November 28, 2003 (No. 1-6571)
4.7	—	Third Supplemental Indenture to the 2003 Indenture (including Form of Note), dated September 17, 2007 — Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed September 17, 2007 (No. 1-6571)

Exhibit Number		Description
4.8	—	Fifth Supplemental Indenture to the 2003 Indenture, dated November 3, 2009 — Incorporated by reference to Exhibit 4.4 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
4.9	—	Indenture, dated as of January 6, 2010, between Merck & Co., Inc. and U.S. Bank Trust National Association, as Trustee — Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed December 10, 2010 (No. 1-6571)
4.10	—	Long-term debt instruments under which the total amount of securities authorized does not exceed 10% of Merck & Co., Inc.'s total consolidated assets are not filed as exhibits to this report. Merck & Co., Inc. will furnish a copy of these agreements to the Securities and Exchange Commission on request.
*10.1	—	Merck & Co., Inc. Executive Incentive Plan (as amended and restated effective June 1, 2015) — Incorporated by reference to Merck & Co., Inc.'s Schedule 14A filed April 13, 2015 (No. 1-6571)
*10.2	—	Merck & Co., Inc. Deferral Program Including the Base Salary Deferral Plan (Amended and Restated effective December 1, 2015) — Incorporated by reference to Exhibit 10.2 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2016 filed February 28, 2017 (No. 1-6571)
*10.3	—	Merck Sharp & Dohme Corp. 2007 Incentive Stock Plan (effective as amended and restated as of November 3, 2009) — Incorporated by reference to Exhibit 10.7 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
*10.4	—	Amendment One to the Merck Sharp & Dohme Corp. 2007 Incentive Stock Plan (effective February 15, 2010) — Incorporated by reference to Exhibit 10.2 to Merck & Co., Inc.'s Current Report on Form 8-K filed February 18, 2010 (No. 1-6571)
*10.5	—	Merck & Co., Inc. 2010 Incentive Stock Plan (as amended and restated June 1, 2015) — Incorporated by reference to Merck & Co., Inc.'s Schedule 14A filed April 13, 2015 (No. 1-6571)
*10.6	—	Form of stock option terms for a non-qualified stock option under the Merck Sharp & Dohme Corp. 2007 Incentive Stock Plan and the Schering-Plough 2006 Stock Incentive Plan — Incorporated by reference to Exhibit 10.3 to Merck & Co., Inc.'s Current Report on Form 8-K filed February 18, 2010 (No. 1-6571)
*10.7	—	Form of stock option terms for 2011 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.2 to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the period ended March 31, 2011 filed May 9, 2011 (No. 1-6571)
*10.8	—	Form of stock option terms for 2012 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.20 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2011 filed February 28, 2012 (No. 1-6571)
*10.9	—	Form of stock option terms for 2013 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.19 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2012 filed February 28, 2013 (No. 1-6571)
*10.10	—	Form of stock option terms for 2014 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.18 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2014 filed February 27, 2015 (No. 1-6571)
*10.11	—	Form of stock option terms for 2015 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.20 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2015 filed February 26, 2016 (No. 1-6571)
10.12	—	Form of stock option terms for 2018 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan

Exhibit Number		Description
*10.13	—	Form of restricted stock unit terms for 2015 quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.22 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2015 filed February 26, 2016 (No. 1-6571)
*10.14	—	Form of performance share unit terms for 2015 grants under the Merck & Co., Inc. 2010 Stock Incentive Plan — Incorporated by reference to to Exhibit 10.21 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2015 filed February 26, 2016 (No. 1-6571)
*10.15	—	Form of stock option terms for 2016 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.19 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2016 filed February 28, 2017 (No. 1-6571)
*10.16	—	Form of restricted stock unit terms for 2016 quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.20 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2016 filed February 28, 2017 (No. 1-6571)
*10.17	—	Form of restricted stock unit terms for 2018 quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan
*10.18	—	Form of performance share unit terms for 2016 grants under the Merck & Co., Inc. 2010 Stock Incentive Plan — Incorporated by reference to Exhibit 10.21 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2016 filed February 28, 2017 (No. 1-6571)
*10.19	—	Merck & Co., Inc. Change in Control Separation Benefits Plan (effective as amended and restated, as of January 1, 2013) — Incorporated by reference to Exhibit 10.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 29, 2012 (No. 1-6571)
*10.20	—	Merck & Co., Inc. U.S. Separation Benefits Plan (amended and restated effective as of January 1, 2017) — Incorporated by reference to Exhibit 10.24 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2016 filed February 28, 2017 (No. 1-6571)
*10.21	—	Merck & Co., Inc. 2006 Non-Employee Directors Stock Option Plan (amended and restated as of November 3, 2009) — Incorporated by reference to Exhibit 10.5 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
*10.22	—	Merck & Co., Inc. 2010 Non-Employee Directors Stock Option Plan (amended and restated as of December 1, 2010) — Incorporated by reference to Exhibit 10.17 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2010 filed February 28, 2011 (No. 1-6571)
*10.23	—	Retirement Plan for the Directors of Merck & Co., Inc. (amended and restated June 21, 1996) — Incorporated by reference to Exhibit 10.C to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1996 filed August 13, 1996 (No. 1-3305)
*10.24	—	Merck & Co., Inc. Plan for Deferred Payment of Directors' Compensation (effective as amended and restated as of January 1, 2018)
10.25	—	Distribution agreement between Schering-Plough and Centocor, Inc., dated April 3, 1998 — Incorporated by reference to Exhibit 10(u) to Schering-Plough's Amended 10-K for the year ended December 31, 2003 filed May 3, 2004 (No. 1-6571)†
10.26	—	Amendment Agreement to the Distribution Agreement between Centocor, Inc., CAN Development, LLC, and Schering-Plough (Ireland) Company — Incorporated by reference to Exhibit 10.1 to Schering-Plough's Current Report on Form 8-K filed December 21, 2007 (No. 1-6571)†
10.27	—	Accelerated Share Purchase Agreement between Merck & Co., Inc. and Goldman, Sachs & Co., dated May 20, 2013 — Incorporated by reference to Exhibit 10 to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the period ended June 30, 2013 filed August 7, 2013 (No. 1-6571)
12	—	Computation of Ratios of Earnings to Fixed Charges
21	—	Subsidiaries of Merck & Co., Inc.
23	—	Consent of Independent Registered Public Accounting Firm
24.1	—	Power of Attorney
24.2	—	Certified Resolution of Board of Directors

Exhibit Number		Description
31.1	—	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
31.2	—	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer
32.1	—	Section 1350 Certification of Chief Executive Officer
32.2	—	Section 1350 Certification of Chief Financial Officer
101	—	The following materials from Merck & Co., Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2017, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statement of Income, (ii) the Consolidated Statement of Comprehensive Income, (iii) the Consolidated Balance Sheet, (iv) the Consolidated Statement of Equity, (v) the Consolidated Statement of Cash Flows, and (vi) Notes to Consolidated Financial Statements.

* *Management contract or compensatory plan or arrangement.*

† *Certain portions of the exhibit have been omitted pursuant to a request for confidential treatment. The non-public information has been filed separately with the Securities and Exchange Commission pursuant to rule 24b-2 under the Securities Exchange Act of 1934, as amended.*

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: February 27, 2018

MERCK & CO., INC.

By: KENNETH C. FRAZIER
(Chairman, President and Chief Executive Officer)

By: /S/ MICHAEL J. HOLSTON
Michael J. Holston
(Attorney-in-Fact)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signatures	Title	Date
KENNETH C. FRAZIER	Chairman, President and Chief Executive Officer; Principal Executive Officer; Director	February 27, 2018
ROBERT M. DAVIS	Executive Vice President, Chief Financial Officer and Global Services; Principal Financial Officer	February 27, 2018
RITA A. KARACHUN	Senior Vice President Finance-Global Controller; Principal Accounting Officer	February 27, 2018
LESLIE A. BRUN	Director	February 27, 2018
THOMAS R. CECH	Director	February 27, 2018
PAMELA J. CRAIG	Director	February 27, 2018
THOMAS H. GLOCER	Director	February 27, 2018
ROCHELLE B. LAZARUS	Director	February 27, 2018
JOHN H. NOSEWORTHY	Director	February 27, 2018
CARLOS E. REPRESAS	Director	February 27, 2018
PAUL B. ROTHMAN	Director	February 27, 2018
PATRICIA F. RUSSO	Director	February 27, 2018
CRAIG B. THOMPSON	Director	February 27, 2018
WENDELL P. WEEKS	Director	February 27, 2018
PETER C. WENDELL	Director	February 27, 2018

Michael J. Holston, by signing his name hereto, does hereby sign this document pursuant to powers of attorney duly executed by the persons named, filed with the Securities and Exchange Commission as an exhibit to this document, on behalf of such persons, all in the capacities and on the date stated, such persons including a majority of the directors of the Company.

By: /S/ MICHAEL J. HOLSTON
Michael J. Holston
(Attorney-in-Fact)

EXHIBIT INDEX

Exhibit Number		Description
3.1	—	Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) — Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
3.2	—	By-Laws of Merck & Co., Inc. (effective July 22, 2015) — Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed July 28, 2015 (No. 1-6571)
4.1	—	Indenture, dated as of April 1, 1991, between Merck Sharp & Dohme Corp. (f/k/a Schering Corporation) and U.S. Bank Trust National Association (as successor to Morgan Guaranty Trust Company of New York), as Trustee (the 1991 Indenture) — Incorporated by reference to Exhibit 4 to MSD's Registration Statement on Form S-3 (No. 33-39349)
4.2	—	First Supplemental Indenture to the 1991 Indenture, dated as of October 1, 1997 — Incorporated by reference to Exhibit 4(b) to MSD's Registration Statement on Form S-3 filed September 25, 1997 (No. 333-36383)
4.3	—	Second Supplemental Indenture to the 1991 Indenture, dated November 3, 2009 — Incorporated by reference to Exhibit 4.3 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No.1-6571)
4.4	—	Third Supplemental Indenture to the 1991 Indenture, dated May 1, 2012 — Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the period ended March 31, 2012 (No. 1-6571)
4.5	—	Indenture, dated November 26, 2003, between Merck & Co., Inc. (f/k/a Schering-Plough Corporation) and The Bank of New York as Trustee (the 2003 Indenture) — Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed November 28, 2003 (No. 1-6571)
4.6	—	Second Supplemental Indenture to the 2003 Indenture (including Form of Note), dated November 26, 2003 — Incorporated by reference to Exhibit 4.3 to Schering-Plough's Current Report on Form 8-K filed November 28, 2003 (No. 1-6571)
4.7	—	Third Supplemental Indenture to the 2003 Indenture (including Form of Note), dated September 17, 2007 — Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed September 17, 2007 (No. 1-6571)
4.8	—	Fifth Supplemental Indenture to the 2003 Indenture, dated November 3, 2009 — Incorporated by reference to Exhibit 4.4 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
4.9	—	Indenture, dated as of January 6, 2010, between Merck & Co., Inc. and U.S. Bank Trust National Association, as Trustee — Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed December 10, 2010 (No. 1-6571)
4.10	—	Long-term debt instruments under which the total amount of securities authorized does not exceed 10% of Merck & Co., Inc.'s total consolidated assets are not filed as exhibits to this report. Merck & Co., Inc. will furnish a copy of these agreements to the Securities and Exchange Commission on request.
*10.1	—	Merck & Co., Inc. Executive Incentive Plan (as amended and restated effective June 1, 2015) — Incorporated by reference to Merck & Co., Inc.'s Schedule 14A filed April 13, 2015 (No. 1-6571)
*10.2	—	Merck & Co., Inc. Deferral Program Including the Base Salary Deferral Plan (Amended and Restated effective December 1, 2015) — Incorporated by reference to Exhibit 10.2 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2016 filed February 28, 2017 (No. 1-6571)
*10.3	—	Merck Sharp & Dohme Corp. 2007 Incentive Stock Plan (effective as amended and restated as of November 3, 2009) — Incorporated by reference to Exhibit 10.7 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
*10.4	—	Amendment One to the Merck Sharp & Dohme Corp. 2007 Incentive Stock Plan (effective February 15, 2010) — Incorporated by reference to Exhibit 10.2 to Merck & Co., Inc.'s Current Report on Form 8-K filed February 18, 2010 (No. 1-6571)

Exhibit Number		Description
*10.5	—	Merck & Co., Inc. 2010 Incentive Stock Plan (as amended and restated June 1, 2015) — Incorporated by reference to Merck & Co., Inc.'s Schedule 14A filed April 13, 2015 (No. 1-6571)
*10.6	—	Form of stock option terms for a non-qualified stock option under the Merck Sharp & Dohme Corp. 2007 Incentive Stock Plan and the Schering-Plough 2006 Stock Incentive Plan — Incorporated by reference to Exhibit 10.3 to Merck & Co., Inc.'s Current Report on Form 8-K filed February 18, 2010 (No. 1-6571)
*10.7	—	Form of stock option terms for 2011 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.2 to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the period ended March 31, 2011 filed May 9, 2011 (No. 1-6571)
*10.8	—	Form of stock option terms for 2012 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.20 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2011 filed February 28, 2012 (No. 1-6571)
*10.9	—	Form of stock option terms for 2013 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.19 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2012 filed February 28, 2013 (No. 1-6571)
*10.10	—	Form of stock option terms for 2014 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.18 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2014 filed February 27, 2015 (No. 1-6571)
*10.11	—	Form of stock option terms for 2015 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.20 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2015 filed February 26, 2016 (No. 1-6571)
*10.12	—	Form of stock option terms for 2018 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan
*10.13	—	Form of restricted stock unit terms for 2015 quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.22 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2015 filed February 26, 2016 (No. 1-6571)
*10.14	—	Form of performance share unit terms for 2015 grants under the Merck & Co., Inc. 2010 Stock Incentive Plan — Incorporated by reference to to Exhibit 10.21 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2015 filed February 26, 2016 (No. 1-6571)
*10.15	—	Form of stock option terms for 2016 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.19 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2016 filed February 28, 2017 (No. 1-6571)
*10.16	—	Form of restricted stock unit terms for 2016 quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.20 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2016 filed February 28, 2017 (No. 1-6571)
*10.17	—	Form of restricted stock unit terms for 2018 quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan
*10.18	—	Form of performance share unit terms for 2016 grants under the Merck & Co., Inc. 2010 Stock Incentive Plan — Incorporated by reference to Exhibit 10.21 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2016 filed February 28, 2017 (No. 1-6571)
*10.19	—	Merck & Co., Inc. Change in Control Separation Benefits Plan (effective as amended and restated, as of January 1, 2013) — Incorporated by reference to Exhibit 10.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 29, 2012 (No. 1-6571)

Exhibit Number		Description
*10.20		Merck & Co., Inc. U.S. Separation Benefits Plan (amended and restated effective as of January 1, 2017) — Incorporated by reference to Exhibit 10.24 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2016 filed February 28, 2017 (No. 1-6571)
*10.21	—	Merck & Co., Inc. 2006 Non-Employee Directors Stock Option Plan (amended and restated as of November 3, 2009) — Incorporated by reference to Exhibit 10.5 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
*10.22	—	Merck & Co., Inc. 2010 Non-Employee Directors Stock Option Plan (amended and restated as of December 1, 2010) — Incorporated by reference to Exhibit 10.17 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2010 filed February 28, 2011 (No. 1-6571)
*10.23	—	Retirement Plan for the Directors of Merck & Co., Inc. (amended and restated June 21, 1996) — Incorporated by reference to Exhibit 10.C to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1996 filed August 13, 1996 (No. 1-3305)
*10.24	—	Merck & Co., Inc. Plan for Deferred Payment of Directors' Compensation (effective as amended and restated as of January 1, 2018
10.25	—	Distribution agreement between Schering-Plough and Centocor, Inc., dated April 3, 1998 — Incorporated by reference to Exhibit 10(u) to Schering-Plough's Amended 10-K for the year ended December 31, 2003 filed May 3, 2004 (No. 1-6571)†
10.26	—	Amendment Agreement to the Distribution Agreement between Centocor, Inc., CAN Development, LLC, and Schering-Plough (Ireland) Company — Incorporated by reference to Exhibit 10.1 to Schering-Plough's Current Report on Form 8-K filed December 21, 2007 (No. 1-6571)†
10.27	—	Accelerated Share Purchase Agreement between Merck & Co., Inc. and Goldman, Sachs & Co., dated May 20, 2013 — Incorporated by reference to Exhibit 10 to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the period ended June 30, 2013 filed August 7, 2013 (No. 1-6571)
12	—	Computation of Ratios of Earnings to Fixed Charges
21	—	Subsidiaries of Merck & Co., Inc.
23	—	Consent of Independent Registered Public Accounting Firm
24.1	—	Power of Attorney
24.2	—	Certified Resolution of Board of Directors
31.1	—	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
31.2	—	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer
32.1	—	Section 1350 Certification of Chief Executive Officer
32.2	—	Section 1350 Certification of Chief Financial Officer
101	—	The following materials from Merck & Co., Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2017, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statement of Income, (ii) the Consolidated Statement of Comprehensive Income, (iii) the Consolidated Balance Sheet, (iv) the Consolidated Statement of Equity, (v) the Consolidated Statement of Cash Flows, and (vi) Notes to Consolidated Financial Statements.

* *Management contract or compensatory plan or arrangement.*

† *Certain portions of the exhibit have been omitted pursuant to a request for confidential treatment. The non-public information has been filed separately with the Securities and Exchange Commission pursuant to rule 24b-2 under the Securities Exchange Act of 1934, as amended.*