

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:

<u>Title of Each Class</u>	<u>Trading Symbol(s)</u>	<u>Name of Each Exchange on which Registered</u>
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
Non-accelerated filer

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

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 of Form 10-K

Part III



Table of Contents

Table of Contents

	<u>Page</u>
	<u>Part I</u>
Item 1. <u>Business</u>	1
Item 1A. <u>Risk Factors</u>	26
	<u>Cautionary Factors that May Affect Future Results</u> 41
Item 1B. <u>Unresolved Staff Comments</u>	42
Item 2. <u>Properties</u>	42
Item 3. <u>Legal Proceedings</u>	43
Item 4. <u>Mine Safety Disclosures</u>	43
	<u>Executive Officers of the Registrant</u> 44
	<u>Part II</u>
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	45
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	47
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	78
Item 8. <u>Financial Statements and Supplementary Data</u>	79
	(a) <u>Financial Statements</u>
	<u>Notes to Consolidated Financial Statements</u> 83
	<u>Report of Independent Registered Public Accounting Firm</u> 136
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	138
Item 9A. <u>Controls and Procedures</u>	138
	<u>Management's Report</u> 138
Item 9B. <u>Other Information</u>	139
	<u>Part III</u>
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	140
Item 11. <u>Executive Compensation</u>	140
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	141
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	141
Item 14. <u>Principal Accountant Fees and Services</u>	141
	<u>Part IV</u>
Item 15. <u>Exhibits and Financial Statement Schedules</u>	142
Item 16. <u>Form 10-K Summary</u>	146
	<u>Signatures</u> 147

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.

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, 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."

[Table of Contents](#)

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
<i>Keytruda</i>	14,380	11,084	7,171
<i>Januvia/Janumet</i>	5,276	5,524	5,914
<i>Gardasil/Gardasil 9</i>	3,938	3,737	3,151
<i>ProQuad/M-M-R II/Varivax</i>	1,878	2,275	1,798
<i>Bridion</i>	1,198	1,131	917
<i>Pneumovax 23</i>	1,087	926	907
<i>Isentress/Isentress HD</i>	857	975	1,140
<i>Simponi</i>	838	830	893
<i>RotaTeq</i>	797	791	728
Alliance revenue - Lynparza ⁽¹⁾	725	444	187
<i>Implanon/Nexplanon</i>	680	787	703
<i>Zetia/Vytorin</i>	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/ethynodiol 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 bacterin) 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	Approval
<i>Dificid</i> ⁽¹⁾	January 2020	U.S. Food and Drug Administration (FDA) approved <i>Dificid</i> as an oral suspension, and <i>Dificid</i> tablets for the treatment of Clostridioides (formerly Clostridium) difficile-associated diarrhea in children aged six months and older.
<i>Gardasil</i>	November 2020	China's National Medical Products Administration (NMPA) granted expanded approval for <i>Gardasil</i> for use in girls and women from 9 to 45 years of age.
<i>Gardasil 9</i>	December 2020	Japan's Ministry of Health, Labour and Welfare (MHLW) approved additional indication, dosage and administrations of <i>Gardasil 9</i> (marketed as <i>Silgard 9</i>) for the prevention of anal cancer (squamous cell cancer) and precursor lesions (anal intraepithelial neoplasia (AIN) grade 1/2/3) caused by HPV types 6, 11, 16 and 18 for individuals 9 years and older and for Genital Warts (condyloma acuminate) for men 9 years and older.
	July 2020	Japan's Pharmaceuticals and Medical Devices Agency (PMDA) approved <i>Gardasil 9</i> for use in girls and women 9 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.
	June 2020	FDA granted accelerated approval for an expanded indication for <i>Gardasil 9</i> for the prevention of oropharyngeal and other head and neck cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58.

[Table of Contents](#)

Keytruda	December 2020	NMPA approved <i>Keytruda</i> as monotherapy for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC whose tumors express PD-L1 (Combined Positive Score CPS ≥20) as determined by a fully validated test.
	November 2020	FDA granted accelerated approval for <i>Keytruda</i> in combination with chemotherapy for patients with locally recurrent unresectable or metastatic triple-negative breast cancer whose tumors express PD-L1 (CPS ≥10).
	October 2020	FDA approved an expanded label for <i>Keytruda</i> , as monotherapy for the treatment of adult patients with relapsed or refractory cHL.
	August 2020	PMDA approved <i>Keytruda</i> for use at an additional recommended dosage of 400 mg every six weeks (Q6W) administered as an intravenous infusion over 30 minutes across all adult indications, including <i>Keytruda</i> monotherapy and combination therapy.
	August 2020	PMDA approved <i>Keytruda</i> for the treatment of patients whose tumors are PD-L1-positive, and have radically unresectable, advanced or recurrent esophageal squamous cell carcinoma (ESCC) who have progressed after chemotherapy.
	June 2020	FDA approved <i>Keytruda</i> as monotherapy for the first-line treatment of patients with unresectable or metastatic MSI-H or dMMR colorectal cancer.
	June 2020	FDA approved <i>Keytruda</i> as monotherapy for the treatment of patients with recurrent or metastatic cSCC that is not curable by surgery or radiation.
	June 2020	NMPA approved <i>Keytruda</i> as monotherapy for the treatment of patients with locally advanced or metastatic ESCC whose tumors express PD-L1 (CPS ≥10) as determined by a fully validated test, following failure of one prior line of systemic therapy.
	June 2020	FDA granted accelerated approval for <i>Keytruda</i> as monotherapy for the treatment of adult and pediatric patients with unresectable or metastatic TMB-H [≥ 10 mutations/megabase (mut/Mb)] solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options.
	April 2020	FDA granted accelerated approval for <i>Keytruda</i> for use at an additional recommended dose of 400 mg every six weeks (Q6W) for all approved adult indications.
Koselugo ⁽²⁾	January 2020	FDA approved <i>Keytruda</i> for patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer with carcinoma in situ with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy.
	April 2020	FDA approved the kinase inhibitor Koselugo for the treatment of pediatric patients two years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN).
Lenvima	November 2020	NMPA approved Lenvima as a monotherapy for the treatment of differentiated thyroid cancer.

[Table of Contents](#)

Lynparza ⁽²⁾	December 2020	PMDA approved Lynparza for the treatment of patients with <i>BRCA</i> gene-mutated (<i>BRCA</i> m) castration-resistant prostate cancer with distant metastasis.
	December 2020	PMDA approved Lynparza as maintenance treatment after platinum-based chemotherapy for patients with <i>BRCA</i> m curatively unresectable pancreas cancer.
	December 2020	PMDA approved Lynparza as maintenance treatment after first-line chemotherapy containing bevacizumab (genetical recombination) in patients with homologous recombination repair deficient (HRD) ovarian cancer.
	November 2020	The European Commission (EC) approved Lynparza for the maintenance treatment of adult patients with advanced (FIGO stages III and IV) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy in combination with bevacizumab and whose cancer is associated with HRD-positive status defined by either a breast cancer susceptibility gene 1/2 (<i>BRCA</i> 1/2) mutation and/or genomic instability.
	November 2020	EC approved Lynparza as monotherapy for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC) and <i>BRCA</i> 1/2 mutations (germline and/or somatic) who have progressed following a prior therapy that included a new hormonal agent.
	July 2020	EC approved Lynparza as a monotherapy for the maintenance treatment of adult patients with germline <i>BRCA</i> 1/2 mutations who have metastatic adenocarcinoma of the pancreas and have not progressed after a minimum of 16 weeks of platinum treatment within a first-line chemotherapy regimen.
	May 2020	FDA approved Lynparza for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated mCRPC, as determined by an FDA-approved test, who have progressed following prior treatment with enzalutamide or abiraterone.
	May 2020	FDA approved Lynparza in combination with bevacizumab as a first-line maintenance treatment of 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 whose cancer is associated with HRD positive status defined by either a deleterious or suspected deleterious <i>BRCA</i> mutation, and/or genomic instability, as determined by an FDA-approved test.
	June 2020	FDA approved <i>Recarbrio</i> for the treatment of patients 18 years of age and older with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP).
Steglattro ⁽³⁾	July 2020	NMPA approved <i>Steglattro</i> 5 mg tablets for the treatment of type 2 diabetes.

⁽¹⁾ Difidid 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 copayments 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

[Table of Contents](#)

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)	Year of Expiration (China)
<i>Januvia</i>	2023	2022	2025-2026	2022
<i>Janumet</i>	2023	2023	N/A	2022
<i>Janumet XR</i>	2023	N/A	N/A	2022
<i>Isentress</i>	2024	2023 ⁽³⁾	2022-2026	2022
<i>Simponi</i>	N/A ⁽⁴⁾	2024 ⁽⁵⁾	N/A ⁽⁴⁾	N/A ⁽⁴⁾
<i>Lenvima⁽⁶⁾</i>	2025 ⁽³⁾ (with pending PTE)	2021 (patents), 2026 ⁽³⁾ (SPCs)	2026	2021
<i>Adempas⁽⁷⁾</i>	2026 ⁽³⁾	2028 ⁽³⁾	2027-2028	2023
<i>Bridion</i>	2026 ⁽³⁾ (with pending PTE)	2023	2024	Expired
<i>Nexplanon</i>	2027 (device)	2025 (device)	N/A	2025
<i>Bravecto</i>	2027 (with pending PTE)	2025 (patents), 2029 (SPCs)	2029	2033
<i>Gardasil</i>	2028	2021 ⁽³⁾	Expired	N/A
<i>Gardasil 9</i>	2028	2025 (patents), 2030 ⁽³⁾ (SPCs)	N/A	2025
<i>Keytruda</i>	2028	2028 (patents), 2030 ⁽³⁾ (SPCs)	2032-2033	2028
<i>Lynparza⁽⁸⁾</i>	2028 ⁽³⁾ (with pending PTE)	2024 (patents), 2029 ⁽³⁾ (SPCs)	2028-2029	2024
<i>Zerbaxa</i>	2028 ⁽³⁾	2023 (patents), 2028 ⁽³⁾ (SPCs)	2028 (with pending PTE)	N/A
<i>Sivextro</i>	2028	2024 (patents), 2029 (SPCs)	2029	2024
<i>Belsomra</i>	2029 ⁽³⁾	N/A	2031	N/A
<i>Prevymis</i>	2029 ⁽³⁾ (with pending PTE)	2024 (patents), 2029 ⁽³⁾ (SPCs)	2029	N/A
<i>Segluromet⁽⁹⁾</i>	2031 (with pending PTE)	2029 (patents), 2034 (SPCs)	N/A ⁽¹⁰⁾	N/A
<i>Steglatro⁽⁹⁾</i>	2031 ⁽³⁾ (with pending PTE)	2029 (patents), 2034 ⁽³⁾ (SPCs)	N/A ⁽¹⁰⁾	2029
<i>Steglujan⁽⁹⁾</i>	2031 (with pending PTE)	2029 (patents), 2034 (SPCs)	N/A ⁽¹⁰⁾	N/A
<i>Verquvo⁽⁷⁾</i>	2031 (with pending PTE)	N/A ⁽¹¹⁾	N/A ⁽¹¹⁾	N/A ⁽¹¹⁾
<i>Delstrigo</i>	2032 (with pending PTE)	2031 (patents), 2033 (SPCs)	N/A	N/A
<i>Pifelstro</i>	2032 (with pending PTE)	2031 (patents), 2033 (SPCs)	2036	2031
<i>Recarbio</i>	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.

[Table of Contents](#)

- (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 $\geq 50\%$). 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-2 α (HIF-2 α) 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 (NRTI), and doravirine (*Pifelro*) 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 Steglatiro (ertugliflozin) to incorporate the results of the Phase 3 VERTIS cardiovascular (CV) outcomes trial in the product labeling. The VERTIS CV trial evaluated Steglatiro, 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 Steglatiro 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 Steglatiro. 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.

Table of Contents

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 <i>Keytruda</i> 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 <i>Keytruda</i> 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 <i>Keytruda</i> • 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

[Table of Contents](#)

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	Offices and Business Experience
Kenneth C. Frazier	66	Chairman, President and Chief Executive Officer (since December 2011)
Sanat Chattopadhyay	61	Executive Vice President and President, Merck Manufacturing Division (since March 2016)
Frank Clyburn	56	Executive Vice President, Chief Commercial Officer (since January 2019); President, Global Oncology Business Unit (October 2013-December 2018)
Robert M. Davis	54	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.	58	Executive Vice President and President, Merck Animal Health (since September 2011)
Michael W. Fleming	62	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	65	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	57	Senior Vice President Finance - Global Controller (since March 2014)
Dean Li	58	President, Merck Research Laboratories (since January 2021); Senior Vice President, Discovery Sciences and Translational Medicine, Merck Research Laboratories (November 2017-January 2020); Vice President, Translational Medicine (March 2017-November 2017); Prior to that, Chief Scientific Officer and Associate Vice President, University of Utah Health Sciences
Steven C. Mizell	60	Executive Vice President, Chief Human Resources Officer (since December 2016); Executive Vice President, Human Resources, Monsanto Company (August 2011-December 2016)
Michael T. Nally	45	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)
Jennifer Zachary	43	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)

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

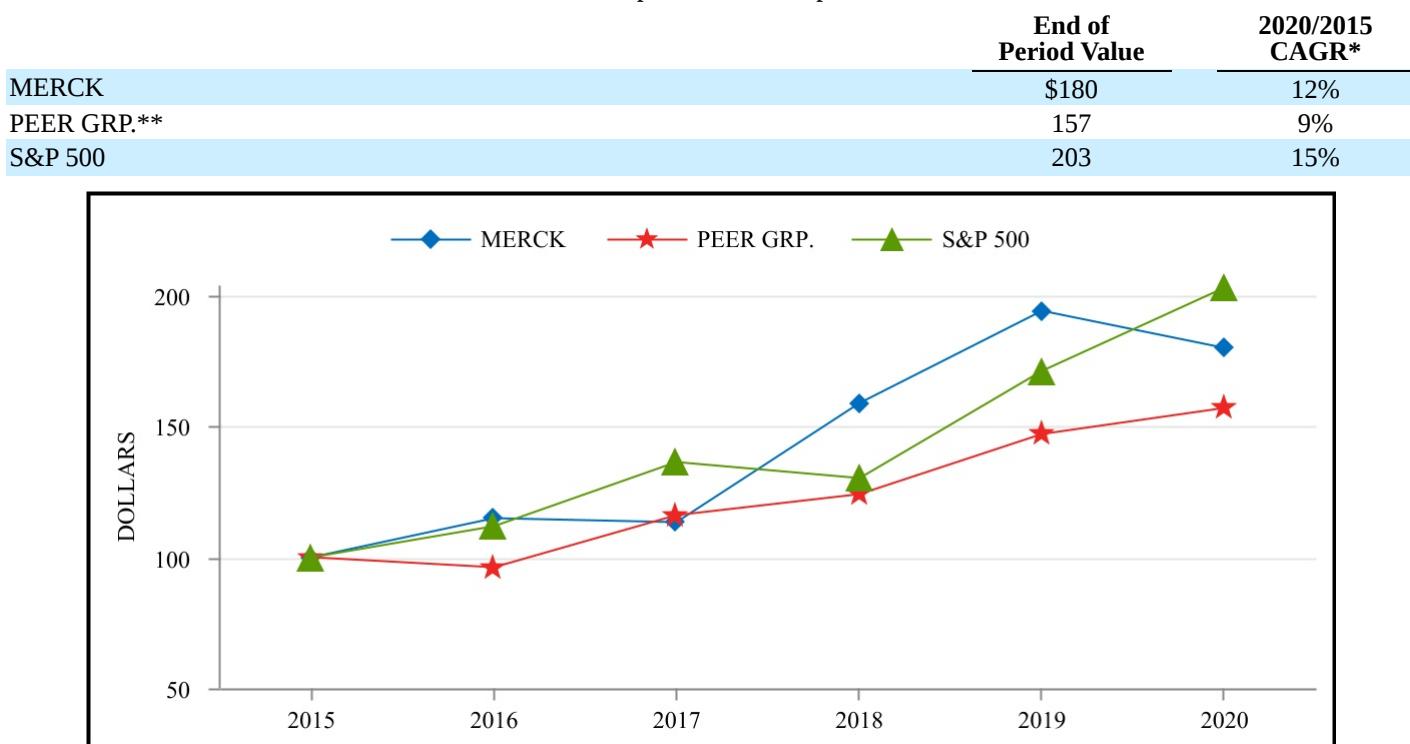
⁽¹⁾ The Company did not purchase any shares during the three months ended December 31, 2020 under the plan approved by the Board of Directors in October 2018 to purchase up to \$10 billion in Merck shares for its treasury.

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



	2015	2016	2017	2018	2019	2020
MERCK	100.0	115.1	113.4	158.9	194.3	180.1
PEER GRP.	100.0	96.9	116.1	124.1	147.2	157.2
S&P 500	100.0	112.0	136.4	130.4	171.4	203.0

* 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.

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 *BRCA1/2* 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 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-2 α) 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

[Table of Contents](#)

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
			2020			2019	
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
			2020			2019	
<i>Keytruda</i>	\$ 14,380	30 %	30 %	\$ 11,084	55 %	58 %	\$ 7,171
<i>Alliance Revenue - Lynparza</i> ⁽¹⁾	725	63 %	62 %	444	137 %	141 %	187
<i>Alliance Revenue - Lenvima</i> ⁽¹⁾	580	44 %	43 %	404	171 %	173 %	149
<i>Emend</i>	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 *BRCA1/2* 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 *BRCA1/2* 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
			2020			2018	
<i>Gardasil/Gardasil 9</i>	\$ 3,938	5 %	6 %	\$ 3,737	19 %	21 %	\$ 3,151
<i>ProQuad</i>	678	(10)%	(10)%	756	27 %	29 %	593
<i>M-M-R II</i>	378	(31)%	(31)%	549	28 %	29 %	430
<i>Varivax</i>	823	(15)%	(15)%	970	25 %	28 %	774
<i>Pneumovax 23</i>	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	
			2019	2018			2019	2018
<i>Bridion</i>	\$ 1,198	6 %	7 %	\$ 1,131	23 %	26 %	\$ 917	
<i>Noxafil</i>	329	(50)%	(50)%	662	(11)%	(7)%	742	
<i>Prevymis</i>	281	70 %	69 %	165	128 %	131 %	72	
<i>Cubicin</i>	152	(41)%	(40)%	257	(30)%	(28)%	367	
<i>Zerbaxa</i>	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 allogeneic 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	2019	% Change	% Change	2018
			Excluding Foreign Exchange			Excluding Foreign Exchange	
<i>Simponi</i>	\$ 838	1 %	1 %	\$ 830	(7)%	(2)%	\$ 893
<i>Remicade</i>	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	2019	% Change	% Change	2018
			Excluding Foreign Exchange			Excluding Foreign Exchange	
<i>Isentress/Isentress HD</i>	\$ 857	(12)%	(11)%	\$ 975	(15)%	(10)%	\$ 1,140
<i>Zepatier</i>	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	2019	% Change	% Change	2018
			Excluding Foreign Exchange			Excluding Foreign Exchange	
<i>Zetia/Vytorin</i>	\$ 664	(24)%	(24)%	\$ 874	(35)%	(34)%	\$ 1,355
<i>Atozet</i>	453	16 %	16 %	391	13 %	18 %	347
<i>Rosuzet</i>	130	8 %	9 %	120	107 %	115 %	58
<i>Alliance revenue - Adempas</i> ⁽¹⁾	281	38 %	38 %	204	47 %	47 %	139
<i>Adempas</i>	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	2019	% Change	% Change	2018
			Excluding Foreign Exchange			Excluding Foreign Exchange	
<i>Januvia/Janumet</i>	\$ 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	2019	% Change	% Change	2018
			Excluding Foreign Exchange			Excluding Foreign Exchange	
<i>Implanon/Nexplanon</i>	680	(14)%	(13)%	787	12 %	14 %	703
<i>NuvaRing</i>	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	2019	% Change	% Change	2018
			Excluding Foreign Exchange			Excluding Foreign Exchange	
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	2019	% Change	% Change	2018
			Excluding Foreign Exchange			Excluding Foreign Exchange	
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

<i>(\$ in millions)</i>	<i>2020</i>	<i>2019</i>	<i>2018</i>
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).

[Table of Contents](#)

A reconciliation between GAAP financial measures and non-GAAP financial measures is as follows:

<i>(\$ in millions except per share amounts)</i>	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:

<i>Payments Due by Period</i>	Total	2021	2022—2023	2024—2025	Thereafter
<i>(</i> \$ in millions <i>)</i>					
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.

[Table of Contents](#)

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	1,788	1,788
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.

[Table of Contents](#)

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 expedites 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.

[Table of Contents](#)

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:

<i>Years Ended December 31</i>	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
<i>December 31</i>	2020	2019	
Receivables from AstraZeneca included in <i>Other current assets</i>	\$ 215	\$ 128	
Payables to AstraZeneca included in <i>Accrued and other current liabilities</i> ⁽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:

<i>Years Ended December 31</i>	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
<i>December 31</i>	2020	2019	
Receivables from Eisai included in <i>Other current assets</i>	\$ 157	\$ 150	
Payables to Eisai included in <i>Accrued and other current liabilities</i> ⁽³⁾	335	700	
Payables to Eisai included in <i>Other Noncurrent Liabilities</i> ⁽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:

<i>Years Ended December 31</i>	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
<i>December 31</i>	2020	2019	
Receivables from Bayer included in <i>Other current assets</i>	\$ 65	\$ 49	
Payables to Bayer included in <i>Other Noncurrent Liabilities</i> ⁽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:

Years Ended December 31	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		
	2020	2019	2018	2020	2019	2018
<i>Net Investment Hedging Relationships</i>						
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:

Debt Instrument	2020		
	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.

[Table of Contents](#)

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:

Balance Sheet Caption	2020			2019		
	Fair Value of Derivative		U.S. Dollar Notional	Fair Value of Derivative		U.S. Dollar Notional
	Asset	Liability		Asset	Liability	
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	—
Interest rate swap contracts	Accrued and other current liabilities	—	—	—	—	1,250
Foreign exchange contracts	Other current assets	12	—	3,183	152	—
Foreign exchange contracts	Other Assets	45	—	2,030	55	—
Foreign exchange contracts	Accrued and other current liabilities	—	217	5,049	—	22
Foreign exchange contracts	Other Noncurrent Liabilities	—	1	52	—	1
		\$ 112	\$ 218	\$ 13,714	\$ 222	\$ 24
						14,728
Derivatives Not Designated as Hedging Instruments						
Foreign exchange contracts	Other current assets	\$ 70	\$ —	\$ 7,260	\$ 66	\$ —
Foreign exchange contracts	Accrued and other current liabilities	—	307	11,810	—	73
		\$ 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

[Table of Contents](#)

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:

Years Ended December 31	Sales			Other (income) expense, net ⁽¹⁾			Other comprehensive income (loss)		
	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:

Years Ended December 31	Derivatives Not Designated as Hedging Instruments	Income Statement Caption	Amount of Derivative Pretax (Gain) Loss Recognized in Income		
			2020	2019	2018
Foreign exchange contracts ⁽¹⁾	Foreign exchange contracts	Other (income) expense, net	\$ (12)	\$ 174	\$ (260)
Forward contract related to Seagen common stock	Interest rate contracts ⁽²⁾	Sales	13	1	(8)
	Research and development expenses	Other (income) expense, net	9	—	—
		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				
	Amortized Cost	Gross Unrealized		Fair Value	Amortized Cost	Gross Unrealized		Fair Value		
		Gains	Losses			Gains	Losses			
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 price 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.

[Table of Contents](#)

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																
<i>Investments</i>																
Foreign government bonds	\$ —	\$ 5	\$ —	\$ 5	\$ —	\$ 668	\$ —	\$ 668								
Commercial paper	—	—	—	—	—	621	—	621								
Corporate notes and bonds	—	—	—	—	—	227	—	227								
Asset-backed securities	—	—	—	—	—	209	—	209								
U.S. government and agency securities	—	—	—	—	518	—	—	518								
Publicly traded equity securities	780	—	—	780	518	—	—	518								
	780	5	—	785	518	1,725	—	2,243								
<i>Other assets ⁽¹⁾</i>																
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								
<i>Derivative assets ⁽²⁾</i>																
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																
<i>Other liabilities</i>																
Contingent consideration	\$ —	\$ —	\$ 841	\$ 841	\$ —	\$ 767	\$ —	\$ 767								
<i>Derivative liabilities ⁽²⁾</i>																
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; *Difidid*, \$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 (gefaapixant) 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.

[Table of Contents](#)

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
Balance January 1	3,577	1,038	3,577	985	3,577
Purchases of treasury stock	—	16	—	66	—
Issuances ⁽¹⁾	—	(7)	—	(13)	—
Balance December 31	3,577	1,047	3,577	1,038	3,577

⁽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:

Years Ended December 31	Pension Benefits						Other Postretirement Benefits		
	U.S.			International					
	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.

[Table of Contents](#)

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	
<i>Investment funds</i>										
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
<i>Equity securities</i>										
Developed markets	2,819	—	—	—	2,819	2,451	—	—	—	2,451
<i>Fixed income securities</i>										
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	
<i>Investment funds</i>										
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
<i>Equity securities</i>										
Developed markets	505	—	—	—	505	565	—	—	—	565
<i>Fixed income securities</i>										
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
<i>Other investments</i>										
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.

[Table of Contents](#)

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	\$ 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	
<i>Investment funds</i>										
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	—	—	—	—	—
<i>Equity securities</i>	258	—	—	258	225	—	—	—	—	225
<i>Fixed income securities</i>										
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	\$ 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*:

Years Ended December 31	Pension Plans						Other Postretirement Benefit Plans		
	U.S.			International					
	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:

December 31	U.S. Pension and Other Postretirement Benefit Plans			International Pension Plans		
	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:

<i>Years Ended December 31</i>	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:

<i>Years Ended December 31</i>	2020	2019	2018
<i>Current provision</i>			
Federal	\$ 962	\$ 514	\$ 536
Foreign	1,362	1,806	2,281
State	53	(77)	200
	2,377	2,243	3,017
<i>Deferred provision</i>			
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:

<i>Years Ended December 31</i>	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.

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.

[Table of Contents](#)

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
Other segment sales ⁽⁴⁾	23	—	23	174	1	175	248	2	250
Total segment sales	20,956	26,791	47,747	20,433	25,885	46,319	18,228	23,923	42,151
Other ⁽⁵⁾	71	176	247	86	436	521	118	26	143
	\$ 21,027	\$ 26,967	\$ 47,994	\$ 20,519	\$ 26,321	\$ 46,840	\$ 18,346	\$ 23,949	\$ 42,294

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.

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.

PricewaterhouseCoopers LLP

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.

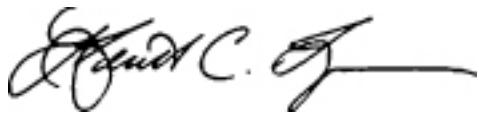
Management's Report on Internal Control Over Financial Reporting

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.



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 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)

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.

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 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 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
(Attorney-in-Fact)