

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, 2022

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.

126 East Lincoln Avenue
Rahway New Jersey 07065

(908) 740-4000

22-1918501

(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
0.5000% Notes due 2024	MRK 24	New York Stock Exchange
1.875% Notes due 2026	MRK/26	New York Stock Exchange
2.5000% Notes due 2034	MRK/34	New York Stock Exchange
1.375% Notes due 2036	MRK 36A	New York Stock Exchange

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.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

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

Number of shares of Common Stock (\$0.50 par value) outstanding as of January 31, 2023: 2,538,592,467.

Aggregate market value of Common Stock (\$0.50 par value) held by non-affiliates on June 30, 2022 based on the closing price on June 30, 2022: \$ 230,820,000,000 .

Documents Incorporated by Reference:

Document

Part of Form 10-K

Proxy Statement for the Annual Meeting of Shareholders to be held May 23, 2023, to be filed with the
Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this report

Part III

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PART I**Item 1. Business.**

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

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

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

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

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 service marks are those of their respective owners.

Product Sales

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

<i>(\$ in millions)</i>	2022	2021	2020
Total Sales	\$ 59,283	\$ 48,704	\$ 41,518
Pharmaceutical	52,005	42,754	36,610
Keytruda	20,937	17,186	14,380
Gardasil/Gardasil 9	6,897	5,673	3,938
Lagevrio	5,684	952	—
Januvia/Janumet	4,513	5,288	5,276
ProQuad/M-M-R II/Varivax	2,241	2,135	1,878
Bridion	1,685	1,532	1,198
Alliance revenue - Lynparza ⁽¹⁾	1,116	989	725
Alliance revenue - Lenvima ⁽¹⁾	876	704	580
RotaTeq	783	807	797
Simponi	706	825	838
Animal Health	5,550	5,568	4,703
Livestock	3,300	3,295	2,939
Companion Animals	2,250	2,273	1,764
Other Revenues ⁽²⁾	1,728	382	205

⁽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 miscellaneous corporate revenues, including revenue hedging activities, as well as revenue from third-party manufacturing arrangements.

Pharmaceutical

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

Oncology

Keytruda (pembrolizumab), the Company's anti-PD-1 (programmed death receptor-1) therapy, as monotherapy for the treatment of certain patients with cervical cancer, classical Hodgkin lymphoma (CHL), cutaneous squamous cell carcinoma (cSCC), esophageal or gastroesophageal junction (GEJ) carcinoma, head and neck squamous cell carcinoma (HNSCC), hepatocellular carcinoma (HCC), non-small-cell lung cancer (NSCLC), melanoma, Merkel cell carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer (solid tumors), including MSI-H/dMMR colorectal cancer (CRC), MSI-H/dMMR advanced endometrial carcinoma, primary mediastinal large B-cell lymphoma (PMBCL), tumor mutational burden-high (TMB-H) cancer (solid tumors), and urothelial carcinoma, including non-muscle invasive bladder cancer. *Keytruda* is also approved for the treatment of certain patients in combination with chemotherapy for metastatic squamous and non-squamous NSCLC, in combination with chemotherapy for HNSCC, in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy for human epidermal growth factor 2 (HER2)-positive gastric or GEJ adenocarcinoma, in combination with platinum-and fluoropyrimidine-based chemotherapy for esophageal or GEJ carcinoma, in combination with chemotherapy, with or without bevacizumab, for advanced cervical cancer, in combination with chemotherapy for locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC), and in combination with axitinib for advanced renal cell carcinoma (RCC). *Keytruda* is also approved for certain patients with high-risk early-stage TNBC in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery. *Keytruda* is also approved as a monotherapy for the adjuvant treatment of certain patients with RCC, for certain patients with completely resected stage IIB, IIC or III melanoma, and for adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage IB (T2a \geq 4 cm), II, or IIIA NSCLC. 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 or recurrent ovarian, early or metastatic breast, metastatic pancreatic, and metastatic castration-resistant prostate cancers; alliance revenue related to sales of *Lenvima* (lenvatinib), an oral receptor tyrosine kinase inhibitor, for certain types of thyroid cancer, RCC, HCC, in combination with everolimus for certain patients with advanced RCC, and in combination with *Keytruda* for certain patients with advanced endometrial carcinoma or advanced RCC; and alliance revenue related to *Reblozyl* (luspatercept-aamt) for the treatment of certain types of anemia.

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); *RotaTeq* (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children; *Pneumovax 23* (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease; and *Vaqta* (hepatitis A vaccine, inactivated) indicated for the prevention of disease caused by hepatitis A virus in persons 12 months of age and older.

Hospital Acute Care

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

Cardiovascular

Adempas (riociguat), a cardiovascular drug for the treatment of chronic thromboembolic pulmonary hypertension or pulmonary arterial hypertension in certain patients; *Verquvo* (vericiguat), a medicine to reduce the

risk of cardiovascular death and heart failure hospitalization following a hospitalization for heart failure or need for outpatient intravenous diuretics in certain adults with symptomatic chronic heart failure and reduced ejection fraction.

Virology

Lagevrio, an investigational oral antiviral COVID-19 medicine available in the U.S. under Emergency Use Authorization (EUA); *Isentress/Isentress HD* (raltegravir), an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection.

Neuroscience

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

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 Türkiye.

Diabetes

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

Animal Health

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

Livestock Products

Nuflor (Florfenicol) antibiotic range for use in cattle and swine; *Bovilis/Vista* vaccine lines for infectious diseases in cattle; *Banamine* (Flunixin meglumine) bovine and swine anti-inflammatory; *Estrumate* (cloprostenol sodium) for the treatment of fertility disorders in cattle; *Matrix* (altrenogest) fertility management for swine; *Resflor* (florfenicol and flunixin meglumine), a combination broad-spectrum antibiotic and non-steroidal anti-inflammatory drug for bovine respiratory disease; *Zuprevo* (Tildipirosin) for bovine respiratory disease; *Zilmax* (zilpaterol hydrochloride) and *Revalor* (trenbolone acetate and estradiol) to improve production efficiencies in beef cattle; *Safe-Guard* (fenbendazole) de-wormer for cattle; *M+Pac* (*Mycoplasma Hyopneumoniae* Bacterin) swine pneumonia vaccine; *Porcilis* (*Lawsonia intracellularis* 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.

2022 Product Approvals

Set forth below is a summary of significant product approvals received by the Company in 2022.

Product	Date	Approval
Keytruda	January 2022	European Commission (EC) approved <i>Keytruda</i> as monotherapy for the adjuvant treatment of adults with RCC at increased risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.
	February 2022	Japan's Ministry of Health, Labor and Welfare (MHLW) approved <i>Keytruda</i> plus Lenvima for radically unresectable or metastatic RCC.
	February 2022	MHLW approved <i>Keytruda</i> for the treatment of adult patients with advanced or recurrent TMB-H solid tumors that have progressed after chemotherapy (limited to use when difficult to treat with standard of care).
	March 2022	U.S. Food and Drug Administration (FDA) approved <i>Keytruda</i> as a single agent for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.
	April 2022	EC approved <i>Keytruda</i> in combination with chemotherapy, with or without bevacizumab, for the treatment of persistent, recurrent or metastatic cervical cancer in certain adults whose tumors express PD-L1.
	April 2022	EC approved <i>Keytruda</i> as monotherapy for the treatment of certain patients with unresectable or metastatic MSI-H/dMMR colorectal, gastric, small intestine or biliary cancer, as well as advanced or recurrent MSI-H/dMMR endometrial carcinoma.
	May 2022	EC approved <i>Keytruda</i> in combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery for adults with locally advanced or early-stage TNBC at high risk of recurrence.
Keytruda	June 2022	EC approved <i>Keytruda</i> as monotherapy for the adjuvant treatment of adults and adolescents aged 12 years and older with stage IIB or IIC melanoma and who have undergone complete resection. Additionally, EC approved expanded indications in advanced (unresectable or metastatic) melanoma and stage III melanoma with lymph node involvement (as adjuvant treatment following complete resection) to include adolescent patients aged 12 years and older.
	August 2022	MHLW approved <i>Keytruda</i> as monotherapy for the adjuvant treatment of certain patients with RCC at increased risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.
	September 2022	MHLW approved <i>Keytruda</i> in combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery for patients with hormone receptor-negative and HER2-negative breast cancer at high risk of recurrence.
	September 2022	MHLW approved <i>Keytruda</i> in combination with chemotherapy, with or without bevacizumab, for the treatment of patients with advanced or recurrent cervical cancer with no prior chemotherapy who are not amenable to curative treatment.
	September 2022	MHLW approved <i>Keytruda</i> as monotherapy for the adjuvant treatment of patients with stage IIB or IIC melanoma after complete resection.
	October 2022	China's National Medical Products Administration (NMPA) approved <i>Keytruda</i> as monotherapy for the treatment of patients with HCC who have been previously treated with sorafenib or oxaliplatin-based chemotherapy.
	November 2022	NMPA approved <i>Keytruda</i> for the treatment of patients with high-risk early-stage TNBC whose tumors express PD-L1, in combination with chemotherapy as neoadjuvant treatment, and then continued as a monotherapy as adjuvant treatment after surgery.

<i>Lagevrio⁽¹⁾</i>	December 2022	NMPA granted emergency conditional approval for <i>Lagevrio</i> for the treatment of moderate COVID-19 in adults who are at risk for progressing to severe COVID-19.
<i>Lynparza⁽²⁾</i>	March 2022	FDA approved Lynparza for the adjuvant treatment of adult patients with deleterious suspected deleterious germline <i>BRCA</i> -mutated, HER2-negative high-risk early cancer who have been treated with neoadjuvant or adjuvant chemotherapy.
	August 2022	MHLW approved Lynparza for the adjuvant treatment for patients with <i>BRCA</i> -negative, HER2-negative high recurrent risk breast cancer.
	August 2022	EC approved Lynparza as monotherapy or in combination with endocrine therapy adjuvant treatment of adult patients with germline <i>BRCA1/2</i> -mutations who have negative, high-risk early breast cancer previously treated with neoadjuvant or adjuvant chemotherapy.
	September 2022	NMPA approved Lynparza as first-line maintenance treatment for adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who have complete or partial response to first-line platinum-based chemotherapy in combination with bevacizumab and whose cancer is associated with homologous recombination deficiency (HRD)-positive status.
	December 2022	EC approved Lynparza in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated.
	June 2022	FDA approved an expanded indication for <i>Vaxneuvance</i> (Pneumococcal 13-valent Conjugate Vaccine) to include children 6 weeks through 17 years of age. <i>Vaxneuvance</i> is now indicated for active immunization for the prevention of invasive disease caused by <i>Streptococcus pneumoniae</i> serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F and 33F in individuals 6 weeks of age and older.
<i>Vaxneuvance</i>	September 2022	MHLW approved <i>Vaxneuvance</i> for prevention of infections caused by <i>Streptococcus pneumoniae</i> in the elderly or adults who are considered at increased risk for infection caused by <i>Streptococcus pneumoniae</i> .
	October 2022	EC approved an expanded indication for <i>Vaxneuvance</i> to include active immunization for the prevention of invasive disease, pneumonia and acute otitis media caused by <i>Streptococcus pneumoniae</i> in infants, children and adolescents from 6 weeks to 18 years of age.

⁽¹⁾ Being jointly developed in collaboration with Ridgeback Biotherapeutics LP.

⁽²⁾ Being jointly developed and commercialized in a worldwide collaboration with AstraZeneca.

Competition and the Health Care Environment

Competition

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

Pharmaceutical competition involves a rigorous search for technological innovations and the ability to market these innovations effectively. With its long-standing emphasis on research and development, the Company is well-positioned to compete in the search for technological innovations. The Company is active in acquiring and

marketing products through external alliances, such as licensing arrangements and collaborations and has been refining its sales and marketing efforts to address changing industry conditions. However, the introduction of new products and processes by competitors may result in price reductions and product displacements, even for products protected by patents. For example, the number of compounds available to treat a particular disease typically increases over time and can result in slowed sales growth or reduced sales for the Company's products in that therapeutic category.

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

Health Care Environment and Government Regulation

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access. Changes to the U.S. health care system as part of health care reform enacted in prior years, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, have contributed to pricing pressure. In several international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. In addition, the Company's sales performance in 2022 was negatively affected by other cost-reduction measures taken by governments and other third parties to lower health care costs. In the U.S., the Biden Administration and Congress continue to discuss legislation designed to control health care costs, including the cost of drugs. The Company anticipates all of these actions and additional actions in the future will continue to negatively affect sales and profits.

United States

The Company faces increasing pricing pressure from managed care organizations, government agencies and programs that could negatively affect the Company's sales and profit margins, including, through (i) practices of managed care organizations, federal and state exchanges, and institutional and governmental purchasers, and (ii) federal laws and regulations related to Medicare and Medicaid, including the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Patient Protection and Affordable Care Act of 2010 (ACA), the American Rescue Plan Act of 2021 (American Rescue Plan Act), and the Inflation Reduction Act of 2022 (Inflation Reduction Act).

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

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

In order to provide information about the Company's pricing practices, the Company annually posts on its website its Pricing Transparency Report for the U.S. The report provides the Company's average annual list price, net price increases, and average discounts across the Company's U.S. portfolio dating back to 2010. In 2022, the Company's gross U.S. sales were reduced by 39.7% as a result of rebates, discounts and returns.

Legislative Changes

In 2022, Congress passed the Inflation Reduction Act, which makes significant changes to how drugs are covered and paid for under the Medicare program, including the creation of financial penalties for drugs whose prices rise faster than the rate of inflation, redesign of the Medicare Part D program to require manufacturers to bear more of

the liability for certain drug benefits, and government price-setting for certain Medicare Part D drugs, starting in 2026, and Medicare Part B drugs starting in 2028.

The long-term implications of the Inflation Reduction Act remain uncertain and subject to various factors, including the manner in which U.S. Department of Health and Human Services decides to implement the statute. Many experts and analysts, both within the industry and outside, have predicted that the law will harm innovation in the pharmaceutical industry and result in fewer new treatments being developed and approved over time. Merck is working to mitigate the potentially harmful effects that the law could have on innovation.

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

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

[*Regulatory Changes*](#)

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

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

[*European Union*](#)

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

Additionally, EU Member States have the power to restrict the range of pharmaceutical products for which their national health insurance systems provide reimbursement. In the EU, pricing and reimbursement plans vary widely from Member State to Member State. Some EU Member States provide that drug products may be marketed only after a reimbursement price has been agreed. Some EU Member States may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to already available therapies or so-called health technology assessments (HTA), in order to obtain reimbursement or pricing approval. The HTA of pharmaceutical products is becoming an increasingly common part of the pricing and reimbursement procedures in

most EU Member States. The HTA process, which is governed by the national laws of these countries, involves the assessment of the cost-effectiveness, public health impact, therapeutic impact and/or the economic and social impact of use of a given pharmaceutical product in the national health care system of the individual country in which it is conducted. Ultimately, HTA measures the added value of a new health technology compared to existing ones. The outcome of HTAs regarding specific pharmaceutical products will often influence the pricing and reimbursement status granted to these pharmaceutical products by the regulatory authorities of individual EU Member States. A negative HTA of one of the Company's products may mean that the product is not reimbursable or may force the Company to reduce its reimbursement price or offer discounts or rebates.

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

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

Japan

In Japan, the pharmaceutical industry is subject to government-mandated annual price reductions of pharmaceutical products and certain vaccines. Furthermore, the government can order re-pricings for specific products if it determines that use of such product will exceed certain thresholds defined under applicable re-pricing rules. In addition, if a Merck product has the same medical action or composition of another product that is subject to market expansion re-pricing, the Merck product could also be subject to re-pricing unless it meets exception criteria. The next government-mandated price reduction will occur in April 2023.

China

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

Emerging Markets

The Company's focus on emerging markets, in addition to China, has continued. Governments in many emerging markets are also focused on constraining health care costs and have enacted price controls and measures impacting intellectual property, including in exceptional cases, threats of compulsory licenses, 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, and other

developments that may adversely impact the business environment for the Company. Further, the Company may engage third-party agents to assist in operating in emerging market countries, which may affect its ability to realize continued growth and may also increase the Company's risk exposure.

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

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

Regulation

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

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

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

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

Access to Medicines

As a global health care company, Merck's primary role is to discover and develop innovative medicines and vaccines. The Company also recognizes that, in collaboration with key stakeholders, it has a role to play in helping to ensure that its science advances health care, and its products are accessible and affordable. The Company is committed to ensuring a reliable, safe global supply of its quality medicines and vaccines, and to developing, testing and implementing innovative solutions that address barriers to access and affordability of its medicines and vaccines. The Company's approach is designed to enable it to serve the greatest number of patients today, while meeting the needs of patients in the future. The Company's efforts in this regard are wide-ranging and include a set of principles that the Company strives to embed into its operations and business strategies to guide the Company's worldwide approach to expanding access to health care. The Company systematically evaluates its pipeline candidates to identify potential to address significant public health burden and unmet medical needs in underserved health care settings. Products continue to be evaluated for their potential throughout their life cycle to account for changes in the external environment. The Company also collaborates with different stakeholders,

including private, governmental, multilateral and non-profit organizations, to design and deliver sustainable solutions to help address access challenges at the payer, provider and patient levels.

In addition, through innovative social investments, including philanthropic programs and impact investing, Merck is helping to strengthen health systems and build capacity, particularly in under-resourced communities. The Merck Patient Assistance Program provides certain medicines and adult vaccines for free to people in the U.S. who do not have prescription drug or health insurance coverage and who, without the Company's assistance, cannot afford their Merck medicines and vaccines. Globally, Merck has made substantial contributions to access to health through key initiatives, including product donations for humanitarian assistance in low-income countries through the Medical Outreach Program. The Mectizan Donation Program, the longest running disease-specific drug donation program of its kind, supports the elimination of two neglected tropical diseases – onchocerciasis and lymphatic filariasis. Additionally, through Merck for Mothers the Company provides funding, and scientific and business acumen to help global health partners end preventable deaths from complications of pregnancy and childbirth. Merck has also provided funds to the Merck Foundation, an independent grantmaking organization, which supports a variety of organizations dedicated to addressing systemic barriers to health equity.

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 imposes penalties of up to 4% of global revenue.

The GDPR and related implementing laws in individual EU Member States govern the collection and use of personal health data and other personal data in the EU. The GDPR increased responsibility and liability in relation to personal data that the Company processes. It also imposes a number of strict obligations and restrictions on the ability to process (which includes collection, analysis and transfer of) personal data, including health data from clinical trials and adverse event reporting. The GDPR also includes requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals prior to processing their personal data or personal health data, notification of data processing obligations to the national data protection authorities, and the security and confidentiality of the personal data. Further, the GDPR prohibits the transfer of personal data to countries outside of the EU that are not considered by the EC to provide an adequate level of data protection, including to the U.S., except if the data controller meets very specific requirements. Following the Schrems II decision of the Court of Justice of the EU in 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. Since then, the Company diligently entered into the EU-approved Standard Contractual Clauses with its vendors, suppliers, collaboration partners and clinical trial sites in order to facilitate the lawful transfer of personal data from the EU to the U.S. In addition, President Biden issued an Executive Order on October 7, 2022 to address the data privacy concerns raised in the Schrems II decision through introducing, among other measures, further safeguards and oversight of personal data collection by U.S. signals intelligence activities and providing individuals with a redress mechanism in the U.S. for their data protection concerns. Further certainty for the international transfer of personal data from the EU via the EU-U.S. Data Privacy Framework (successor to the invalidated EU-U.S. Privacy Shield) may come by way of a new EU Adequacy Decision, issued in draft form by the EU Commission on December 13, 2022 and expected to come into force in mid-2023. However, it remains likely that such a new Adequacy Decision will be contested by privacy advocates and be subject to legal review.

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

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

different regulatory frameworks further adds to the complexity that the Company faces with regard to data protection regulation.

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

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

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

Distribution

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

Patents, Trademarks and Licenses

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

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

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

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

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

N/A: Currently no marketing approval.

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

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

⁽³⁾ As a result of favorable court rulings and settlement agreements related to a later expiring patent directed to the specific sitagliptin salt form of the products, the Company expects that these products will not lose market exclusivity in the U.S. before the end of 2023, and it is likely that exclusivity will extend through May 2026.

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

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

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

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

⁽⁸⁾ Eligible for 6 months Pediatric Exclusivity.

⁽⁹⁾ Part of a global strategic oncology collaboration with AstraZeneca.

⁽¹⁰⁾ Being commercialized in a worldwide collaboration with Bayer AG.

⁽¹¹⁾ The Company has no marketing rights in the U.S.

⁽¹²⁾ The Company has no marketing rights in the EU, Japan or China.

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

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

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

Phase 3 Drug Candidate	Currently Anticipated Year of Expiration (in the U.S.)
MK-7962 (sotatercept) ⁽¹⁾	2027
MK-8591A (doravirine + islatravir)	2032 (pending PTE for doravirine)
MK-1308A (quavonlimab + pembrolizumab)	2035
MK-7684A (vibostolimab + pembrolizumab)	2035
MK-4280A (favezelimab + pembrolizumab)	2035
MK-1654 (clesrovimab)	2036
MK-4482 <i>Lagevrio</i> ⁽²⁾	2038
V-116 (pneumococcal vaccine)	2038
MK-3475A (pembrolizumab + hyaluronidase subcutaneous)	2039

⁽¹⁾ As a biologic product, sotatercept will be eligible for 12 years of data exclusivity upon approval in the U.S.

⁽²⁾ Received Emergency Use Authorization from the FDA for the treatment of high-risk adults with mild to moderate COVID-19.

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

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

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

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

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

Royalty income in 2022 on patent and know-how licenses and other rights amounted to \$537 million. Merck also incurred royalty expenses amounting to \$3.0 billion in 2022 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, 2022, approximately 19,200 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 for unmet medical needs 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 through acquisitions as well as a licensing and external alliance strategy focused on the entire spectrum of collaborations from early research to late-stage compounds, as well as access to new technologies.

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

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

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

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

In the U.S., the FDA review process begins once a complete NDA or BLA is submitted, received and accepted for review by the agency. Within 60 days after receipt, the FDA determines if the application is sufficiently complete to permit a substantive review. The FDA also assesses, at that time, whether the application will be granted.

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

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

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

The primary method the Company uses to obtain marketing authorization of pharmaceutical products in the EU is through the "centralized procedure." This procedure is compulsory for certain pharmaceutical products, in particular those using biotechnological processes, and is also available for certain new chemical compounds and products. A company seeking to market an innovative pharmaceutical product through the centralized procedure must file a complete set of safety data and efficacy data as part of a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA). After the EMA evaluates the MAA, it provides a recommendation to the EC and the EC then approves or denies the MAA. It is also possible for new chemical products to obtain marketing authorization in the EU through a "mutual recognition procedure" in which an application is made to a single member state and, if the member state approves the pharmaceutical product under a national procedure, the applicant may submit that approval to the mutual recognition procedure of some or all other EU Member States.

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

Research and Development Update

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

MK-4482, *Lagevrio*, is an investigational oral antiviral medicine for the treatment of mild to moderate COVID-19 in adults who are at risk for progressing to severe disease. Merck is developing *Lagevrio* in collaboration with Ridgeback Biotherapeutics LP (Ridgeback). The FDA granted Emergency Use Authorization (EUA) for *Lagevrio* in December 2021; last issued in February 2023, to authorize *Lagevrio* for the treatment of adults with a current diagnosis of mild-to-moderate COVID-19, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate. The authorization is based on the Phase 3 MOVe-OUT trial. *Lagevrio* is not approved for any use in the U.S. and is authorized only for the duration of the declaration that circumstances exist justifying the authorization of its emergency use under the Food, Drug and Cosmetic Act, unless the authorization is terminated or revoked sooner. In November 2021, the EMA issued a positive scientific opinion for *Lagevrio*, which is intended to support national decision-making on the possible use of *Lagevrio* prior to marketing authorization. In October 2021, the EMA initiated a rolling review for *Lagevrio* for the treatment of COVID-19 in adults. On February 24, 2023, Merck and Ridgeback announced that the Committee for Medicinal Products for Human Use (CHMP) of the EMA has recommended the refusal of the marketing authorization for *Lagevrio*. Merck and Ridgeback will appeal the decision and request a re-examination of the CHMP's opinion. Applications to other regulatory bodies worldwide are underway.

In October 2022, Merck provided an update on new clinical and non-clinical studies of *Lagevrio*. A preliminary analysis of the University of Oxford's PANORAMIC study, conducted in the UK in highly-vaccinated adults mostly over 65 years of age, showed no evidence of a difference between *Lagevrio* added to usual care compared to usual care alone for the reduction of hospitalizations and deaths through Day 28 (primary endpoint was not met); the incidence of hospitalizations and death through Day 28 was very low overall. The main secondary endpoint (time to first self-reported recovery) in the PANORAMIC study was 6 days shorter with the *Lagevrio* group compared to the usual care group; in addition, the use of *Lagevrio* also was associated with earlier recovery across a wide range of other symptom measures, as compared to the usual care group. Additionally, an analysis of real-world data from a separate study conducted by investigators in Israel (known as the Clalit study) showed that in a cohort of non-hospitalized, high-risk patients, *Lagevrio* reduced hospitalizations and mortality due to COVID-19 in patients 65 years and above; no evidence of benefit was found in younger adults ages 40 to 64 years. Also, Merck reported results from a separate, non-clinical 6-month carcinogenicity study in transgenic mice, which demonstrated that *Lagevrio* was not carcinogenic at any dose tested.

MK-7264, gefapixant, is an investigational, orally administered, selective P2X3 receptor antagonist, for the treatment of refractory chronic cough or unexplained chronic cough in adults under review by the FDA and the EMA. The marketing applications for gefapixant are based on results from the COUGH-1 and COUGH-2 clinical trials. In January 2022, the FDA issued a Complete Response Letter (CRL) regarding Merck's NDA for gefapixant. In the CRL, the FDA requested additional information related to the cough counting system that was used to assess efficacy. The CRL was not related to the safety of gefapixant. The Company is performing additional analyses and anticipates submitting this information to the FDA in the first half of 2023 in response to the CRL. The review period in the EU has been extended pending the receipt of additional information from the Company. Merck plans to submit the information to the EMA in the first half of 2023.

MK-3475, *Keytruda*, is an anti-PD-1 therapy approved for the treatment of many cancers that is in clinical development for expanded indications. These approvals were the result of a broad clinical development program that currently consists of more than 1,650 clinical trials, including more than 1,200 trials that combine *Keytruda* with other cancer treatments. These studies encompass more than 30 cancer types including: biliary, estrogen receptor positive breast cancer, cervical, colorectal, cutaneous squamous cell, endometrial, esophageal, gastric, glioblastoma, head and neck, hepatocellular, Hodgkin lymphoma, non-Hodgkin lymphoma, non-small-cell lung, small-cell lung, melanoma, mesothelioma, ovarian, prostate, renal, triple-negative breast, and urothelial, many of which are currently in Phase 3 clinical development. Further trials are being planned for other cancers.

Keytruda is under review by the FDA for the treatment of patients with previously treated advanced HCC. This submission is based on data from the Phase 3 KEYNOTE-394 trial along with supportive data from the KEYNOTE-240 and KEYNOTE-224 trials. *Keytruda* is approved for this indication in the U.S. under the FDA's accelerated approval process. This submission is to convert the accelerated approval to full (regular) approval.

Keytruda is under priority review by the FDA for use in combination with Padcev (enfortumab vedotin-ejfv) for the treatment of certain patients with locally advanced or metastatic urothelial cancer who are not eligible to receive cisplatin-containing chemotherapy. The FDA set a PDUFA date of April 21, 2023 for the supplemental BLAs

for *Keytruda* and Pedcev. The combination regimen was granted Breakthrough Therapy designation by the FDA in February 2020. The applications are supported by efficacy and safety data from the Phase 1b/2 EV-103 trial (also known as KEYNOTE-869) Dose Escalation/Cohort A and Cohort K. Results from Dose Escalation/Cohort A were published in the *Journal of Clinical Oncology*. Results from Cohort K were presented in a late-breaking session at the 2022 European Society for Medical Oncology Congress.

Keytruda is also under review by the FDA for the treatment of adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma. This submission is based on data from the Phase 3 KEYNOTE-913 trial. *Keytruda* is approved for this indication in the U.S. under the FDA's accelerated approval process. This submission is to convert the accelerated approval to full (regular) approval.

Additionally, *Keytruda* is under review by the FDA for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options. This submission is based on data from the Phase 2 KEYNOTE-158 trial along with supportive data from the KEYNOTE-164 and KEYNOTE-051 trials. *Keytruda* is approved for this indication in the U.S. under the FDA's accelerated approval process. This submission is to convert the accelerated approval to full (regular) approval.

Keytruda is under review in the EU for the adjuvant treatment of patients with stage IB (≥ 4 cm), II or IIIA NSCLC following complete surgical resection. The submission is based on data from the pivotal Phase 3 KEYNOTE-091 trial, also known as EORTC-1416-LCG/ETOP-8-15 – PEARLS.

Keytruda is under review in Japan for the treatment of patients with relapsed or refractory PMBLC. This submission is based on data from the Phase 2 KEYNOTE-170 study and the Phase 1 KEYNOTE-A33 study.

In January 2023, Merck announced that it will stop the Phase 3 KEYNOTE-991 trial investigating *Keytruda* in combination with enzalutamide and androgen deprivation therapy (ADT) for the treatment of patients with metastatic hormone-sensitive prostate cancer. Merck is discontinuing the study based on the recommendation of an independent Data Monitoring Committee (DMC) which reviewed data from a planned interim analysis. At the interim analysis, *Keytruda* in combination with enzalutamide and ADT did not demonstrate an improvement in overall survival or radiographic progression-free survival, the trial's dual primary endpoints, compared to placebo plus enzalutamide and ADT. Data from this study will be presented at an upcoming medical meeting.

MK-7339, Lynparza, is an oral PARP inhibitor currently approved for certain types of advanced or recurrent ovarian, early or metastatic breast, metastatic pancreatic and metastatic castration-resistant prostate cancers being co-developed for multiple cancer types as part of a collaboration with AstraZeneca PLC.

In August 2022, the FDA granted priority review for a supplemental NDA for Lynparza in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with mCRPC. The supplemental NDA was based on results from the Phase 3 PROpel trial, which were presented at the 2022 American Society of Clinical Oncology Genitourinary Cancers Symposium and later published in *NEJM Evidence*. The FDA initially set a PDUFA date in the fourth quarter of 2022, but in December 2022 the FDA extended the PDUFA date by three months to provide further time for the full review of the submission. Lynparza is also under review in Japan for the treatment of certain patients with mCRPC based on the PROpel trial.

MK-7902, Lenvima, is an oral receptor tyrosine kinase inhibitor being developed as part of a collaboration with Eisai Co., Ltd. (Eisai). Merck and Eisai are studying the *Keytruda* plus Lenvima combination through the LEAP (LEnvatinib And Pembrolizumab) clinical program that includes studies across 13 different tumor types (biliary cancer, CRC, endometrial carcinoma, esophageal cancer, gastric cancer, HCC, HNSCC, melanoma, pancreatic cancer, prostate cancer, NSCLC, small-cell-lung cancer (SCLC) and RCC).

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

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

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

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

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

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

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

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

In December 2021, Merck announced that the FDA had placed clinical holds on the investigational new drug applications for islatravir (MK-8591) programs that were in development for the treatment and prevention of HIV-1 infection. The FDA's clinical hold was based on observations of decreases in total lymphocyte and CD4+ T-cell counts in some participants receiving islatravir in clinical studies. In September 2022, Merck announced it will initiate a new doravirine/islatravir (MK-8591A) Phase 3 clinical program for the treatment of people with HIV-1 infection. These new Phase 3 studies will evaluate a once-daily oral combination of doravirine 100 mg and a lower dose of islatravir in previously untreated adults and as a switch in antiretroviral therapy in virologically suppressed adults with HIV-1 infection. The Phase 2 clinical trial evaluating an investigational oral once-weekly combination treatment regimen of islatravir and Gilead Sciences' lenacapavir in adults with HIV-1 infection who are virologically suppressed will resume under an amended protocol with a lower dose of islatravir. The investigational NDA for the islatravir + lenacapavir once-weekly treatment regimen remains under a partial clinical hold for any studies that would use weekly oral islatravir doses higher than the doses considered for the revised clinical program. Additionally, Merck announced it will discontinue the development of once-monthly oral islatravir for PrEP. The Company remains committed to developing compounds for long-acting HIV prevention and believes in the potential of the nucleoside reverse transcriptase translocation inhibitor (NRTTI) mechanism. A Phase 1b study in adults with HIV-1 infection assessing MK-8527, a novel NRTTI candidate, will commence shortly.

V116 is an investigational 21-valent pneumococcal conjugate vaccine (PCV) for treatment of pneumococcal infection in adults. In June 2022, Merck announced the presentation of positive results from a Phase 1/2 study evaluating the safety, tolerability and immunogenicity of V116 in pneumococcal vaccine-naïve adults 18-49 years of age (Phase 1) and 50 years of age and older (Phase 2). In both populations, V116 met the primary immunogenicity objectives and was well-tolerated with an overall safety profile generally comparable to *Pneumovax* 23 across age groups. In April 2022, Merck announced that V116 received Breakthrough Therapy designation from the FDA for the prevention of invasive pneumococcal disease and pneumococcal pneumonia caused by *Streptococcus pneumoniae* serotypes 3, 6A/C, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B/C, 16F, 17F, 19A, 20, 22F, 23A, 23B, 24F, 31, 33F, 35B in adults 18 years of age and older. Phase 3 trials evaluating V116 are ongoing.

MK-7962, sotatercept, is an investigational activin receptor type IIA-Fc fusion protein being evaluated as an add-on to stable background therapy for the treatment of pulmonary arterial hypertension (PAH). Sotatercept was obtained in connection with Merck's acquisition of Acceleron Pharma Inc. in 2021. In October 2022, Merck announced positive top-line results from the pivotal Phase 3 STELLAR trial evaluating the safety and efficacy of sotatercept for the treatment of PAH (World Health Organization [WHO] Group 1). The trial met its primary efficacy outcome measure, demonstrating a statistically significant and clinically meaningful improvement in 6-minute walk distance (6MWD, which measures how far patients can walk in 6 minutes). Eight of nine secondary efficacy outcome measures achieved statistical significance, including the outcome measure of proportion of participants achieving multicomponent improvement (defined as improvement in 6MWD, improvement in N-terminal pro-B-type natriuretic peptide level, and either improvement in WHO Functional Class [FC] or maintenance of WHO FC II), and the outcome measure of time to death or the first occurrence of a clinical worsening event. The Cognitive/Emotional Impacts domain score of PAH-SYMPACT, which was assessed as the ninth and final secondary outcome measure, did not achieve statistical significance. Results will be presented at the upcoming American College of Cardiology Annual Scientific Session. The Company anticipates filing sotatercept with regulatory authorities in 2023.

MK-1654, clesrovimab, is a respiratory syncytial virus (RSV) monoclonal antibody that is being evaluated for the prevention of RSV medically attended lower respiratory tract infection in infants and certain children over 1 year of age. Two Phase 3 trials are currently enrolling.

In October 2022, Merck and Royalty Pharma plc (Royalty Pharma) entered into a funding arrangement under which Royalty Pharma paid Merck \$50 million to co-fund Merck's development costs for a Phase 2b trial of MK-8189, an investigational oral phosphodiesterase 10A (PDE10A) inhibitor, which is being evaluated for the treatment of schizophrenia. Under the agreement, Royalty Pharma has no rights to MK-8189 and has no decision-making authority over the program. If Merck elects to advance MK-8189 into a Phase 3 study, Royalty Pharma has the option to provide additional funding of 50% of the development costs up to \$375 million for the Phase 3 trial. If

such additional funding is provided, Royalty Pharma becomes eligible to receive future regulatory milestone payments contingent upon certain marketing approvals, as well as royalties.

The charts below reflect the Company's research pipeline as of February 17, 2023. Candidates shown in Phase 3 include 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.

Phase 2		
<p>Cancer</p> <p>MK-0482⁽²⁾ Non-Small-Cell Lung MK-1026 (nemtabrutinib) Hematological Malignancies MK-1308 (quavonlimab)⁽²⁾ Non-Small-Cell Lung MK-1308A (quavonlimab+pembrolizumab) Colorectal Hepatocellular Melanoma Small-Cell Lung MK-2140 (zilovertamab vedotin) Bladder Breast Gastric Hematological Malignancies Non-Small-Cell Lung Ovarian Pancreatic MK-2870⁽¹⁾⁽³⁾ Neoplasm Malignant MK-3475 Keytruda Advanced Solid Tumors MK-3543 (bomedemstat) Myeloproliferative Disorders MK-4280 (favezelimab)⁽²⁾ Non-Small-Cell Lung MK-4280A (favezelimab+pembrolizumab) Esophageal Melanoma Renal Cell Small-Cell Lung MK-4830⁽²⁾ Colorectal Esophageal Melanoma Non-Small-Cell Lung Ovarian Renal Cell Small-Cell Lung MK-5684⁽¹⁾ Prostate MK-5890 (boserolimab)⁽²⁾ Non-Small-Cell Lung Small-Cell Lung</p>	<p>Cancer</p> <p>MK-6440 (ladiratuzumab vedotin)⁽¹⁾⁽³⁾ Breast Esophageal Gastric Head and Neck Melanoma Non-Small-Cell Lung Prostate Small-Cell Lung MK-6482 Welireg⁽³⁾ Biliary Colorectal Endometrial Esophageal Hepatocellular Pancreatic Rare cancers Von Hippel-Lindau Disease-Associated Tumors (EU) MK-7119 Tukysa⁽¹⁾ Advanced Solid Tumors Biliary Bladder Cervical Endometrial Gastric Non-Small-Cell Lung MK-7339 Lynparza⁽¹⁾⁽³⁾ Advanced Solid Tumors MK-7684A (vibostolimab+pembrolizumab) Biliary Bladder Breast Cervical Colorectal Endometrial Esophageal Gastric Head and Neck Hematological Malignancies Hepatocellular Ovarian Prostate</p>	<p>Cancer</p> <p>MK-7902 Lenvima⁽¹⁾⁽²⁾ Biliary Pancreatic Prostate Small-Cell Lung V940⁽¹⁾⁽²⁾ Melanoma Dengue Fever Virus Vaccine V181 HIV-1 Infection MK-8591B (islatravir+MK-8507)⁽⁴⁾ MK-8591D (islatravir+lenacapavir)⁽¹⁾⁽⁵⁾ Hypercholesterolemia MK-0616 Nonalcoholic Steatohepatitis (NASH) MK-6024 (efinopegdutide) Overgrowth Syndrome MK-7075 (miransertib) Pulmonary Arterial Hypertension MK-5475 Pulmonary Hypertension Due To Left Heart Disease MK-7962 (sotatercept) Schizophrenia MK-8189⁽⁶⁾ Thrombosis MK-2060 Treatment Resistant Depression MK-1942</p>

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Phase 3 (Phase 3 entry date)	Under Review
<p>Antiviral COVID-19 MK-4482 <i>Lagevrio</i> (U.S.) (May 2021)^{(1)/(7)}</p> <p>Cancer MK-1308A (quavonlimab+pembrolizumab) Renal Cell (April 2021) MK-3475 <i>Keytruda</i> Biliary (September 2019) Cutaneous Squamous Cell (August 2019) (EU) Gastric (May 2015) (EU) Hepatocellular (May 2016) (EU) Mesothelioma (May 2018) Ovarian (December 2018) Prostate (May 2019) Small-Cell Lung (May 2017) MK-3475 (pembrolizumab subcutaneous) Non-Small-Cell Lung (August 2021) MK-3475A (pembrolizumab+hyaluronidase subcutaneous) Non-Small-Cell Lung (February 2023) MK-4280A (favelizimab+pembrolizumab) Colorectal (November 2021) Hematological Malignancies (October 2022) MK-6482 <i>Welireg</i>⁽³⁾ Renal Cell (February 2020) MK-7119 <i>Tukysa</i>⁽¹⁾ Breast (October 2019) Colorectal (August 2022) MK-7339 <i>Lynparza</i>^{(1)/(2)} Non-Small-Cell Lung (June 2019) Small-Cell Lung (December 2020) MK-7684A (vibostolimab+pembrolizumab) Melanoma (January 2023) Non-Small-Cell Lung (April 2021) Small-Cell Lung (March 2022) MK-7902 <i>Lenvima</i>^{(1)/(2)} Colorectal (April 2021) Esophageal (July 2021) Gastric (December 2020) Head and Neck (February 2020) Melanoma (March 2019) Non-Small-Cell Lung (March 2019) HIV-1 Infection MK-8591A (doravirine+islatravir) (February 2020)⁽⁵⁾ Pneumococcal Vaccine Adult V116 (July 2022) Pulmonary Arterial Hypertension MK-7962 (sotatercept) (January 2021) Respiratory Syncytial Virus MK-1654 (clesrovimab) (November 2021)</p>	<p>New Molecular Entities Antiviral COVID-19 MK-4482 <i>Lagevrio</i> (EU)⁽¹⁾ Cough MK-7264 (gefapixant) (U.S.)⁽⁸⁾ (EU)</p> <p>Certain Supplemental Filings Cancer MK-3475 <i>Keytruda</i> <ul style="list-style-type: none"> • Second-Line Hepatocellular Cancer (KEYNOTE-394) (U.S.) • First-Line Locally Advanced Or Metastatic Urothelial Carcinoma (KEYNOTE-869) (U.S.) • Locally Advanced Or Metastatic Merkel Cell Carcinoma (KEYNOTE-913) (U.S.) • Adjuvant Non-Small-Cell Lung Cancer (KEYNOTE-091) (EU) • Relapsed Or Refractory Primary Mediastinal B-Cell Lymphoma (KEYNOTE-170/KEYNOTE-A33) (JPN) MK-7339 <i>Lynparza</i>⁽¹⁾ <ul style="list-style-type: none"> • First-Line Metastatic Prostate Cancer (PROpel) (U.S.) (JPN) </p> <p>Footnotes:</p> <p>(1) Being developed in a collaboration.</p> <p>(2) Being developed in combination with <i>Keytruda</i>.</p> <p>(3) Being developed as monotherapy and/or in combination with <i>Keytruda</i>.</p> <p>(4) On FDA clinical hold.</p> <p>(5) On FDA partial clinical hold for higher doses than those used in current clinical trials.</p> <p>(6) Phase 2b development costs are being co-funded.</p> <p>(7) Available in the U.S. under Emergency Use Authorization.</p> <p>(8) In response to the CRL received from the FDA for this application in January 2022, Merck is performing additional analyses and anticipates submitting this information to the FDA in the first half of 2023.</p>

Human Capital

As of December 31, 2022, the Company had approximately 69,000 employees worldwide, with approximately 28,000 employed in the U.S., including Puerto Rico, and, additionally, approximately 15,000 third-party contractors globally.⁽¹⁾ Approximately 67,000 of the Company's employees are full-time employees. Globally, women comprise 50% of employees, and in the U.S. individuals from underrepresented ethnic groups comprise 34% of its workforce (the Company defines workforce as its employees). Women comprise 46% of the members of the Board of Directors. Additionally, the Company's senior management team is made up of 34% women. Approximately 22% of the Company's employees are represented by various collective bargaining groups. The Company's voluntary turnover rate was approximately 8.5% and 8.8%, respectively, in 2022 and 2021.

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

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

Talent Acquisition

The Company uses a comprehensive approach to ensure recruiting, retention and leadership development goals are systematically executed throughout the Company and that it hires talented leaders to achieve improved gender parity and representation across all dimensions of diversity. The Company provides training to its

managers and external recruiting organizations on strategies to mitigate unconscious bias in the candidate selection and hiring process. In addition, the Company utilizes a comprehensive communications strategy, employee branding and marketing outreach, social media and strategic alliance partnerships to reach a broad pool of talent in its critical business areas. In 2022, the Company hired approximately 8,900 employees across the globe through various channels including the Company's external career site, direct passive candidate sourcing, diversity partnerships, employee referrals, universities and other external sources.

Global Diversity and Inclusion

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

The Company's diversity goals include increasing representation in senior management roles (defined as an individual holding either a Vice President or Senior Vice President title) by 2024 of (i) women globally to 40%, up from 31% in 2020, (ii) Black/African Americans in the U.S. to 10%, up from 3% in 2020, and (iii) Hispanics/Latinos in the U.S. to 10%, up from 5% in 2020. As of December 31, 2022, representation in senior management roles at the Company for (i) women globally was 34%, (ii) Black/African Americans in the U.S. was 6%, and (iii) Hispanics/Latinos in the U.S. was 8%. In addition, by 2025, the Company seeks to maintain or exceed both its current inclusion index score and its current employee engagement index score based on employee surveys.

Gender and Ethnicity Data ⁽¹⁾⁽²⁾	2022	2021	2020
Women on the Board of Directors	46%	46%	46%
Women in senior management roles ⁽³⁾	34%	36%	31%
Women in management roles ⁽⁴⁾	45%	44%	42%
Women in the workforce	50%	50%	50%
New hires that were women	52%	53%	50%
Members of underrepresented ethnic groups on the Board of Directors	15%	23%	23%
Members of underrepresented ethnic groups in senior management roles (U.S.) ⁽³⁾	28%	25%	20%
Members of underrepresented ethnic groups in management roles (U.S.) ⁽⁴⁾	27%	26%	25%
Members of underrepresented ethnic groups in the workforce (U.S.)	34%	32%	30%
New hires that were members of underrepresented ethnic groups (U.S.)	47%	46%	40%

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

⁽²⁾ 2020 data has not been restated to adjust for the Organon Spin-Off in 2021.

⁽³⁾ "Senior management role" is defined as an individual holding either a Vice President or Senior Vice President title.

⁽⁴⁾ "Management role" is defined as all managers with direct reports other than individuals holding an Executive Vice President title.

Compensation and Benefits

The Company provides a valuable suite of compensation and benefits programs that reflect its commitment to attract, retain and motivate its talent, and support its employees and their families in every stage of life. The Company continuously monitors and adjusts its compensation and benefit programs to ensure they are competitive, contemporary, helpful and engaging, and that they support strategic imperatives such as diversity and inclusion, equity, flexibility, quality, security and affordability. For example, the Company regularly monitors and evaluates its pay practices and policies to ensure that it is paying employees equitably across all genders, races and ethnicities. The Company offers 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 provides enhanced cancer screening benefits with cash incentives, immediate access to a leading cancer center of excellence for U.S. employees and high value cancer support resources (e.g., caregiving and mental health) for employees and their families. Globally, the Company implemented a minimum standard of 12 weeks of paid parental leave, which inclusively applies to all parents. In the U.S., the Company's benefits rank in the top quartile of Fortune 100 companies under the Aon 2022 Benefits Index. The Company has been included in the

Seramount (previously the Working Mother) 100 Best Companies ranking for 36 consecutive years and was named a top ten Best Company for Moms in 2022.

Employee Well-being

The Company is committed to helping its employees and their families improve their own health and well-being, whether physical, mental, financial, or social. The Company's programs ensure quality, competitive value, protection from significant financial hardship and access to tools and resources to support employees and their families in all stages of their career and their lives, winning the Company awards such as the Best Employers Excellence in Health & Well-being from the Business Group on Health 2022. The Company fosters an array of flexible work arrangements that includes flextime, summer hours, remote work, telework, job sharing and part-time work to help employees succeed personally as well as professionally. As part of the Company's overall culture of well-being, it also offers onsite services so employees can thrive. For example, in the U.S., these include onsite health care professionals at many major sites, cafeterias committed to healthy menu offerings, onsite childcare, onsite gyms, and the convenient option to bank through its two employee credit unions.

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 guidance around hygiene measures and travel and how to best collaborate via the Company's hybrid work model. Examples of pandemic support resources and programs available to the Company's employees include pay continuation for workers who have been sick or exposed, an updated policy that enables 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, childcare resources and more.

Engaging Employees

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

Talent Management and Development

As the Company pursues its goal of becoming the world's premier research-based biopharmaceutical company, there is a consistent focus on the importance of continuously developing its diverse and talented people. The Company is committed to talent growth for all, allowing its employees to move more fluidly across the organization, unlocking an environment that allows them to shape their career pathways via non-linear and inclusive opportunities and experience. Merck's current talent management system supports company-wide performance management, leadership development, talent reviews and succession planning. Annual performance reviews help further the professional development of the Company's employees and ensure that the Company's workforce is aligned with the Company's objectives. The Company seeks to continuously build the skills and capabilities of its workforce to accelerate talent, improve performance and mitigate risk through relevant continuous learning experiences. This includes, but is not limited to, building leadership and management skills, as well as providing technical and functional training to all employees.

Environmental Matters

Environmental Sustainability

The Company strives to be a strong environmental steward, and realizes that its strategy and efforts need to continuously evolve in the face of a changing climate. The Company's environmental sustainability strategy has three focus areas:

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

A primary focus of the Company in each of these areas is on climate action. Merck believes that climate change could present risks to its business, as discussed in further detail in Item 1A. "Risk Factors" under the

headings “Climate change or legal, regulatory or market measures to address climate change may negatively affect the Company’s business, results of operations, cash flows and prospects” and “Environmental, social and governance (ESG) matters may impact the Company’s business and reputation.” Some of the potential impacts of climate change to the Company’s 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.

In 2021, the Company’s Scope 1, 2 and 3, reduction targets were verified by the Science-Based Targets initiative (SBTi). The Company has made progress toward its climate goals and aspires to meet and exceed the evolving expectations of its stakeholders and employees. These goals include achieving carbon neutrality for greenhouse gas emissions across operations (Scopes 1 and 2) by 2025, reducing Scope 1 and 2 operational greenhouse gas emissions 46% by 2030 (from a 2019 baseline), reducing Scope 3 greenhouse gas emissions by 30% by 2030 (from a 2019 baseline), and sourcing 100% of its purchased electricity from renewables by 2025. Other environmental sustainability initiatives of the Company include:

- **Low Carbon Transition Playbook.** In 2021, the Company launched its Low Carbon Transition Playbook, a tool intended to help create a site strategy by identifying gaps, uncovering opportunities and creating a common platform for assessment of levers and resource deployment across a range of sustainability initiatives. It also details how employees and stakeholders can accelerate the Company’s environmental work, along with explanations of the collective benefits of these actions for the business and for stakeholders. Functions across the Company are expected to take advantage of this document to strategize and develop new ways to meet many of the Company’s broader sustainability goals and streamline the Company’s tracking and reporting of specific metrics and categories.
- **Waste Diversion Playbook.** In 2022, the Company created its Waste Diversion Playbook, which is a tool, similar to the Low Carbon Transition Playbook, to help sites self-assess and develop their waste diversion strategies to achieve the Company’s corporate waste goals. The objectives are to identify and prioritize the most effective and least resource intensive actions, improve tracking and reporting and generate knowledge sharing between sites.
- **Partnering for progress across the Company’s value chain.** The Company is a signatory to Schneider Electric’s Energize program, a pioneering collaboration to help pharmaceutical and health care suppliers address their own operational Scope 2 greenhouse gas emissions through green power procurement, which in turn is intended to help the signatories reduce their Scope 3 emissions.
- **Product stewardship and green and sustainable science.** The Company’s product stewardship program focuses on identifying and either preventing or minimizing potential safety and environmental hazards throughout a product’s life cycle. The Company is also committed to understanding, managing and reducing the environmental impacts of its products and the materials associated with discovering and producing them. The Company’s green and sustainable science program uses a “green-by-design” approach. By using more efficient and innovative processing methods and technologies, the Company is reducing the amount of energy, water and raw materials the Company uses to make the Company’s products, thereby reducing the amount of waste the Company generates and lowering the Company’s production costs.

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

Environmental Regulation and Remediation

The Company believes that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on the Company. The Company is also remediating environmental contamination resulting from past industrial activity at certain of its sites. Expenditures for remediation and environmental liabilities were \$4 million in 2022 and are estimated to be \$23 million in the aggregate for the years 2023 through 2027. 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 \$39 million and \$40 million at December 31, 2022 and 2021, respectively. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed approximately \$35 million in the aggregate. Management also does not believe that these expenditures should have a material adverse effect on the Company’s financial condition, results of operations, liquidity or capital resources for any year.

Geographic Area Information

The Company's operations outside the U.S. are conducted primarily through subsidiaries. Sales worldwide by subsidiaries outside the U.S. as a percentage of total Company sales was 54% in both 2022 and 2021 and 53% in 2020.

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

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

Available Information

The Company's Internet website address is merck.com. The Company will make available, free of charge at the "Investors" portion of its website, its Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after such reports are electronically filed with, or furnished to, the U.S. Securities and Exchange Commission (SEC). The address of that website is sec.gov. In addition, the Company will provide without charge a copy of its Annual Report on Form 10-K, including financial statements and schedules, upon the written request of any shareholder to the Office of the Secretary, Merck & Co., Inc., 126 East Lincoln Avenue, Rahway, NJ 07065 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 <https://www.merck.com/company-overview/leadership/board-of-directors/> and all such information is available in print to any shareholder who requests it from the Company.

The Company's 2021/2022 Environmental, Social & Governance (ESG) Progress Report, which provides enhanced ESG disclosures, is available on the Company's website at <https://www.merck.com/company-overview/esg/esg-resources/>. Information in the Company's ESG Progress Report is not incorporated by reference into this Form 10-K.

Item 1A. Risk Factors.

Summary Risk Factors

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

- The Company is dependent on its patent rights, and if its patent rights are invalidated or circumvented, its business could be materially adversely affected.
- As the Company's products lose market exclusivity, the Company generally experiences a significant and rapid loss of sales from those products.
- Key products generate a significant amount of the Company's profits and cash flows, and any events that adversely affect the markets for its leading products could have a material adverse effect on the Company's results of operations and financial condition. The Company expects that sales of *Lagevrio*, which were \$5.7 billion in 2022, will decline significantly to approximately \$1.0 billion in 2023.
- The Company's research and development efforts may not succeed in developing commercially successful products and the Company may not be able to acquire commercially successful products in other ways; in consequence, the Company may not be able to replace sales of successful products that lose patent protection.
- The Company's success is dependent on the successful development and marketing of new products, which are subject to substantial risks.
- The Company faces continued pricing pressure with respect to its products.
- Unfavorable or uncertain economic conditions, together with cost-reduction measures being taken by certain governments, could negatively affect the Company's operating results.

- The Company faces intense competition from lower cost generic products.
- The Company faces intense competition from competitors' products.
- COVID-19-related disruptions have had an adverse impact on the Company's business, operations and financial performance. The Company is unable to predict the full extent to which the COVID-19 pandemic or any future pandemic, epidemic or similar public health threat will adversely impact its business, operations, financial performance, results of operations, and financial condition.
- The Company has significant global operations, which expose it to additional risks, and any adverse event could have a material adverse effect on the Company's results of operations and financial condition.
- Climate change or legal, regulatory or market measures to address climate change may negatively affect the Company's business, results of operations, cash flows and prospects.
- Environmental, social and governance (ESG) matters may impact the Company's business and reputation.
- Failure to attract and retain highly qualified personnel could affect the Company's ability to successfully develop and commercialize products.
- The Company may experience difficulties and delays in manufacturing certain of its products, including vaccines.
- The Company may not be able to realize the expected benefits of its investments in emerging markets.
- The ongoing war between Russia and Ukraine and related global disruptions could adversely affect the Company's business, results of operations and financial condition.
- The Company is exposed to market risk from fluctuations in currency exchange rates and interest rates.
- Pharmaceutical products can develop unexpected safety or efficacy concerns.
- Reliance on third-party relationships and outsourcing arrangements could materially adversely affect the Company's business.
- Negative events in the animal health industry could have a material adverse effect on future results of operations and financial condition.
- Biologics and vaccines carry unique risks and uncertainties, which could have a material adverse effect on the Company's future results of operations and financial condition.
- The health care industry in the U.S. has been, and will continue to be, subject to increasing regulation and political action.
- The Company's products, including products in development, cannot be marketed unless the Company obtains and maintains regulatory approval.
- Developments following regulatory approval may adversely affect sales of the Company's products.
- The Company is subject to a variety of U.S. and international laws and regulations.
- The Company is subject to evolving and complex tax laws, which may result in additional liabilities that may affect results of operations and financial condition.
- Adverse outcomes in current or future legal matters could negatively affect Merck's business.
- Product liability insurance for products may be limited, cost prohibitive or unavailable.
- The Company is increasingly dependent on sophisticated software applications and computing infrastructure. The Company could be a target of future cyber-attacks that could lead to a disruption of its worldwide operations, including manufacturing, research and sales operations.
- Social media and mobile messaging platforms present risks and challenges.

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

Risk Factors

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

Risks Related to the Company's Business

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

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

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

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

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

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

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

The Company depends upon patents to provide it with exclusive marketing rights for its products for some period of time. Loss of patent protection for one of the Company's products typically leads to a significant and rapid loss of sales for that product as lower priced generic versions of that drug become available. In the case of products that contribute significantly to the Company's sales, the loss of market exclusivity can have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects. While the key U.S.

patent for *Januvia* and *Janumet* claiming the sitagliptin compound expired in January 2023, as a result of favorable court rulings and settlement agreements related to a later expiring patent directed to the specific sitagliptin salt form of the products, the Company expects that these products will not lose market exclusivity in the U.S. until May 2026. However, certain of the rulings are currently being appealed, and an unfavorable court decision would likely cause the products to lose exclusivity in the U.S. toward the end of 2023. The Company lost market exclusivity for *Januvia* in all of the EU and for *Janumet* in some European countries in September 2022. Merck expects that exclusivity for *Janumet* will be lost in other European countries in April 2023. While the Company lost market exclusivity for *Januvia* in China in 2022 with the approval of a generic equivalent product, the impact on sales in 2023 is expected to be modest. It is anticipated that a generic equivalent of *Janumet* will be approved in China in the first quarter of 2023, but the impact to sales in 2023 is also expected to be modest. As these products lose exclusivity, the Company anticipates that sales of *Januvia* and *Janumet* will decline substantially.

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 expects that sales of *Lagevrio*, which were \$5.7 billion in 2022, will decline significantly to approximately \$1.0 billion in 2023.

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

In particular, in 2022, sales of *Lagevrio*, which were \$5.7 billion, represented a substantial portion of the Company's revenue and profit growth. The Company expects that sales of *Lagevrio* will decline significantly to approximately \$1.0 billion in 2023.

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

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

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

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

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

In order to provide information about the Company's pricing practices, the Company annually posts on its website its Pricing Transparency Report for the U.S. The report provides the Company's average annual list price and net price increases across the Company's U.S. portfolio dating back to 2010. In 2022, the Company's gross U.S. sales were reduced by 39.7% as a result of rebates, discounts and returns.

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

The Company expects pricing pressures to continue in the future.

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

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

As discussed above in "Competition and the Health Care Environment," global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. Changes to the U.S. health care system as part of health care reform, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, have contributed to pricing pressure. In several international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. In addition, the Company's sales performance in 2022 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 negatively affect sales and profits.

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.

As a result of global macroeconomic conditions, the Company is experiencing some minor disruption and volatility in its global supply chain network. These disruptions could increase in the future and cause delays in shipments of raw materials and packaging, as well as related cost inflation. Any such disruptions, delays or costs may result in the Company's inability to meet demand for the Company's products.

The Company faces intense competition from lower cost generic products.

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

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

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

The Company's business and financial results have been negatively impacted by COVID-19-related disruptions since the start of the pandemic. Merck believes that global health systems and patients have largely adapted to the impacts of COVID-19, however, a substantial portion of Merck's Pharmaceutical segment revenue is comprised of physician-administered products which could be adversely affected by the pandemic if it continues. The continued duration and severity of the COVID-19 pandemic is uncertain and difficult to predict. The degree to which COVID-19-related disruptions impact the Company's results in 2023 will depend on future developments, beyond the Company's knowledge or control, including governmental and third-party actions taken to contain or prevent the spread and treatment of the virus and mitigate its public health and economic effects. In addition, any future pandemic, epidemic or similar public health threat could present similar risks to the Company's business, cash flow, results of operations, financial condition and prospects.

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

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

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

In addition, there may be changes to the Company's business and political position if there is instability, disruption or destruction in a significant geographic region, regardless of cause, including war, terrorism, riot, civil insurrection or social unrest; and natural or man-made disasters, including famine, flood, fire, earthquake, storm or disease. Events like these could result in material adverse effects on macroeconomic conditions, currency exchange rates and financial markets.

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

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

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

New legal or regulatory requirements may be enacted to prevent, mitigate, or adapt to the implications of a changing climate and its effects on the environment. These regulations, which may differ across jurisdictions, could result in the Company being subject to new or expanded carbon pricing or taxes, increased compliance costs,

restrictions on greenhouse gas emissions, investment in new technologies, increased carbon disclosure and transparency, investments in data gathering and reporting systems, upgrades of facilities to meet new building codes, and the redesign of utility systems, which could increase the Company's operating costs, including the cost of electricity and energy used by the Company. The Company's supply chain would likely be subject to these same transitional risks and would likely pass along any increased costs to the Company, all of which may affect the Company's ability to procure raw materials or other supplies required for the operation of the Company's business at the quantities and levels we require.

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

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

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

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

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

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

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

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

The Company's business in China has grown rapidly in the past few years, and the importance of China to the Company's overall pharmaceutical and vaccines business outside the U.S. has increased accordingly. In addition to its commercial operations, the Company has significant research and manufacturing operations in China. If geopolitical tensions were to increase and disrupt the Company's operations in China, such disruption could result in a material adverse effect on the Company's product development, sales, business, cash flow, results of operations, financial condition and prospects.

Also, continued growth of the Company's business in China is dependent upon ongoing development of a favorable environment for innovative pharmaceutical products and vaccines, sustained access for the Company's currently marketed products, and the absence of trade impediments or adverse pricing controls. As noted above in "Competition and the Health Care Environment," pricing pressure in China has increased as the Chinese government has been taking steps to reduce costs, including implementing health care reform that has led to the acceleration of generic substitution, where available. While the mechanism for drugs being added to the NRD^L evolves, inclusion may require a price negotiation which could impact the outlook in the market for selected brands. In 2021, drugs were added to the NRD^L with an average of more than 60% price reductions. A new NRD^L was recently completed in which new entries averaged 60% price reductions. While pricing pressure has always existed in China, health care reform has increased this pressure in part due to the acceleration of generic substitution through the government's VBP program. In 2019, the government implemented the VBP program through a tendering process for mature products which have generic substitutes with a Generic Quality Consistency Evaluation approval. Mature products that have entered into the last five rounds of VBP had, on average, a price reduction of more than 50%. The Company expects VBP to be a semi-annual process that will have a significant impact on mature products moving forward.

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

The ongoing war between Russia and Ukraine and related global disruptions could adversely affect the Company's business, results of operations and financial condition.

The ongoing war between Russia and Ukraine, and the financial and economic sanctions imposed by the U.S., the EU and other countries in response, are having pervasive direct and indirect effects on the global economy, and may adversely affect the Company's business, results of operations and financial condition. The Company is working cross-functionally across the globe to monitor and mitigate interruptions to business continuity resulting from the war, including its impact on Merck's supply chain, operations and clinical trials.

For humanitarian reasons, the Company is continuing to supply essential medicines and vaccines in Russia while working to maintain compliance with international sanctions. Merck is donating profits resulting from its operations in Russia to humanitarian causes. The Company does not have research or manufacturing facilities in Russia, currently does not plan to make further investments in Russia, and has suspended screening and enrollment in ongoing clinical trials as well as planning for new studies in Russia, although the Company continues to treat patients already enrolled in existing clinical trials and collect data from these studies.

The financial impacts of the war between Russia and Ukraine were immaterial to the Company's consolidated financial statements in 2022. However, the degree to which the war and related disruptions will impact the Company's results in the future is difficult to predict and will depend on developments outside of the Company's control, including, but not limited to, the duration and severity of the war, ongoing and additional financial and economic sanctions imposed by governments in response, restrictions on travel, regional instability, geopolitical

shifts, and adverse effects on fuel and energy costs, supply chains, macroeconomic conditions, currency exchange rates and financial markets. Such developments may negatively impact the Company directly or indirectly as well as the parties with which the Company conducts business. In addition, the effects of the war between Russia and Ukraine could heighten other risks disclosed herein, which could materially adversely affect the Company's business, results of operations and financial condition.

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.

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

Pharmaceutical products can develop unexpected safety or efficacy concerns.

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

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

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

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

Future sales of key animal health products could be adversely affected by a number of risk factors including certain risks that are specific to the animal health business. For example, the outbreak of disease carried by animals, such as African Swine Fever, could lead to their widespread death and precautionary destruction as well as the reduced consumption and demand for animals, which could adversely affect the Company's results of operations. Also, the outbreak of any highly contagious diseases near the Company's main production sites could require the Company to immediately halt the manufacture of its animal health products at such sites or force the Company to incur substantial expenses in procuring raw materials or products elsewhere. Other risks specific to animal health include epidemics and pandemics, government procurement and pricing practices, weather and global agribusiness economic events. In addition, in 2022, sales of *Bravecto* were \$1.0 billion, which represented approximately 19% of the Company's Animal Health segment sales. Any negative event with respect to *Bravecto* could have a material adverse effect on the Company's Animal Health sales. If the Animal Health segment of the Company's business becomes more significant, the impact of any such events on future results of operations could also become more significant.

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

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

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

Risks Relating to Government Regulation and Legal Proceedings**The health care industry in the U.S. has been, and will continue to be, subject to increasing regulation and political action.**

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

In 2022, Congress passed the Inflation Reduction Act, which makes significant changes to how drugs are covered and paid for under the Medicare program, including the creation of financial penalties for drugs whose prices rise faster than the rate of inflation, redesign of the Medicare Part D program to require manufacturers to bear more of the liability for certain drug benefits, and government price-setting for certain Medicare Part D drugs, starting in 2026, and Medicare Part B drugs starting in 2028.

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

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

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

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

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

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

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

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

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

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

If previously unknown side effects are discovered or if there is an increase in negative publicity regarding known side effects of any of the Company's products, it could significantly reduce demand for the product or require the Company to take actions that could negatively affect sales, including removing the product from the market, restricting its distribution or applying for labeling changes. Further, in the current environment in which all pharmaceutical companies operate, the Company is at risk for product liability and consumer protection claims and

civil and criminal governmental actions related to its products, research and/or marketing activities. In addition, dissemination of promotional materials through evolving digital channels serves to increase visibility and scrutiny in the marketplace.

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

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

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

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

The Company has taken the position, based on the opinions of tax counsel, that its distribution of Organon common stock in connection with the 2021 Spin-Off qualifies as a transaction that is tax-free for U.S. federal income tax purposes. If any facts, assumptions, representations, and undertakings from the Company and Organon regarding the past and future conduct of their respective businesses and other matters are incorrect or not otherwise satisfied, the Spin-Off may not qualify for tax-free treatment, which could result in significant U.S. federal income tax liabilities for the Company and its shareholders.

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

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

As previously disclosed, Merck, along with certain subsidiaries, are defendants in a number of lawsuits filed starting in 2018 on behalf of direct and indirect purchasers of Zetia (ezetimibe) alleging violations of federal and state antitrust laws, as well as other state statutory and common law causes of action. The lawsuits filed on behalf of

twenty-five direct purchasers, eight retailers, and a class of indirect purchasers are scheduled to proceed to trial on April 17, 2023. In these cases, plaintiffs seek up to a maximum of \$12.7 billion in damages after trebling.

See Item 8. "Financial Statements and Supplementary Data," Note 11, "Contingencies and Environmental Liabilities" for more information on the Company's legal matters.

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

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

Risks Related to Technology

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

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 replace outmoded technology and improve the efficacy and efficiency of its business processes, including data acquisition; the use of which can create new risks.

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

Social media and mobile messaging platforms present risks and challenges.

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

Cautionary Factors that May Affect Future Results

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

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

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

- Changes in tax laws including changes related to the taxation of foreign earnings.

• Changes in accounting pronouncements promulgated by standard-setting or regulatory bodies, including the Financial Accounting Standards Board and the SEC, that are adverse to the Company.

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

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

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

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

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

Item 3. Legal Proceedings.

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

Item 4. Mine Safety Disclosures.

Not Applicable.

Executive Officers of the Registrant (ages as of February 1, 2023)

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
Robert M. Davis	56	Chairman, President and Chief Executive Officer (since December 2022); Chief Executive Officer and President (July 2021-December 2022); Executive Vice President, Global Services, and Chief Financial Officer (April 2016-July 2021)
Sanat Chattopadhyay	63	Executive Vice President and President, Merck Manufacturing Division (since March 2016)
Richard R. DeLuca, Jr.	60	Executive Vice President and President, Merck Animal Health (since September 2011)
Cristal Downing	54	Executive Vice President and Chief Communications & Public Affairs Officer (since August 2021); Vice President Medical Devices, Global Communications and Public Affairs Johnson & Johnson (December 2020-August 2021); Vice President Financial Communication, Johnson & Johnson (January 2018-December 2020); Prior to that, Senior Director Communications at Johnson & Johnson
Chirfi Guindo	57	Senior Vice President, Chief Marketing Officer, Human Health (since July 2022); Prior to that, Executive Vice President, Head of Global Product Strategy and Commercialization, Biogen Inc. (July 2018-July 2022); Executive Vice President, Head of Global Marketing, Market Access and Customer Innovation, Biogen Inc. (November 2017-June 2018)
Rita A. Karachun	59	Senior Vice President Finance - Global Controller (since March 2014)
Michael A. Klobuchar	47	Executive Vice President, Chief Strategy Officer (since July 2021); Senior Vice President, CFO of Merck R&D and Head of Global Portfolio and Alliance Management (January 2019-June 2021); Senior Vice President of Corporate Strategy and Planning and President of Emerging Businesses (December 2017-January 2019)
Lisa LeCointe-Cephas	41	Senior Vice President, Chief Ethics and Compliance Officer (since April 2021); Executive Director, Head of Global Investigations (February 2018-April 2021); Prior to that, Senior Counsel, Litigation and Government Investigations, Bristol-Myers Squibb Company
Dean Li	60	Executive Vice President, President, Merck Research Laboratories (since January 2021); Senior Vice President, Discovery Sciences and Translational Medicine, Merck Research Laboratories (November 2017-January 2021); Vice President, Translational Medicine (March 2017-November 2017)
Caroline Litchfield	54	Executive Vice President and Chief Financial Officer (since April 2021); Senior Vice President, Corporate Treasurer (January 2018-March 2021)
Steven C. Mizell	62	Executive Vice President, Chief Human Resources Officer (since October 2018); Prior to that, Executive Vice President, Human Resources, Monsanto Company
Johannes J. Oosthuizen	55	Senior Vice President and President Merck U.S. Human Health (since January 2022); Senior Vice President and Head of Global Oncology Commercial (January 2021-December 2021); Senior Vice President and President of MSD K.K. (July 2016-December 2020)
Joseph Romanelli	49	Senior Vice President and President MSD International Human Health (since July 2022); Chief Executive Officer JiXing Pharmaceuticals (July 2021-July 2022); President MSD China (December 2016-July 2021)
David M. Williams	54	Executive Vice President, Chief Information and Digital Officer (since August 2020); Acting Chief Information and Digital Officer (December 2019-August 2020); Vice President and Chief Information Officer, Merck Animal Health (May 2017-December 2019)
Jennifer Zachary	45	Executive Vice President, General Counsel and Corporate Secretary (since January 2020); Executive Vice President and General Counsel (April 2018-January 2020); Prior to that, Partner, Covington & Burling LLP

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, 2023, there were approximately 95,850 shareholders of record of the Company's Common Stock.

Issuer purchases of equity securities for the three months ended December 31, 2022 were as follows:

Issuer Purchases of Equity Securities

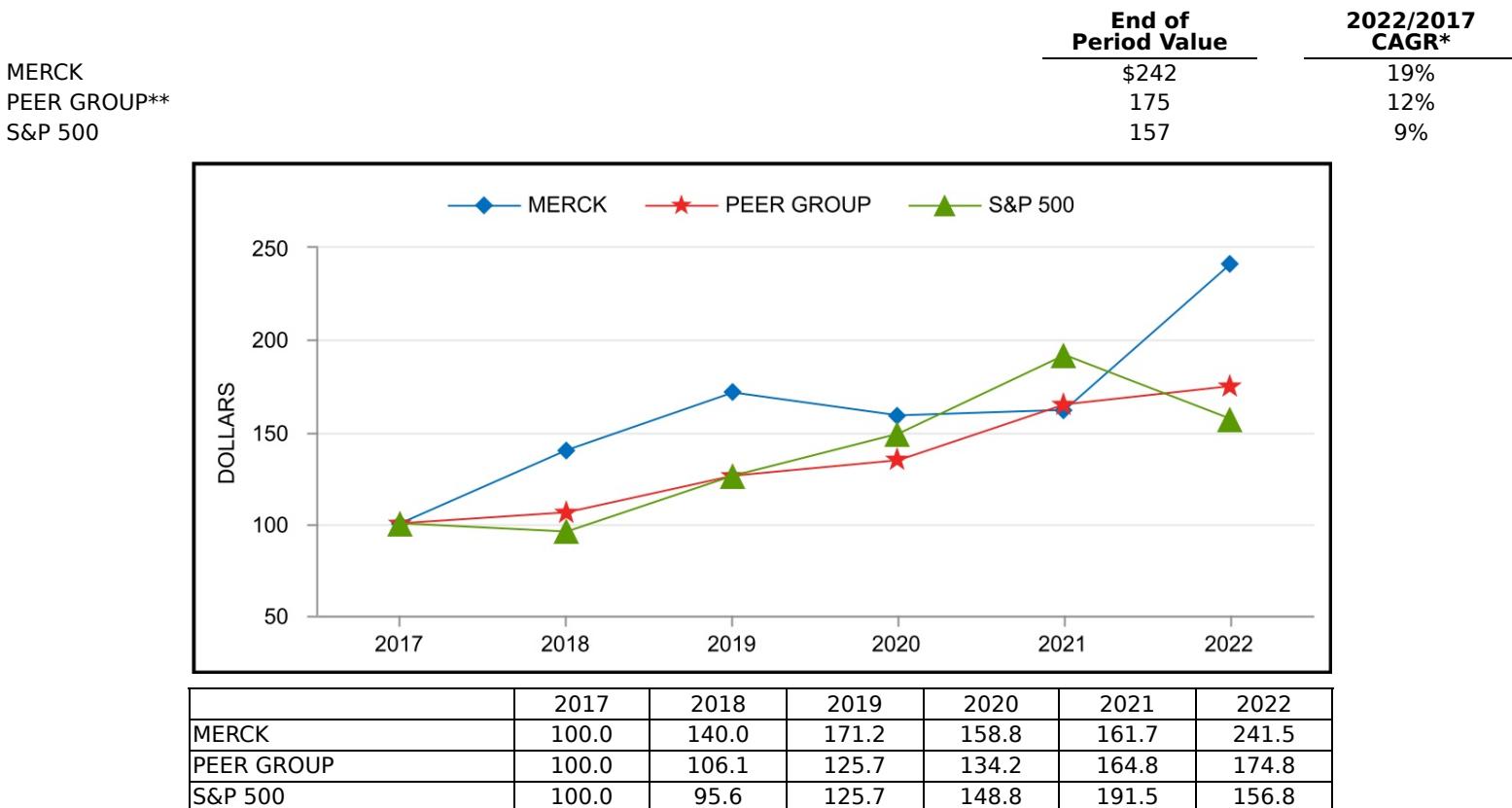
Period	Total Number of Shares Purchased ⁽¹⁾	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	(\$ in millions) Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs ⁽¹⁾
October 1 — October 31	—	—	—	\$5,047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

⁽¹⁾ The Company did not purchase any shares during the three months ended December 31, 2022 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, 2017, and reinvestment of all dividends, in each of the Company's Common Stock, the S&P 500 Index, and a composite peer group of major U.S. and European-based pharmaceutical companies, which are: AbbVie Inc., Amgen Inc., AstraZeneca plc, Bristol-Myers Squibb Company, Johnson & Johnson, Eli Lilly and Company, Gilead Sciences Inc., 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



* Compound Annual Growth Rate

** Peer group average was calculated on a market cap weighted basis as of December 31, 2017.

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 6. [Reserved]

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

The following section of this Form 10-K generally discusses 2022 and 2021 results and year-to-year comparisons between 2022 and 2021. Discussion of 2020 results and year-to-year comparisons between 2021 and 2020 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, 2021 filed on February 25, 2022.

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, including biologic therapies, vaccines and animal health products. The Company's operations are principally managed on a product basis and include two operating segments, Pharmaceutical and Animal Health, both of which are reportable segments.

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

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

Spin-Off of Organon & Co.

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

Overview

Financial Highlights

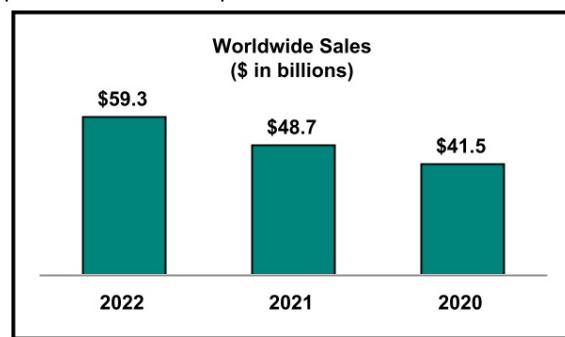
(\$ in millions except per share amounts)	2022	% Change	% Change Excluding Foreign Exchange		2021	% Change	% Change Excluding Foreign Exchange		2020
			26 %	\$ 48,704			17 %	16 %	
Sales	\$ 59,283	22 %							\$ 41,518
Net Income from Continuing Operations Attributable to Merck & Co., Inc.:									
GAAP	\$ 14,519	18 %	21 %	\$ 12,345	*	*	*	\$ 4,519	
Non-GAAP ⁽¹⁾	\$ 19,005	40 %	43 %	\$ 13,623	81 %	98 %	\$ 7,545		
Earnings per Common Share Assuming Dilution from Continuing Operations Attributable to Merck & Co., Inc. Common Shareholders:									
GAAP	\$ 5.71	17 %	21 %	\$ 4.86	*	*	\$ 1.78		
Non-GAAP ⁽¹⁾	\$ 7.48	39 %	43 %	\$ 5.37	81 %	98 %	\$ 2.97		

* > 100%

⁽¹⁾ Non-GAAP net income and non-GAAP earnings per share (EPS) exclude acquisition and divestiture-related costs, restructuring costs, gains and losses from investments in equity securities, and certain other items from Merck's results prepared in accordance with generally accepted accounting principles in the U.S. (GAAP). In 2022, the Company changed the treatment of certain items for purposes of its non-GAAP reporting. Prior periods have been recast to conform to the current presentation. For further discussion and a reconciliation of GAAP to non-GAAP net income and EPS, see "Non-GAAP Income and Non-GAAP EPS from Continuing Operations" below.

Executive Summary

Merck's 2022 results reflect sustained strong demand for the Company's innovative product portfolio benefiting patients globally, enabled by strong operational and commercial execution, the completion of business development transactions to support its science-led strategy, as well as progress in its pipeline across therapeutic areas, modalities and stage of development.



Worldwide sales were \$59.3 billion in 2022, an increase of 22% compared with 2021, or 26% excluding the unfavorable effect of foreign exchange. The sales increase was primarily due to growth in virology (driven by the benefit of Lagevrio sales), oncology, vaccines and hospital acute care. Sales within the Animal Health business were consistent with prior year. As discussed below, COVID-19-related disruptions negatively affected sales in 2022, but to a lesser extent than in 2021, which benefited year-over-year sales growth.

Merck continues to execute strategic business development opportunities to augment its robust internal pipeline with compelling external science. Highlights of 2022 activity include the following:

- Exercised an option to jointly develop and commercialize personalized therapeutic cancer vaccine mRNA-4157/V940 under an existing collaboration and license agreement with Moderna, Inc. (Moderna).
- Entered into a collaboration with Orna Therapeutics (Orna), a company pioneering a new investigational class of engineered circular RNA therapies, to discover, develop, and commercialize multiple programs, including vaccines and therapeutics in the areas of infectious disease and oncology.
- Entered into a global co-development and co-commercialization agreement for Orion Corporation's (Orion) investigational candidate ODM-208 (MK-5684) currently being evaluated for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC).

- Entered into a license and collaboration agreement with Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (Kelun-Biotech) for the development, manufacture and commercialization of an investigational antibody drug conjugate (ADC) (MK-1200) for the treatment of solid tumors.
- Exercised an option to obtain an exclusive license (outside of Chinese mainland, Hong Kong, Macau and Taiwan) for the development, manufacture and commercialization of Kelun-Biotech's trophoblast antigen 2 (TROP2)-targeting ADC programs, including its lead compound SKB-264 (MK-2870).
- Entered into a license and collaboration agreement expanding the Company's relationship with Kelun-Biotech pursuant to which Merck gained exclusive rights for the research, development, manufacture and commercialization of up to seven investigational preclinical ADCs for the treatment of cancer (Kelun-Biotech retained rights for certain licensed and option ADCs for Chinese mainland, Hong Kong and Macau); the transaction closed in February 2023.
- Entered into agreement to acquire Imago BioSciences, Inc. (Imago), a clinical stage biopharmaceutical company developing new medicines for the treatment of myeloproliferative neoplasms and other bone marrow diseases; the acquisition closed in January 2023.

During 2022, the Company received numerous regulatory approvals within oncology. *Keytruda* received approval for additional indications in the U.S. and/or internationally as monotherapy in the therapeutic areas of biliary, colorectal, endometrial, gastric, melanoma, small intestine and renal cell cancers, as well as in combination with chemotherapy in the therapeutic areas of breast and cervical cancers. *Keytruda* was also approved in combination with Lenvima in Japan for the treatment of certain adult patients with radically unresectable or metastatic renal cell carcinoma (RCC). Lenvima is being developed in collaboration with Eisai Co., Ltd. (Eisai). Lynparza, which is being developed in collaboration with AstraZeneca PLC (AstraZeneca), received approval in the U.S., the European Union (EU) and Japan for the adjuvant treatment of certain adult patients with high-risk early breast cancer and in the EU for the treatment of certain patients with mCRPC.

Also in 2022, *Vaxneuvance*, a vaccine to help prevent pneumococcal disease, was approved for expanded indications in the U.S. and the EU to include use in infants, adolescents and children. Additionally in 2022, *Lyfnua* (gefapixant) was approved in Japan for adults with refractory or unexplained chronic cough. In addition, in 2022, *Lagevrio*, which is being developed in a collaboration with Ridgeback Biotherapeutics LP (Ridgeback), received emergency conditional approval in China for the treatment of mild to moderate COVID-19 in adults who are at risk for progressing to severe COVID-19.

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

Keytruda is under review in the U.S. and/or internationally for supplemental indications for the treatment of certain patients with hepatocellular, Merkel cell, non-small-cell lung and urothelial cancers, as well as primary mediastinal B-cell lymphoma (PMBCL). Lynparza is under review for supplemental indications in the U.S. and Japan for the treatment of certain patients with mCRPC. MK-4482, *Lagevrio*, an investigational oral antiviral COVID-19 medicine, is under a rolling review by the European Medicines Agency (EMA); the Committee for Medicinal Products for Human Use of the EMA has recommended the refusal of the marketing authorization, which Merck and Ridgeback intend to appeal. MK-7264, gefapixant, a selective, non-narcotic, orally-administered, investigational P2X3-receptor antagonist being developed for the treatment of refractory, chronic cough is under review in the U.S. and the EU.

The Company's Phase 3 oncology programs include:

- *Keytruda* in the therapeutic areas of biliary, cutaneous squamous cell, gastric, hepatocellular, mesothelioma, ovarian, prostate and small-cell lung cancers;
- Lynparza in combination with *Keytruda* for non-small-cell lung and small-cell lung cancers;
- Lenvima in combination with *Keytruda* for colorectal, esophageal, gastric, head and neck, melanoma and non-small-cell lung cancers;
- MK-1308A, the coformulation of quavonlimab, Merck's novel investigational anti-CTLA-4 antibody, and pembrolizumab for RCC;
- MK-3475, subcutaneous pembrolizumab for non-small-cell lung cancer (NSCLC);
- MK-3475A, the subcutaneous coformulation of pembrolizumab with hyaluronidase, for NSCLC;
- MK-4280A, the coformulation of favezelimab, Merck's novel investigational anti-LAG3 therapy, and pembrolizumab for colorectal cancer and hematological malignancies;
- *Welireg* for RCC;

- MK-7119, Tukysa (tucatinib), which is being developed in collaboration with Seagen Inc. (Seagen), for breast and colorectal cancers; and
- MK-7684A, the coformulation of vibostolimab, an anti-TIGIT therapy, and pembrolizumab for melanoma, non-small-cell and small-cell lung cancers.

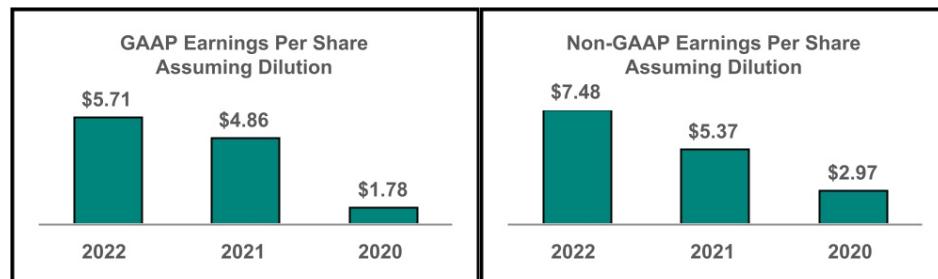
Additionally, the Company currently has candidates in Phase 3 clinical development in several other therapeutic areas including:

- V116, an investigational 21-valent pneumococcal conjugate vaccine for the prevention of invasive pneumococcal disease and pneumococcal pneumonia in adults;
- MK-7962, sotatercept, for the treatment of pulmonary arterial hypertension (PAH);
- MK-1654, clesrovimab, for the prevention of respiratory syncytial virus;
- MK-8591A, islatravir in combination with doravirine for the treatment of HIV-1 infection (which is on partial clinical hold for higher doses than those used in current clinical trials); and
- MK-4482, *Lagevrio*, which is reflected in Phase 3 development in the U.S. as it remains investigational following Emergency Use Authorization in 2021.

Merck's capital allocation priorities are to make investments in its business to drive near- and long-term growth, including investing in opportunities to address important unmet medical needs and supporting the Company's commercial opportunities. In addition, Merck remains committed to its dividend and will continue to pursue the most compelling external science through value-enhancing business development transactions. Research and development expenses in 2022 reflect higher clinical development spending particularly in the therapeutic areas of oncology, cardiovascular, infectious diseases and vaccines.



In November 2022, Merck's Board of Directors approved an increase to the Company's quarterly dividend, raising it to \$0.73 per share from \$0.69 per share on the Company's outstanding common stock. During 2022, the Company returned \$7.0 billion to shareholders through dividends.



GAAP and Non-GAAP EPS were negatively affected in 2022, 2021 and 2020 by \$0.22, \$0.65, and \$1.56, respectively, of charges for certain upfront and pre-approval milestone payments related to collaborations and licensing agreements, as well as charges related to pre-approval assets obtained in transactions accounted for as asset acquisitions.

War in Ukraine

In February 2022, Russia invaded Ukraine. The Company's primary concerns are the safety and well-being of its employees and ensuring patients and customers have continued access to medicines and vaccines needed for patient and public health. The Company is working cross-functionally across the globe to monitor and mitigate interruptions to business continuity resulting from the war, including its impact on Merck's supply chain, operations and clinical trials. For humanitarian reasons, the Company is continuing to supply essential medicines and vaccines in Russia while working to maintain compliance with international sanctions. Merck is donating profits

resulting from its operations in Russia to humanitarian causes. The Company does not have research or manufacturing facilities in Russia, currently does not plan to make further investments in Russia, and has suspended screening and enrollment in ongoing clinical trials as well as planning for new studies in Russia, although the Company continues to treat patients already enrolled in existing clinical trials and collect data from these studies. The Company is also using its resources to help alleviate the humanitarian crisis in Ukraine, including through donations of funds and products. The financial impacts of the war were immaterial to the Company's consolidated financial statements for 2022. Sales to Russia were approximately 1% of total Merck consolidated sales for 2022 and are expected to decline in future periods. The Company is unable to determine at this time the future direct or indirect impacts of this war on the Company's business.

COVID-19

Although COVID-19-related disruptions had some negative effect on sales in 2022, Merck continues to believe that global health systems and patients have largely adapted to the impacts of the COVID-19 pandemic. Merck's revenue in 2022 benefited from sales of *Lagevrio*, which were \$5.7 billion. Merck expects sales of *Lagevrio* will decline significantly in 2023 to approximately \$1.0 billion.

In 2021, COVID-19-related disruptions resulted in an estimated negative impact to Pharmaceutical segment sales of approximately \$1.3 billion because a substantial portion of Pharmaceutical segment revenue is comprised of physician-administered products, which were unfavorably affected by social distancing measures and fewer well visits. Sales in 2021 benefited from \$952 million of *Lagevrio* sales.

In April 2021, Merck announced it was discontinuing the development of MK-7110 for the treatment of hospitalized patients with COVID-19, which was obtained as part of Merck's acquisition of OncoImmune (see Note 4 to the consolidated financial statements). This decision resulted in charges of \$207 million to *Cost of sales* in 2021.

Operating expenses in 2021 reflect a minor positive effect as investments in COVID-19-related research largely offset the favorable impact of lower spending in other areas due to the COVID-19 pandemic.

In March 2021, Merck announced it had entered into multiple agreements to support efforts to expand manufacturing capacity and supply of SARS-CoV-2/COVID-19 medicines and vaccines. The Biomedical Advanced Research and Development Authority (BARDA), a division of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services, provided Merck with \$102 million of funding in the first quarter of 2022 to adapt and make available a number of existing manufacturing facilities for the production of SARS-CoV-2/COVID-19 vaccines and medicines. The funding was recognized as a reduction to *Cost of sales* over the expected production period, offsetting the depreciation expense related to the amounts that were capitalized in connection with the modification of the manufacturing facilities. Merck and Johnson & Johnson have commenced an arbitration regarding a dispute concerning two agreements pursuant to which Merck was supporting the manufacturing and supply of Johnson & Johnson's SARS-CoV-2/COVID-19 vaccine and vaccine drug product. The amounts included in the consolidated financial statements for these agreements were immaterial in 2022. Merck does not believe the outcome of the arbitration will have a material impact on the Company's financial statements.

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 enacted in prior years 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 sales performance in 2022 was negatively affected by other cost-reduction measures taken by governments and other third parties to lower health care costs. In 2022, the U.S. Congress passed the Inflation Reduction Act, which makes significant changes to how drugs are covered and paid for under the Medicare program, including the creation of financial penalties for drugs whose prices rise faster than the rate of inflation, redesign of the Medicare Part D program to require manufacturers to bear more of the liability for certain drug benefits, and government price-setting for certain Medicare Part D drugs (starting in 2026) and Medicare Part B drugs (starting in 2028). In the U.S., the Biden Administration and Congress continue to discuss legislation designed to control health care costs, including the cost of drugs. The Company anticipates all of these actions and additional actions in the future will negatively affect sales and profits.

Supply Chain

As a result of global macroeconomic conditions, the Company is experiencing some minor disruption and volatility in its global supply chain network. These disruptions could increase in the future and cause delays in shipments of raw materials and packaging, as well as related cost inflation.

Operating Results

Sales

(\$ in millions)	2022	% Change	% Change Excluding Foreign Exchange	2021	% Change	% Change Excluding Foreign Exchange	2020
			2021			2020	
United States	\$ 27,206	21 %	21 %	\$ 22,425	14 %	14 %	\$ 19,588
International	32,077	22 %	29 %	26,279	20 %	17 %	21,930
Total	\$ 59,283	22 %	26 %	\$ 48,704	17 %	16 %	\$ 41,518

Worldwide sales grew 22% in 2022 attributable in part to higher sales in the virology franchise driven by *Lagevrio*. Also contributing to revenue growth were higher sales in the oncology franchise largely due to strong growth of *Keytruda* and increased alliance revenue from *Lenvima* and *Lynparza*, as well as higher sales in the vaccines franchise, primarily attributable to growth in *Gardasil/Gardasil 9* and the launch of *Vaxneuvance* for pediatric use. Higher sales of hospital acute care products, including *Bridion*, *Zerbaxa*, *Diflucan* and *Prevymis*, as well as higher revenue related to third-party manufacturing arrangements also drove revenue growth in 2022. As discussed above, COVID-19-related disruptions had some negative effects on sales in 2022, but to a lesser extent than in 2021, which benefited year-over-year sales growth. Sales growth in 2022 was partially offset by lower sales of diabetes products *Januvia* and *Janumet*, the *Pneumovax 23* vaccine, and virology products *Isentress/Isentress HD*.

Sales in the U.S. grew 21% in 2022 primarily driven by higher sales of *Keytruda*, *Lagevrio*, *Gardasil 9*, as well as increased alliance revenue from *Lenvima* and *Reblozyl* (obtained as part of the Acceleron Pharma Inc. (Acceleron) acquisition in November 2021), and the launch of *Vaxneuvance* for pediatric use. Higher sales of *Bridion*, *Welireg*, *Zerbaxa* and *Diflucan*, as well as increased revenue from third-party manufacturing arrangements also contributed to U.S. sales growth in 2022. Lower sales of *Pneumovax 23* and *Januvia* partially offset revenue growth in the U.S. in 2022.

International sales grew 22% in 2022 primarily due to higher sales of *Lagevrio*, *Gardasil/Gardasil 9*, *Keytruda*, and *Zerbaxa*, as well as increased revenue from third-party manufacturing arrangements, partially offset by lower sales of *Januvia/Janumet*, *Simponi*, *Isentress/Isentress HD*, *Remicade*, and *Pneumovax 23*. International sales represented 54% of total sales in both 2022 and 2021.

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

Pharmaceutical Segment

Oncology

(\$ in millions)	2022	% Change	% Change Excluding Foreign Exchange	2021	% Change	% Change Excluding Foreign Exchange	2020
			2021			2020	
<i>Keytruda</i>	\$ 20,937	22 %	27 %	\$ 17,186	20 %	18 %	\$ 14,380
Alliance Revenue - <i>Lynparza</i> ⁽¹⁾	1,116	13 %	18 %	989	36 %	35 %	725
Alliance Revenue - <i>Lenvima</i> ⁽¹⁾	876	24 %	28 %	704	21 %	20 %	580
Alliance Revenue - <i>Reblozyl</i> ⁽²⁾	166	*	*	17	—	—	—

* > 100%

⁽¹⁾ Alliance revenue represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs (see Note 5 to the consolidated financial statements).

⁽²⁾ Alliance revenue represents royalties and, for 2022, also includes a payment received related to the achievement of a regulatory approval milestone (see Note 5 to the consolidated financial statements).

Keytruda is an anti-PD-1 (programmed death receptor-1) therapy that has been approved as monotherapy for the treatment of certain patients with cervical cancer, classical Hodgkin lymphoma, cutaneous squamous cell carcinoma, esophageal or gastroesophageal junction (GEJ) carcinoma, head and neck squamous cell carcinoma (HNSCC), hepatocellular carcinoma (HCC), NSCLC, melanoma, Merkel cell carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer (solid tumors) including MSI-H/dMMR colorectal cancer, MSI-H/dMMR advanced endometrial carcinoma, PMBCL, tumor mutational burden-high (TMB-H) cancer (solid tumors), and urothelial carcinoma, including non-muscle invasive bladder cancer. Additionally, *Keytruda* is approved as monotherapy for the adjuvant treatment of certain patients with RCC at intermediate-high or high risk of recurrence and for certain patients with completely resected stage IIB, IIC or III melanoma, and for adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage IB (T2a ≥4 cm), II, or IIIA NSCLC. *Keytruda*

is also approved for certain patients with high-risk early-stage triple-negative breast cancer (TNBC) in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery. In addition, *Keytruda* is approved for the treatment of certain patients in combination with chemotherapy for metastatic squamous and nonsquamous NSCLC, in combination with chemotherapy, with or without bevacizumab for advanced cervical cancer, in combination with chemotherapy for esophageal cancer, in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy for human epidermal growth factor 2 (HER2)-positive gastric or GEJ adenocarcinoma, in combination with chemotherapy for HNSCC, in combination with chemotherapy for locally recurrent unresectable or metastatic TNBC, in combination with axitinib for advanced RCC, and in combination with Lenvima for certain patients with advanced endometrial carcinoma or advanced RCC. The *Keytruda* clinical development program includes studies across a broad range of cancer types.

Global sales of *Keytruda* grew 22% in 2022 primarily driven by higher demand as the Company continues to launch *Keytruda* with multiple new indications globally. Sales in the U.S. continue to build across the multiple approved metastatic indications, in particular for the treatment of certain types of RCC, HNSCC, and MSI-H cancers. *Keytruda* sales growth in the U.S. also benefited from increased uptake across recent launches in earlier-stage indications including in high-risk early stage TNBC, as well as certain types of RCC and melanoma. *Keytruda* sales growth in international markets reflects continued uptake predominately for the NSCLC, HNSCC and RCC indications, particularly in Europe.

Keytruda recently received numerous regulatory approvals summarized below.

Date	Approval
January 2022	EC approval as monotherapy for the adjuvant treatment of adults with RCC at increased risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions, based on the KEYNOTE-564 trial.
February 2022	Japan's Ministry of Health, Labor and Welfare (MHLW) approval of the combination of <i>Keytruda</i> plus Lenvima for radically unresectable or metastatic RCC, based on the CLEAR (Study 307)/KEYNOTE-581 trial.
February 2022	MHLW approval for the treatment of adult patients with advanced or recurrent TMB-H solid tumors that have progressed after chemotherapy (limited to use when difficult to treat with standard of care), based on the KEYNOTE-158 trial.
March 2022	U.S. Food and Drug Administration (FDA) approval as a single agent for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation, based on the KEYNOTE-158 trial (Cohorts D & K).
April 2022	EC approval in combination with chemotherapy, with or without bevacizumab, for the treatment of persistent, recurrent or metastatic cervical cancer in certain adults whose tumors express PD-L1, based on the KEYNOTE-826 trial.
April 2022	EC approval as monotherapy for the treatment of certain adult patients with unresectable or metastatic MSI-H/dMMR colorectal, gastric, small intestine or biliary cancer, as well as advanced or recurrent MSI-H/dMMR endometrial carcinoma, based on the KEYNOTE-164 and KEYNOTE-158 trials.
May 2022	EC approval in combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery for adults with locally advanced or early-stage TNBC at high risk of recurrence, based on the KEYNOTE-522 trial.
June 2022	EC approval as monotherapy for the adjuvant treatment of adults and adolescents aged 12 years and older with stage IIB or IIC melanoma and who have undergone complete resection, based on the KEYNOTE-716 trial. EC approval expanding the indications in advanced (unresectable or metastatic) melanoma and stage III melanoma with lymph node involvement (as adjuvant treatment following complete resection) to include adolescent patients aged 12 years and older.
August 2022	MHLW approval as monotherapy for the adjuvant treatment of certain patients with RCC at increased risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions, based on the KEYNOTE-564 trial.
September 2022	MHLW approval in combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery for patients with hormone receptor-negative and HER2-negative breast cancer at high risk of recurrence, based on the KEYNOTE-522 trial.

September 2022	MHLW approval in combination with chemotherapy, with or without bevacizumab, for the treatment of patients with advanced or recurrent cervical cancer with no prior chemotherapy who are not amenable to curative treatment, based on the KEYNOTE-826 trial.
September 2022	MHLW approval as monotherapy for the adjuvant treatment of patients with stage IIB or IIC melanoma after complete resection, based on the KEYNOTE-716 trial.
October 2022	China's National Medical Products Administration (NMPA) approval as monotherapy for the treatment of patients with HCC who have been previously treated with sorafenib or oxaliplatin-based chemotherapy, based on the KEYNOTE-394 trial.
November 2022	NMPA approval for the treatment of patients with high-risk early-stage TNBC whose tumors express PD-L1, in combination with chemotherapy as neoadjuvant treatment, and then continued as a monotherapy as adjuvant treatment after surgery, based on the KEYNOTE-522 trial.
January 2023	FDA approval as a single agent for adjuvant treatment following surgical resection and platinum-based chemotherapy for adult patients with stage IB (T2a ≥ 4 cm), II, or IIIA NSCLC, based on the KEYNOTE-091 trial.

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 December 2023 to one third party; this royalty will decline to 2.5% for 2024 through 2026 and will terminate thereafter. The Company pays an additional 2% royalty on worldwide sales of *Keytruda* to another third party, the termination date of which varies by country; this royalty will expire in the U.S. in September 2024 and on varying dates in major European markets in the second half of 2025. The royalties are included in *Cost of sales*.

Lynparza is an oral poly (ADP-ribose) polymerase (PARP) inhibitor being developed as part of a collaboration with AstraZeneca (see Note 5 to the consolidated financial statements). *Lynparza* is approved for the treatment of certain types of advanced or recurrent ovarian, early or metastatic breast, metastatic pancreatic and metastatic castration-resistant prostate cancers. Alliance revenue related to *Lynparza* grew 13% in 2022 largely due to higher demand globally across the multiple approved indications, particularly in the U.S. largely attributable to uptake in the earlier-stage breast cancer indication following approval by the FDA in March 2022.

Lynparza received several regulatory approvals in 2022 summarized below.

Date	Approval
March 2022	FDA approval for the adjuvant treatment of adult patients with deleterious or suspected deleterious germline <i>BRCA</i> -mutated, HER2-negative high-risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy, based on the OlympiA trial.
August 2022	MHLW approval for the adjuvant treatment of patients with <i>BRCA</i> -mutated, HER2-negative high recurrent risk breast cancer, based on the OlympiA trial.
August 2022	EC approval as monotherapy or in combination with endocrine therapy for the adjuvant treatment of adult patients with germline <i>BRCA1/2</i> -mutations who have HER2-negative, high-risk early breast cancer previously treated with neoadjuvant or adjuvant chemotherapy, based on the OlympiA trial.
September 2022	NMPA approval as first-line maintenance treatment for 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 combination with bevacizumab and whose cancer is associated with homologous recombination deficiency (HRD)-positive status, based on the PAOLA-1 trial.
December 2022	EC approval in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with mCRPC in whom chemotherapy is not clinically indicated, based on the PROpel trial.

Lenvima is an oral receptor tyrosine kinase inhibitor being developed as part of a collaboration with Eisai (see Note 5 to the consolidated financial statements). *Lenvima* is approved for the treatment of certain types of thyroid cancer, RCC, HCC, in combination with everolimus for certain patients with advanced RCC, and in combination with *Keytruda* for certain patients with advanced endometrial carcinoma or advanced RCC. Alliance revenue related to *Lenvima* grew 24% in 2022 reflecting uptake in the advanced RCC and advanced endometrial carcinoma indications, particularly in the U.S.

Reblozyl is a first-in-class erythroid maturation recombinant fusion protein obtained as part of Merck's November 2021 acquisition of Acceleron that is being developed and commercialized through a global collaboration with Bristol Myers Squibb (see Note 5 to the consolidated financial statements). *Reblozyl* is approved for the treatment of certain types of anemia. Merck recorded alliance revenue of \$166 million in 2022, which includes

royalties of \$146 million, as well as the receipt of a regulatory approval milestone payment of \$20 million, compared with alliance revenue of \$17 million in 2021.

Vaccines

(\$ in millions)	2022	% Change	% Change Excluding Foreign Exchange		2021	% Change	% Change Excluding Foreign Exchange		2020
			2021	% Change			2020		
Gardasil/Gardasil 9	\$ 6,897	22 %	27 %	\$ 5,673	44 %	39 %	\$ 3,938		
ProQuad	839	9 %	11 %	773	14 %	13 %	678		
M-M-R II	411	5 %	7 %	391	3 %	3 %	378		
Varivax	991	2 %	4 %	971	18 %	18 %	823		
Pneumovax 23	602	(33)%	(30)%	893	(18)%	(19)%	1,087		

Combined worldwide sales of *Gardasil* and *Gardasil* 9, vaccines to help prevent certain cancers and other diseases caused by certain types of human papillomavirus (HPV), grew 22% in 2022 driven primarily by strong demand outside of the U.S., particularly in China, which also benefited from increased supply. Sales of *Gardasil* 9 in the U.S. increased due to public sector buying patterns and higher pricing, partially offset by lower demand.

In 2022, China's NMPA expanded the use of *Gardasil* 9 for use in girls and women ages 9 to 45. The vaccine was previously approved for use in girls and women ages 16 to 26.

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 (which expires in December 2023) and an additional 7% royalty on sales of *Gardasil/Gardasil* 9 in the U.S. to another third party (which expires in December 2028). The royalties are included in *Cost of sales*.

Global sales of *ProQuad*, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, grew 9% in 2022 primarily due to higher pricing in the U.S. and higher demand in Europe.

Worldwide sales of *M-M-R II*, a vaccine to help protect against measles, mumps and rubella, grew 5% in 2022 primarily due to higher pricing in the U.S.

Global sales of *Varivax*, a vaccine to help prevent chickenpox (varicella), grew 2% in 2022 primarily reflecting higher pricing in the U.S., partially offset by lower tenders in Latin America.

Worldwide sales of *Pneumovax 23*, a vaccine to help prevent pneumococcal disease, declined 33% in 2022 primarily reflecting lower demand in the U.S. as the market continues to shift toward newer adult pneumococcal conjugate vaccines following changes in the recommendations of the U.S. Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) in 2021. The Company expects the decline in U.S. sales of *Pneumovax 23* to continue. Lower demand in Europe also contributed to the *Pneumovax 23* sales decline in 2022.

In June 2022, the FDA approved an expanded indication for *Vaxneuvance* to include use in individuals 6 weeks of age and older. The FDA's approval was based on data from seven randomized, double-blind clinical studies assessing safety, tolerability and immunogenicity of *Vaxneuvance* in infants and children. Also in June 2022, the CDC's ACIP unanimously voted to include *Vaxneuvance* as a recommended option for vaccination in infants and children, including routine use in children under 2 years of age. These recommendations subsequently were adopted by the director of the CDC and the U.S. Department of Health and Human Services, and published in the CDC's *Morbidity and Mortality Weekly Report (MMWR)*. The ACIP also unanimously voted to include *Vaxneuvance* in the Vaccines for Children program. In October 2022, the EC approved an expanded indication for *Vaxneuvance* to include use in infants, children and adolescents from 6 weeks to less than 18 years of age. *Vaxneuvance* was previously approved for use in the U.S. and the EU in 2021 for individuals 18 years of age and older. In September 2022, *Vaxneuvance* was approved in Japan for use in adult patients. *Vaxneuvance* remains under review in Japan for use in pediatric patients. Sales of *Vaxneuvance* were \$170 million in 2022, largely due to inventory stocking in the U.S. Merck is party to a third-party licensing agreement pursuant to which the Company pays a royalty of 7.25% on net sales of *Vaxneuvance* through 2026; this royalty will decline to 2.5% on net sales from 2027 through 2035. The royalties are included in *Cost of sales*.

Hospital Acute Care

(\$ in millions)	2022	% Change	% Change Excluding Foreign Exchange	2021		% Change	% Change Excluding Foreign Exchange	2020
				2021	% Change			
Bridion	\$ 1,685	10 %	16 %	\$ 1,532	28 %	27 %	\$ 1,198	
Prevymis	428	16 %	24 %	370	32 %	30 %		281
Dificid	263	50 %	50 %	175	60 %	60 %		110
Zerbaxa	169	*	*	(1)	*	*		130
Welireg	123	**	**	13	—	—		—

* Calculation not meaningful.

** >100%

Global sales of *Bridion*, for the reversal of two types of neuromuscular blocking agents used during surgery, grew 10% in 2022 due to higher demand globally, particularly in the U.S., largely attributable to *Bridion*'s growing share among neuromuscular blockade reversal agents and an increase in surgical procedures. *Bridion* will lose market exclusivity in the EU in July 2023 and the Company anticipates sales of *Bridion* in these markets will decline thereafter.

Worldwide sales of *Prevymis*, a medicine for prophylaxis (prevention) of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients of an allogenic hematopoietic stem cell transplant, grew 16% in 2022 due to higher demand globally, particularly in the U.S. and Europe. In February 2023, the FDA granted priority review for a supplemental New Drug Application for *Prevymis* for prophylaxis of CMV disease in adult kidney transplant recipients at high risk (D+/R-); the Prescription Drug User Fee Act (PDUFA), or target action, date is June 5, 2023.

Worldwide sales of *Dificid*, for the treatment of *C. difficile*-associated diarrhea, grew 50% in 2022 due to higher demand in the U.S.

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

Sales of *Welireg*, for the treatment of certain adult patients with von Hippel-Lindau disease-associated RCC, increased to \$123 million in 2022 due to continued uptake in the U.S. following launch in 2021.

Cardiovascular

(\$ in millions)	2022	% Change	% Change Excluding Foreign Exchange	2021		% Change	% Change Excluding Foreign Exchange	2020
				2021	% Change			
Alliance Revenue - Adempas/Verquvo	\$ 341	— %	— %	\$ 342	22 %	22 %	\$ 281	
Adempas	238	(6)%	7 %	252	14 %	11 %		220

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

Adempas and *Verquvo* are part of a worldwide collaboration with Bayer to market and develop soluble guanylate cyclase (sGC) modulators (see Note 5 to the consolidated financial statements). *Adempas* is approved for the treatment of certain types of PAH and chronic thromboembolic pulmonary hypertension. *Verquvo* is approved to reduce the risk of cardiovascular death and heart failure hospitalization following a hospitalization for heart failure or need for outpatient intravenous diuretics in adults with symptomatic chronic heart failure and reduced ejection fraction. *Verquvo* was approved in the U.S., the EU and Japan in 2021 and has since been approved in several other markets. Alliance revenue from the collaboration was essentially flat in 2022 compared with 2021 reflecting higher profit share related to *Adempas* that was partially offset by lower profit share for *Verquvo* reflecting higher launch costs. Revenue also includes sales of *Adempas* and *Verquvo* in Merck's marketing territories. Sales of *Adempas* in Merck's marketing territories declined 6% in 2022; excluding the unfavorable effect of foreign exchange, sales grew 7% primarily reflecting higher demand in Japan.

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Virology

(\$ in millions)	2022	% Change	% Change	2021	% Change	% Change	2020
			Excluding Foreign Exchange			Excluding Foreign Exchange	
Lagevrio	\$ 5,684	*	*	\$ 952	—	—	\$ —
Isentress/Isentress HD	633	(18)%	(13)%	769	(10)%	(11)%	857

* > 100%

Lagevrio is an investigational oral antiviral COVID-19 medicine being developed in a collaboration with Ridgeback (see Note 5 to the consolidated financial statements). Following initial authorizations in certain markets in the fourth quarter of 2021, *Lagevrio* has since received multiple additional authorizations worldwide. The increase in sales of *Lagevrio* in 2022 primarily reflects higher sales in the UK, Japan and the U.S., as well as the launch in Australia. In December 2022, China's NMPA granted emergency conditional approval for *Lagevrio* for the treatment of mild to moderate COVID-19 in adults who are at risk for progressing to severe COVID-19. Merck expects sales of *Lagevrio* will decline significantly in 2023 to approximately \$1.0 billion reflecting in part the waning impact of the COVID-19 pandemic.

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 18% in 2022 due to lower global demand, reflecting in part competitive pressure particularly in Europe, Latin America and the U.S. The Company expects competitive pressure for *Isentress/Isentress HD* to continue. *Isentress/Isentress HD* will lose market exclusivity in the EU in July 2023 and the Company anticipates sales declines of *Isentress/Isentress HD* in these markets will accelerate thereafter.

Diabetes

(\$ in millions)	2022	% Change	% Change	2021	% Change	% Change	2020
			Excluding Foreign Exchange			Excluding Foreign Exchange	
Januvia/Janumet	\$ 4,513	(15)%	(9)%	\$ 5,288	— %	(2)%	\$ 5,276

Worldwide combined sales of *Januvia* and *Janumet*, medicines that help lower blood sugar levels in adults with type 2 diabetes, declined 15% in 2022 primarily reflecting the loss of exclusivity in several markets in Europe and the Asia Pacific region, as well as lower demand in the U.S. The sales decline was partially offset by increased demand in Latin America reflecting in part higher government tenders.

While the key U.S. patent for *Januvia* and *Janumet* claiming the sitagliptin compound expired in January 2023, as a result of favorable court rulings and settlement agreements related to a later expiring patent directed to the specific sitagliptin salt form of the products (see Note 11 to the consolidated financial statements), the Company expects that these products will not lose market exclusivity in the U.S. until May 2026. However, certain of the rulings are currently being appealed, and an unfavorable court decision would likely cause the products to lose exclusivity in the U.S. toward the end of 2023. As a result of competitive pressures, the Company anticipates pricing and volume declines for *Januvia* and *Janumet* in the U.S. in 2023 and thereafter.

The Company lost market exclusivity for *Januvia* in all of the EU and for *Janumet* in some European countries in September 2022. Merck expects that exclusivity for *Janumet* will be lost in other European countries in April 2023. While the Company lost market exclusivity for *Januvia* in China in 2022 with the approval of a generic equivalent product, the impact on sales in 2023 is expected to be modest. It is anticipated that a generic equivalent of *Janumet* will be approved in China in the first quarter of 2023, but the impact to sales in 2023 is also expected to be modest.

Combined sales of *Januvia* and *Janumet* in Europe, China and the U.S. represented 19%, 11% and 36%, respectively, of total combined *Januvia* and *Janumet* sales in 2022.

In response to a request from a regulatory authority, Merck evaluated its sitagliptin-containing products for the presence of nitrosamines. Nitrosamines are organic compounds found at trace levels in water and food. Nitrosamines can also result from chemical reactions and can form in drugs either due to the drug's manufacturing process, chemical structure, or the conditions in which the drugs are stored or packaged. The Company detected a nitrosamine identified as Nitroso-STG-19 (NTTP) in some batches of its sitagliptin-containing medicines. The Company has engaged with major health authorities around the world and has implemented additional quality controls to ensure its portfolio of sitagliptin-containing products meet health authorities' interim acceptable NTTP limits for continuing distribution of product to the market. The Company is making progress in its efforts to reduce the level

of nitrosamines in its sitagliptin-containing medicines. However, difficulties in reducing those levels, or achieving timely regulatory approvals for required changes, could result in product shortages.

Animal Health Segment

(\$ in millions)	2022	% Change	% Change Excluding Foreign Exchange	2021	% Change	% Change Excluding Foreign Exchange	2020
			7 %			10 %	
Livestock	\$ 3,300	— %	7 %	\$ 3,295	12 %	10 %	\$ 2,939
Companion Animal	2,250	(1)%	4 %	2,273	29 %	26 %	1,764

Sales of livestock products were essentially flat in 2022 primarily due to the unfavorable effect of foreign exchange, offset by higher pricing, as well as increased demand for ruminant and poultry products. Sales of companion animal products declined 1% in 2022 reflecting the unfavorable effect of foreign exchange and supply constraints for certain vaccines, largely offset by higher pricing in the portfolio, as well as higher demand for the Bravecto line of products, which had sales of \$1.0 billion in 2022.

Costs, Expenses and Other

(\$ in millions)	2022	% Change	2021	% Change	2020
Cost of sales	\$ 17,411	28 %	\$ 13,626	— %	\$ 13,618
Selling, general and administrative	10,042	4 %	9,634	8 %	8,955
Research and development	13,548	11 %	12,245	(9)%	13,397
Restructuring costs	337	(49)%	661	15 %	575
Other (income) expense, net	1,501	*	(1,341)	51 %	(890)
	\$ 42,839	21 %	\$ 34,825	(2)%	\$ 35,655

* Calculation not meaningful.

Cost of Sales

Cost of sales was \$17.4 billion in 2022 and \$13.6 billion in 2021. Cost of sales includes \$3.0 billion and \$502 million in 2022 and 2021, respectively, related to the collaboration with Ridgeback for Lagevrio (see Note 5 to the consolidated financial statements). Cost of sales also includes the amortization of intangible assets recorded in connection with acquisitions, collaborations, and licensing arrangements, which totaled \$2.0 billion in 2022 and \$1.6 billion in 2021. Amortization expense in 2022 and 2021 includes \$250 million and \$153 million, respectively, of cumulative catch-up amortization related to Merck's collaborations with AstraZeneca and Bayer, respectively (see Note 5 to the consolidated financial statements). Additionally, costs in 2021 include charges of \$225 million related to the discontinuation of COVID-19 development programs (see Note 4 to the consolidated financial statements). Also included in cost of sales are expenses associated with restructuring activities, which amounted to \$205 million in 2022 and \$160 million in 2021, 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 70.6% in 2022 compared with 72.0% in 2021. The gross margin decline primarily reflects the unfavorable impacts of higher amortization of intangible assets (noted above), as well as higher sales of Lagevrio and revenue from third-party manufacturing arrangements, both of which have lower gross margins. The gross margin decline was partially offset by the favorable effects of product mix, foreign exchange and charges in 2021 related to the discontinuation of COVID-19 development programs (noted above).

Selling, General and Administrative

Selling, general and administrative (SG&A) expenses were \$10.0 billion in 2022, an increase of 4% compared with 2021. The increase was primarily due to higher administrative costs, as well as higher promotional spending and selling costs, partially offset by the favorable effects of foreign exchange and lower acquisition-related costs.

Research and Development

Research and development (R&D) expenses were \$13.5 billion in 2022, an increase of 11% compared with 2021 primarily due to higher intangible asset impairment charges (largely related to nemtabrutinib), higher charges for upfront and option payments related to collaborations and licensing arrangements, higher compensation

and benefit costs reflecting in part increased headcount to support expanded clinical development activity, and increased clinical development spending. The increase in R&D expenses was partially offset by a charge in 2021 for the acquisition of Pandion Therapeutics, Inc. (Pandion).

R&D expenses are comprised of the costs directly incurred by Merck Research Laboratories (MRL), the Company's research and development division that focuses on human health-related activities, which were \$7.7 billion in 2022 and \$7.1 billion in 2021. 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 \$4.1 billion in 2022 and \$4.7 billion in 2021. The decrease in these expenses in 2022 largely reflects a \$1.7 billion charge in 2021 for the acquisition of Pandion, partially offset by \$690 million of upfront and option payments in the aggregate for collaboration and licensing agreements with Moderna, Orna and Orion. See Note 4 to the consolidated financial statements for additional information related to these business development transactions. R&D expenses also include impairment charges of \$1.7 billion and \$275 million in 2022 and 2021, respectively, largely related to nemtabrutinib (see Note 9 to the consolidated financial statements). The Company may recognize additional impairment charges in the future related to the cancellation or delay of other pipeline programs that were measured at fair value and capitalized in connection with business combinations and such charges could be material. R&D expenses also include expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration recorded in connection with business combinations. The Company recorded a net reduction in expenses of \$75 million in 2022 compared with \$35 million of expenses in 2021 related to changes in these estimates.

Restructuring Costs

In 2019, Merck approved a global restructuring program (Restructuring Program) as part of a worldwide initiative focused on further optimizing the Company's manufacturing and supply network, as well as reducing its global real estate footprint. This program is a continuation of the Company's plant rationalization and builds on prior restructuring programs. The actions currently contemplated under the Restructuring Program are expected to be substantially completed by the end of 2023, with the cumulative pretax costs to be incurred by the Company to implement the program estimated to be approximately \$3.7 billion. Merck expects to record charges of approximately \$400 million in 2023 related to the Restructuring Program. The Company anticipates the actions under the Restructuring Program will result in cumulative annual net cost savings of approximately \$900 million by the end of 2023.

Restructuring costs, primarily representing separation and other related costs associated with these restructuring activities, were \$337 million in 2022 and \$661 million in 2021. Separation costs incurred were associated with actual headcount reductions, as well as estimated expenses under existing severance programs for involuntary 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 \$666 million in 2022 and \$868 million in 2021 related to restructuring program activities (see Note 6 to the consolidated financial statements).

Other (Income) Expense, Net

Other (income) expense, net, was \$1.5 billion of expense in 2022 compared with \$1.3 billion of income in 2021 primarily due to net unrealized losses from investments in equity securities in 2022 compared with net realized and unrealized gains from investments in equity securities recorded in 2021.

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

Segment Profits

<i>(<i>\$ in millions</i>)</i>	2022	2021	2020
Pharmaceutical segment profits	\$ 36,852	\$ 30,977	\$ 26,106
Animal Health segment profits	1,963	1,950	1,669
Other non-reportable segment profits	—	—	1
Other	(22,371)	(19,048)	(21,913)
Income from Continuing Operations Before Taxes	\$ 16,444	\$ 13,879	\$ 5,863

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

Pharmaceutical segment profits grew 19% in 2022 primarily due to higher sales, partially offset by higher administrative and promotional costs, as well as the unfavorable effect of foreign exchange. Animal Health segment profits grew 1% in 2022 reflecting lower manufacturing costs, partially offset by higher selling and administrative costs and the unfavorable effect of foreign exchange.

Taxes on Income

The effective income tax rates from continuing operations were 11.7% in 2022 and 11.0% in 2021. The tax rate from continuing operations in 2022 and 2021 reflect a favorable mix of income and expense. The tax rate from continuing operations in 2022 also reflects the favorable impact of net unrealized losses from investments in equity securities and intangible asset impairment charges, which were taxed at the U.S. tax rate. These items reduced domestic pretax income by approximately \$2.9 billion in 2022. The tax rate from continuing operations in 2021 also reflects higher foreign tax credits from ordinary business operations that the Company was able to credit, the beneficial impact of the settlement of a foreign tax matter, as well as a net tax benefit of \$207 million related to the settlement of certain federal income tax matters (see Note 16 to the consolidated financial statements). Additionally, the tax rate from continuing operations in 2021 reflects the unfavorable effect of a charge for the acquisition of Pandion for which no tax benefit was recognized.

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

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

Non-GAAP income and non-GAAP EPS are important internal measures for the Company. Senior management receives a monthly analysis of operating results that includes a non-GAAP EPS metric. Management uses non-GAAP 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 a non-GAAP pretax income metric. 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 GAAP.

In 2022, the Company changed the treatment of certain items for purposes of its non-GAAP reporting. Historically, Merck's non-GAAP results excluded expenses for upfront and pre-approval milestone payments related to collaborations and licensing agreements, as well as charges related to pre-approval assets obtained in transactions accounted for as asset acquisitions, to the extent the charges were considered by the Company to be significant to the results of a particular period (as well as any related adjustments recorded in a subsequent period). Merck's non-GAAP results no longer exclude charges related to these items. Prior periods have been recast to conform to the current presentation.

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

(\$ in millions except per share amounts)	2022	2021	2020
Income from continuing operations before taxes as reported under GAAP	\$ 16,444	\$ 13,879	\$ 5,863
Increase (decrease) for excluded items:			
Acquisition and divestiture-related costs ⁽¹⁾	3,704	2,484	3,642
Restructuring costs	666	868	880
Loss (income) from investments in equity securities, net	1,348	(1,884)	(1,292)
Other items:			
Charges for the discontinuation of COVID-19 development programs	—	225	305
Other	—	(4)	(20)
Non-GAAP income from continuing operations before taxes	22,162	15,568	9,378
Taxes on income from continuing operations as reported under GAAP	1,918	1,521	1,340
Estimated tax benefit on excluded items ⁽²⁾	1,232	204	556
Net tax benefit from the settlement of certain federal income tax matters	—	207	—
Adjustment to tax benefits recorded in conjunction with the 2015 Cubist Pharmaceuticals, Inc. acquisition	—	—	(67)
Non-GAAP taxes on income from continuing operations	3,150	1,932	1,829
Non-GAAP net income from continuing operations	19,012	13,636	7,549
Less: Net income attributable to noncontrolling interests as reported under GAAP	7	13	4
Non-GAAP net income from continuing operations attributable to Merck & Co., Inc.	\$ 19,005	\$ 13,623	\$ 7,545
EPS assuming dilution from continuing operations as reported under GAAP	\$ 5.71	\$ 4.86	\$ 1.78
EPS difference	1.77	0.51	1.19
Non-GAAP EPS assuming dilution from continuing operations	\$ 7.48	\$ 5.37	\$ 2.97

⁽¹⁾ Amounts in 2022, 2021 and 2020 include \$1.7 billion, \$302 million and \$1.7 billion, respectively, of intangible asset impairment charges.

⁽²⁾ The estimated tax impact on the excluded items is determined by applying the statutory rate of the originating territory of the non-GAAP adjustments.

Acquisition and Divestiture-Related Costs

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

Restructuring Costs

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

and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation costs.

Income and Losses from Investments in Equity Securities

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

Certain Other Items

Non-GAAP income and non-GAAP EPS exclude certain other items. These items are adjusted for after evaluating them on an individual basis, considering their quantitative and qualitative aspects. Typically, these consist of items that are unusual in nature, significant to the results of a particular period or not indicative of future operating results. Excluded from non-GAAP income and non-GAAP EPS are charges related to the discontinuation of COVID-19 development programs (see Note 4 to the consolidated financial statements), as well as a net tax benefit related to the settlement of certain federal income tax matters (see Note 16 to the consolidated financial statements), and an adjustment to tax benefits recorded in conjunction with the 2015 acquisition of Cubist Pharmaceuticals, Inc.

Research and Development

Research Pipeline

The Company currently has several candidates under regulatory review in the U.S. and internationally, as well as in late-stage clinical development. A chart reflecting the Company's current research pipeline as of February 17, 2023 and related discussion is set forth in Item 1. "Business — Research and Development" above.

Acquisitions, Research Collaborations and Licensing Agreements

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

In February 2023, Merck and Kelun-Biotech closed a license and collaboration agreement expanding their relationship in which Merck gained exclusive rights for the research, development, manufacture and commercialization of up to seven investigational preclinical ADCs for the treatment of cancer. Kelun-Biotech retained the right to research, develop, manufacture and commercialize certain licensed and option ADCs for Chinese mainland, Hong Kong and Macau. Merck will make an upfront payment of \$175 million, which will be recorded in *Research and development expenses* in 2023. In addition, Kelun-Biotech is eligible to receive future contingent milestone payments and tiered royalties on future net sales for any commercialized ADC product. Also, in connection with the agreement, Merck invested \$100 million in Kelun-Biotech's Series B preferred shares in January 2023.

In January 2023, Merck acquired Imago, a clinical stage biopharmaceutical company developing new medicines for the treatment of myeloproliferative neoplasms and other bone marrow diseases, for \$1.35 billion (including payments to settle share-based equity awards) and also incurred approximately \$60 million of transaction costs. Imago's lead candidate bomedemstat, MK-3543 (formerly IMG-7289), is an investigational orally available lysine-specific demethylase 1 inhibitor currently being evaluated in multiple Phase 2 clinical trials for the treatment of essential thrombocythemia, myelofibrosis, and polycythemia vera, in addition to other indications. The transaction was accounted for as an acquisition of an asset. Merck will record net assets of approximately \$200 million and *Research and development expenses* of \$1.2 billion in 2023 related to the transaction. There are no future contingent payments associated with the acquisition.

In September 2022, Merck exercised its option to jointly develop and commercialize personalized therapeutic vaccine mRNA-4157/V940 pursuant to the terms of an existing collaboration and license agreement with Moderna, which resulted in a \$250 million charge to *Research and development expenses* in 2022. mRNA-4157/V940 is currently being evaluated in combination with Keytruda as adjuvant treatment for patients with stage III/IV melanoma following complete resection in a Phase 2 clinical trial being conducted by Moderna. Merck and Moderna will collaborate on development and commercialization and will share costs and any profits equally under this worldwide collaboration. In February 2023, Merck and Moderna announced that mRNA-4157/V940 was granted Breakthrough Therapy Designation by the FDA for the adjuvant treatment of patients with high-risk melanoma following complete resection.

In August 2022, Merck and Orna entered into a collaboration agreement to discover, develop, and commercialize multiple programs, including vaccines and therapeutics in the areas of infectious disease and oncology. Under the terms of the agreement, Merck made an upfront payment to Orna of \$150 million, which was recorded in *Research and development expenses* in 2022. In addition, Orna is eligible to receive future contingent

development-related payments, as well as royalties on any approved products derived from the collaboration. Merck also invested \$100 million in Orna's Series B preferred shares in 2022.

In July 2022, Merck and Orion announced a global co-development and co-commercialization agreement for Orion's investigational candidate ODM-208 (MK-5684) and other drugs targeting cytochrome P450 11A1 (CYP11A1), an enzyme important in steroid production. MK-5684 is an oral, non-steroidal inhibitor of CYP11A1 currently being evaluated in a Phase 2 clinical trial for the treatment of patients with mCRPC. Merck made an upfront payment to Orion of \$290 million, which was recorded in *Research and development* expenses in 2022.

Also in July 2022, Merck and Kelun-Biotech closed a license and collaboration agreement in which Merck gained exclusive worldwide rights for the development, manufacture and commercialization of an investigational ADC (MK-1200) for the treatment of solid tumors. Under the terms of the agreement, Merck and Kelun-Biotech will collaborate on the early clinical development of the investigational ADC. Merck made an upfront payment of \$35 million, which was recorded in *Research and development* expenses in 2022. Kelun-Biotech is also eligible to receive future contingent milestone payments, as well as tiered royalties on future net sales.

In May 2022, in connection with an existing arrangement, Merck exercised its option to obtain an exclusive license outside of Chinese mainland, Hong Kong, Macau and Taiwan for the development, manufacture and commercialization of Kelun-Biotech's TROP2-targeting ADC programs, including its lead compound, SKB-264 (MK-2870), which is currently in Phase 2 clinical development. Under the terms of the agreement, Merck and Kelun-Biotech will collaborate on certain early clinical development plans, including evaluating the potential of MK-2870 as a monotherapy and in combination with Keytruda for advanced solid tumors. Upon option exercise, Merck made a payment of \$30 million, which was recorded in *Research and development* expenses in 2022, and agreed to make additional payments upon completion of specified project activities, technology transfer, as well as payments to fund Kelun-Biotech's ongoing research and development activities. In addition, Kelun-Biotech is eligible to receive future contingent developmental and sales-based milestone payments and royalties on future net sales.

Acquired In-Process Research and Development

In connection with business combinations, the Company has recorded the fair value of in-process research projects which, at the time of acquisition, had not yet reached technological feasibility. At December 31, 2022, the balance of IPR&D was \$7.7 billion, primarily consisting of MK-7962 (sotatercept), \$6.4 billion; MK-7264 (gefapixant), \$832 million; and MK-1026 (nemtabrutinib), \$418 million. Sotatercept is in Phase 3 clinical development and the Company anticipates filing sotatercept with regulatory authorities in 2023. Gefapixant is under review in the U.S. and the EU. Nemtabrutinib is in Phase 2 clinical development.

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

In 2022, 2021, and 2020 the Company recorded IPR&D impairment charges within *Research and development* expenses of \$1.6 billion, \$275 million and \$90 million, respectively (see Note 9 to the consolidated financial statements).

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

Capital Expenditures

Capital expenditures were \$4.4 billion in 2022, \$4.4 billion in 2021 and \$4.4 billion in 2020. Expenditures in the U.S. were \$2.7 billion in 2022, \$2.8 billion in 2021 and \$2.6 billion in 2020. The Company plans to invest approximately \$20 billion in capital projects from 2021-2025, approximately half of which relates to investments in the U.S., including expanding manufacturing capacity for oncology, vaccine and animal health products.

Depreciation expense was \$1.8 billion in 2022, \$1.6 billion in 2021 and \$1.7 billion in 2020, of which \$1.3 billion in 2022, \$1.1 billion in 2021 and \$1.2 billion in 2020, related to locations in the U.S. Total depreciation expense in 2022, 2021 and 2020 included accelerated depreciation of \$120 million, \$91 million and \$268 million, respectively, associated with restructuring activities (see Note 6 to the consolidated financial statements).

Analysis of Liquidity and Capital Resources

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

Selected Data

<i>(\$ in millions)</i>	2022	2021	2020
Working capital	\$ 11,483	\$ 6,394	\$ 437
Total debt to total liabilities and equity	28.1 %	31.3 %	34.7 %
Cash provided by operating activities of continuing operations to total debt	0.6:1	0.4:1	0.2:1

The increase in working capital in 2022 compared with 2021 is primarily due to increased cash and investments reflecting strong operating performance. The increase in working capital in 2021 compared with 2020 is primarily related to decreased short-term debt.

Cash provided by operating activities of continuing operations was \$19.1 billion in 2022 compared with \$13.1 billion in 2021. The increase in cash provided by operating activities of continuing operations reflects stronger operating performance. Cash provided by operating activities of continuing operations was reduced by milestone and option payments related to certain collaborations of \$2.0 billion in 2022 and \$435 million in 2021. Cash provided by operating activities of continuing operations continues to be the Company's primary source of funds to finance operating needs, with excess cash serving as the primary source of funds to finance business development transactions, capital expenditures, dividends paid to shareholders and treasury stock purchases. The mandatory change in R&D capitalization rules that became effective for tax years beginning after December 31, 2021 (related to the Tax Cuts and Jobs Act of 2017 (TCJA)), increased the amount of taxes the Company pays in the U.S. beginning in 2022.

Cash used in investing activities of continuing operations was \$5.0 billion in 2022 compared with \$16.4 billion in 2021. The lower use of cash in investing activities of continuing operations was primarily due to lower cash used for acquisitions, partially offset by higher purchases of securities and other investments coupled with lower proceeds from sales of securities and other investments.

Cash used in financing activities of continuing operations was \$9.1 billion in 2022 compared with cash provided by financing activities of continuing operations of \$3.1 billion in 2021. The change was primarily driven by the cash distribution received in 2021 from Organon in connection with the spin-off (see Note 3 to the consolidated financial statements), proceeds from the issuance of debt in 2021 compared with no such proceeds in 2022, and higher dividends paid to stockholders in 2022, partially offset by net repayments of short-term borrowings and treasury stock purchases in 2021 that did not occur in 2022.

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

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

In 2022, the Company's \$1.25 billion, 2.35% notes and the Company's \$1.0 billion, 2.40% notes matured in accordance with their terms and were repaid. In 2021, the Company's \$1.15 billion, 3.875% notes and the Company's €1.0 billion, 1.125% notes matured in accordance with their terms and were repaid. In 2020, the Company's \$1.25 billion, 1.85% notes and \$700 million floating-rate notes matured in accordance with their terms and were repaid.

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

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

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

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

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

Contingent Milestone Payments — The Company has an accrued liability for a contingent sales-based milestone payment related to a collaboration with AstraZeneca where payment has been deemed probable by the Company but remains subject to the achievement of the related sales-based milestone. See Note 5 to the consolidated financial statements for additional information related to this sales-based milestone.

Purchase Obligations — Purchase obligations are enforceable and legally binding obligations for purchases of goods and services including minimum inventory contracts, research and development and advertising. Purchase obligations also include future inventory purchases the Company has committed to in connection with certain divestitures. As of December 31, 2022, the Company had total purchase obligations of \$6.0 billion, of which \$1.7 billion is estimated to be payable in 2023.

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

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

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

In November 2022, Merck's Board of Directors increased the quarterly dividend, declaring a quarterly dividend of \$0.73 per share on the Company's outstanding common stock for the first quarter of 2023 that was paid in January 2023. In January 2023, the Board of Directors declared a quarterly dividend of \$0.73 per share on the Company's outstanding common stock for the second quarter of 2023 payable in April 2023.

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 did not purchase any shares of its common stock for its treasury during 2022 under this program. As of December 31, 2022, the Company's remaining share repurchase authorization was \$5.0 billion. The Company anticipates making modest share repurchases under this program in 2023. The Company purchased \$840 million and \$1.3 billion of its common stock during 2021 and 2020, respectively, under authorized share repurchase programs.

Financial Instruments Market Risk Disclosures

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

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

Foreign Currency Risk Management

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

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

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

Because Merck principally sells foreign currency in its revenue hedging program, a uniform weakening of the U.S. dollar would yield the largest overall potential loss in the market value of these hedge instruments. The market value of Merck's hedges would have declined by an estimated \$647 million and \$648 million at December 31, 2022 and 2021, 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. 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 Company also uses a balance sheet risk management program to mitigate the exposure of such assets and liabilities from the effects of volatility in foreign exchange. Merck principally utilizes forward exchange contracts to offset the effects of exchange in developed country currencies, primarily the euro, Japanese yen, British pound, Canadian dollar, Australian dollar and Swiss franc. For exposures in developing country currencies, including the Chinese renminbi, the Company will enter into forward contracts to offset the effects of exchange on exposures when it is deemed economical to do so based on a cost-benefit analysis that considers the magnitude of the exposure, the volatility of the exchange rate and the cost of the hedging instrument. The 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 six months. 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, 2022 and 2021, *Income from Continuing Operations Before Taxes* would have declined by approximately \$190 million and \$125 million in 2022 and 2021, 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 Türkiye was determined to be hyperinflationary in 2022. Consequently, in accordance with U.S. GAAP, the Company began remeasuring the monetary assets and liabilities of those operations in earnings beginning in the second quarter of 2022. The impact to the Company's results is 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 *AOCL* until either the sale or complete or substantially complete liquidation of the subsidiary. The Company excludes certain portions of the change in fair value of its derivative instruments from the assessment of hedge effectiveness (excluded components). Changes in fair value of the excluded components are recognized in *OCI*. The Company recognizes in earnings the initial value of the excluded components on a straight-line basis over the life of the derivative instrument, rather than using the mark-to-market approach. The cash flows from these contracts are reported as investing activities in the Consolidated Statement of Cash Flows.

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

Interest Rate Risk Management

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

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, 2022 and 2021 would have positively affected the net aggregate market value of these instruments by \$2.0 billion and \$3.2 billion, respectively. A one percentage point decrease at December 31, 2022 and 2021 would have negatively affected the net aggregate market value by \$2.4 billion and \$3.9 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 in a business combination (primarily IPR&D, other intangible assets and contingent consideration), as well as subsequent fair value measurements. Additionally, estimates are used in determining such items as provisions for sales discounts and returns, depreciable and amortizable lives, recoverability of inventories, including those produced in preparation for product launches, amounts recorded for contingencies, environmental liabilities, accruals for contingent sales-based milestone payments and other reserves, pension and other postretirement benefit plan assumptions, share-based compensation assumptions, restructuring costs, impairments of long-lived assets (including intangible assets and goodwill) and investments, and taxes on income. Because of the uncertainty inherent in such estimates, actual results may differ from these estimates. Application of the following accounting policies result in accounting estimates having the potential for the most significant impact on the financial statements.

Acquisitions and Dispositions

To determine whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses, the Company makes certain judgments, which include assessment of the inputs, processes, and outputs associated with the acquired set of activities. If the Company determines that substantially all of the fair value of gross

assets included in a transaction is concentrated in a single asset (or a group of similar assets), the assets would not represent a business. To be considered a business, the assets in a transaction need to include an input and a substantive process that together significantly contribute to the ability to create outputs.

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

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

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

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

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

If the Company determines the transaction will not be accounted for as an acquisition of a business, the transaction will be accounted for as an asset acquisition rather than a business combination and, therefore, no goodwill will be recorded. In an asset acquisition, acquired IPR&D with no alternative future use is charged to expense and contingent consideration is not recognized at the acquisition date.

Contingent Sales-Based Milestones

The terms of certain collaborative arrangements require the Company to make payments contingent upon the achievement of sales-based milestones. Sales-based milestones payable by Merck to collaborative partners are accrued and capitalized, subject to cumulative amortization catch-up, when determined to be probable of being achieved by the Company based on future sales forecasts. 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 over its remaining useful life, subject to impairment testing.

Revenue Recognition

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

The vast majority of revenues from sales of products are recognized at a point in time when control of the goods is transferred to the customer, which the Company has determined is when title and risks and rewards of ownership transfer to the customer and the Company is entitled to payment. For certain services in the Animal Health segment, revenue is recognized over time, generally ratably over the contract term as services are provided. These service revenues are not material.

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

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

The U.S. provision for aggregate customer discounts covers chargebacks and rebates. Chargebacks are discounts that occur when a contracted customer purchases through an intermediary wholesaler. The contracted customer generally purchases product from the wholesaler at its contracted price plus a mark-up. The wholesaler, in turn, charges the Company back for the difference between the price initially paid by the wholesaler and the contract price paid to the wholesaler by the customer. The provision for chargebacks is based on expected sell-through levels by the Company's wholesale customers to contracted customers, as well as estimated wholesaler inventory levels. Rebates are amounts owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers after the final dispensing of the product to a benefit plan participant. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. The Company uses historical customer segment utilization mix, sales forecasts, changes to product mix and price, inventory levels in the distribution channel, government pricing calculations and prior payment history in order to estimate the expected provision. Amounts accrued for aggregate customer discounts are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal and state agencies, and other customers to the amounts accrued. Merck remains committed to the 340B Program and to providing 340B discounts to eligible covered entities. See Note 11 to the consolidated financial statements for information regarding 340B legal proceedings.

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 2022, 2021 or 2020.

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

(\$ in millions)	2022	2021
Balance January 1	\$ 2,844	\$ 2,776
Current provision	12,408	12,412
Adjustments to prior years	(155)	(110)
Payments	(12,179)	(12,234)
Balance December 31	\$ 2,918	\$ 2,844

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 \$178 million and \$2.7 billion, respectively, at December 31, 2022 and were \$207 million and \$2.6 billion, respectively, at December 31, 2021.

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

The Company maintains a returns policy that allows its U.S. pharmaceutical customers to return product within a specified period prior to and subsequent to the expiration date (generally, three to six months before and 12 months after product expiration). The estimate of the provision for returns is based upon historical experience with actual returns. Additionally, the Company considers factors such as levels of inventory in the distribution channel, product dating and expiration period, whether products have been discontinued, entrance in the market of generic or other competition, changes in formularies or launch of over-the-counter products, among others. The product returns provision for U.S. pharmaceutical sales as a percentage of U.S. net pharmaceutical sales was 1.1% in 2022, 0.9% in 2021 and 0.5% in 2020. Outside of the U.S., returns are only allowed in certain countries on a limited basis.

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

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

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 regulatory approval is considered by the Company to be probable. 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, 2022 and 2021 were \$516 million and \$256 million, respectively.

Contingencies and Environmental Liabilities

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

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of December 31, 2022 and 2021 of approximately \$230 million 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 \$4 million in 2022 and are estimated to be \$23 million in the aggregate for the years 2023 through 2027. In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled \$39 million and \$40 million at December 31, 2022 and 2021, respectively. These liabilities are undiscounted, do not consider potential recoveries from other parties and will be paid out over the periods of remediation for the applicable sites, which are expected to occur primarily over the next 15 years. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed approximately \$35 million in the aggregate. Management also does not believe that these expenditures should result in a material adverse effect on the Company's financial condition, results of operations or liquidity for any year.

Share-Based Compensation

The Company expenses all share-based payment awards to employees, including grants of stock options, over the requisite service period based on the grant date fair value of the awards. The Company determines the fair value of certain share-based awards using the Black-Scholes option-pricing model which uses both historical and current market data to estimate the fair value. This method incorporates various assumptions such as the risk-free interest rate, expected volatility, expected dividend yield and expected life of the options. Total pretax share-based compensation expense from continuing operations was \$541 million in 2022, \$479 million in 2021 and \$441 million in 2020. At December 31, 2022, there was \$813 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 \$554 million in 2022, \$748 million in 2021 and \$450 million in 2020. Net periodic benefit credit for other postretirement benefit plans was \$93 million in 2022, \$83 million in 2021 and \$59 million in 2020. 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 primarily attributable to changes in the discount rates. Additionally, net periodic benefit costs in 2022 and 2021 reflect higher settlement charges incurred by certain plans compared with 2020.

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 5.50% to 5.90% at December 31, 2022, compared with a range of 2.60% to 3.10% at December 31, 2021.

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 2023, the expected rate of return for the Company's U.S. pension and other postretirement benefit plans will be 7.00% compared to 6.70% in 2022.

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 25% to 40% in U.S. equities, 10% to 20% in international equities, 35% to 45% in fixed-income investments, and up to 8% in cash and other investments. The portfolio's equity weighting is consistent with the long-term nature of the plans' benefit obligations. The expected annual standard deviation of returns of the target portfolio, which approximates 10%, reflects both the equity allocation and the diversification benefits among the asset classes in which the portfolio invests. For international pension plans, the targeted investment portfolio varies based on the duration of pension liabilities and local government rules and regulations. Although a significant percentage of plan assets are invested in U.S. equities, concentration risk is mitigated through the use of strategies that are diversified within management guidelines.

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 \$81 million favorable (unfavorable) impact on the Company's net periodic benefit cost in 2022. 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 \$59 million favorable (unfavorable) impact on Merck's net periodic benefit cost in 2022. Required funding obligations for 2023 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 gain/loss amounts, which primarily reflect differences between expected and actual returns on plan assets as well as the effects of changes in actuarial assumptions, are recorded as a component of AOCL. Expected returns for pension plans are based on a calculated market-related value of assets. Net gain/loss amounts in AOCL in excess of certain thresholds are amortized into net periodic benefit cost over the average remaining service life of employees.

Restructuring Costs

Restructuring costs have been recorded in connection with restructuring programs designed to streamline the Company's cost structure. As a result, the Company has made estimates and judgments regarding its future plans, including future termination benefits to be incurred in conjunction with involuntary separations when such separations are probable and estimable. 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 (such as unfavorable clinical trial data, changes in the commercial landscape or delays in the clinical development program and related regulatory filing and approval timelines), by performing a quantitative test that compares the fair value of the IPR&D intangible asset with its carrying value. For impairment testing purposes, the Company may combine separately recorded IPR&D intangible assets into one unit of account based on the relevant facts and circumstances. Generally, the Company will combine IPR&D intangible assets for testing purposes if they operate as a single asset and are essentially inseparable. If the fair value is less than the carrying amount, an impairment loss is recognized in operating results.

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

Taxes on Income

The Company's effective tax rate is based on pretax income, statutory tax rates and tax planning opportunities available in the various jurisdictions in which the Company operates. An estimated effective tax rate for a year is applied to the Company's quarterly operating results. In the event that there is a significant unusual or one-time item recognized, or expected to be recognized, in the Company's quarterly operating results, the tax attributable to that item would be separately calculated and recorded at the same time as the unusual or one-time item. The Company considers the resolution of prior year tax matters to be such items. Significant judgment is required in determining the Company's tax provision and in evaluating its tax positions. The recognition and measurement of a tax position is based on management's best judgment given the facts, circumstances and information available at the reporting date. The Company evaluates tax positions to determine whether the benefits of tax positions are more

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

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

Recently Issued Accounting Standards

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

Cautionary Factors That May Affect Future Results

This report and other written reports and oral statements made from time to time by the Company may contain so-called "forward-looking statements," all of which are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially from those set forth in the statements. One can identify these forward-looking statements by their use of words such as "anticipates," "expects," "plans," "will," "estimates," "forecasts," "projects" and other words of similar meaning, or negative variations of any of the foregoing. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address the Company's growth strategy, financial results, product approvals, product potential, development programs, environmental or other sustainability initiatives, and may 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, 2022 and 2021, 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, 2022, the notes to consolidated financial statements, and the report dated February 24, 2023 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)

	2022	2021	2020
Sales	\$ 59,283	\$ 48,704	\$ 41,518
Costs, Expenses and Other			
Cost of sales	17,411	13,626	13,618
Selling, general and administrative	10,042	9,634	8,955
Research and development	13,548	12,245	13,397
Restructuring costs	337	661	575
Other (income) expense, net	1,501	(1,341)	(890)
	42,839	34,825	35,655
Income from Continuing Operations Before Taxes	16,444	13,879	5,863
Taxes on Income from Continuing Operations	1,918	1,521	1,340
Net Income from Continuing Operations	14,526	12,358	4,523
Less: Net Income Attributable to Noncontrolling Interests	7	13	4
Net Income from Continuing Operations Attributable to Merck & Co., Inc.	14,519	12,345	4,519
Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests	—	704	2,548
Net Income Attributable to Merck & Co., Inc.	\$ 14,519	\$ 13,049	\$ 7,067
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders			
Income from Continuing Operations	\$ 5.73	\$ 4.88	\$ 1.79
Income from Discontinued Operations	—	0.28	1.01
Net Income	\$ 5.73	\$ 5.16	\$ 2.79
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders			
Income from Continuing Operations	\$ 5.71	\$ 4.86	\$ 1.78
Income from Discontinued Operations	—	0.28	1.00
Net Income	\$ 5.71	\$ 5.14	\$ 2.78

Consolidated Statement of Comprehensive Income

Merck & Co., Inc. and Subsidiaries

Years Ended December 31

(\$ in millions)

	2022	2021	2020
Net Income Attributable to Merck & Co., Inc.	\$ 14,519	\$ 13,049	\$ 7,067
Other Comprehensive (Loss) Income Net of Taxes:			
Net unrealized (loss) gain on derivatives, net of reclassifications	(71)	410	(297)
Net unrealized loss on investments, net of reclassifications	—	—	(18)
Benefit plan net gain (loss) and prior service credit (cost), net of amortization	335	1,769	(279)
Cumulative translation adjustment	(603)	(423)	153
	(339)	1,756	(441)
Comprehensive Income Attributable to Merck & Co., Inc.	\$ 14,180	\$ 14,805	\$ 6,626

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)

	2022	2021
Assets		
Current Assets		
Cash and cash equivalents	\$ 12,694	\$ 8,096
Short-term investments	498	—
Accounts receivable (net of allowance for doubtful accounts of \$ 72 in 2022 and \$ 62 in 2021)	9,450	9,230
Inventories (excludes inventories of \$ 2,938 in 2022 and \$ 2,194 in 2021 classified in Other assets - see Note 8)	5,911	5,953
Other current assets	7,169	6,987
Total current assets	35,722	30,266
Investments	1,015	370
Property, Plant and Equipment (at cost)		
Land	295	326
Buildings	13,166	12,529
Machinery, equipment and office furnishings	16,760	16,303
Construction in progress	9,186	8,313
	39,407	37,471
Less: accumulated depreciation	17,985	18,192
	21,422	19,279
Goodwill	21,204	21,264
Other Intangibles, Net	20,269	22,933
Other Assets	9,528	11,582
	\$ 109,160	\$ 105,694
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	\$ 1,946	\$ 2,412
Trade accounts payable	4,264	4,609
Accrued and other current liabilities	14,159	13,859
Income taxes payable	1,986	1,224
Dividends payable	1,884	1,768
Total current liabilities	24,239	23,872
Long-Term Debt	28,745	30,690
Deferred Income Taxes	1,795	3,441
Other Noncurrent Liabilities	8,323	9,434
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 2022 and 2021	44,379	44,238
Other paid-in capital	61,081	53,696
Retained earnings	(4,768)	(4,429)
Accumulated other comprehensive loss	102,480	95,293
Less treasury stock, at cost: 1,039,269,638 shares in 2022 and 1,049,499,023 shares in 2021	56,489	57,109
Total Merck & Co., Inc. stockholders' equity	45,991	38,184
Noncontrolling Interests	67	73
Total equity	46,058	38,257
	\$ 109,160	\$ 105,694

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, 2020	\$ 1,788	\$ 39,660	\$ 46,602	\$ (6,193)	\$ (55,950)	\$ 94	\$ 26,001
Net income attributable to Merck & Co., Inc.	—	—	7,067	—	—	—	7,067
Other comprehensive loss, net of taxes	—	—	—	(441)	—	—	(441)
Cash dividends declared on common stock (\$ 2.48 per share)	—	—	(6,307)	—	—	—	(6,307)
Treasury stock shares purchased	—	—	—	—	(1,281)	—	(1,281)
Net income attributable to noncontrolling interests	—	—	—	—	—	15	15
Distributions attributable to noncontrolling interests	—	—	—	—	—	(22)	(22)
Share-based compensation plans and other	—	(72)	—	—	444	—	372
Balance December 31, 2020	1,788	39,588	47,362	(6,634)	(56,787)	87	25,404
Net income attributable to Merck & Co., Inc.	—	—	13,049	—	—	—	13,049
Other comprehensive income, net of taxes	—	—	—	1,756	—	—	1,756
Cash dividends declared on common stock (\$ 2.64 per share)	—	—	(6,715)	—	—	—	(6,715)
Treasury stock shares purchased	—	—	—	—	(840)	—	(840)
Spin-off of Organon & Co.	—	4,643	—	449	—	(1)	5,091
Net income attributable to noncontrolling interests	—	—	—	—	—	16	16
Distributions attributable to noncontrolling interests	—	—	—	—	—	(29)	(29)
Share-based compensation plans and other	—	7	—	—	518	—	525
Balance December 31, 2021	1,788	44,238	53,696	(4,429)	(57,109)	73	38,257
Net income attributable to Merck & Co., Inc.	—	—	14,519	—	—	—	14,519
Other comprehensive loss, net of taxes	—	—	—	(339)	—	—	(339)
Cash dividends declared on common stock (\$ 2.80 per share)	—	—	(7,134)	—	—	—	(7,134)
Net income attributable to noncontrolling interests	—	—	—	—	—	7	7
Distributions attributable to noncontrolling interests	—	—	—	—	—	(13)	(13)
Share-based compensation plans and other	—	141	—	—	620	—	761
Balance December 31, 2022	\$ 1,788	\$ 44,379	\$ 61,081	\$ (4,768)	\$ (56,489)	\$ 67	\$ 46,058

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

Consolidated Statement of Cash Flows

Merck & Co., Inc. and Subsidiaries

Years Ended December 31

(\$ in millions)

	2022	2021	2020
Cash Flows from Operating Activities of Continuing Operations			
Net income from continuing operations	\$ 14,526	\$ 12,358	\$ 4,523
Adjustments to reconcile net income from continuing operations to net cash provided by operating activities of continuing operations:			
Amortization	2,085	1,636	1,817
Depreciation	1,824	1,578	1,669
Intangible asset impairment charges	1,749	302	1,718
Loss (income) from investments in equity securities, net	1,419	(1,940)	(1,338)
Charge for the acquisition of Pandion Therapeutics, Inc.	—	1,556	—
Charge for the acquisition of VelosBio Inc.	—	—	2,660
Deferred income taxes	(1,568)	187	(566)
Share-based compensation	541	479	441
Other	1,301	805	1,294
Net changes in assets and liabilities:			
Accounts receivable	(644)	(2,033)	(1,002)
Inventories	(161)	(674)	(895)
Trade accounts payable	(289)	405	684
Accrued and other current liabilities	(50)	277	(1,152)
Income taxes payable	380	(540)	814
Noncurrent liabilities	(545)	484	(617)
Other	(1,473)	(1,758)	(2,433)
Net Cash Provided by Operating Activities of Continuing Operations	19,095	13,122	7,617
Cash Flows from Investing Activities of Continuing Operations			
Capital expenditures	(4,388)	(4,448)	(4,429)
Purchase of Seagen Inc. common stock	—	—	(1,000)
Purchases of securities and other investments	(1,204)	(1)	(95)
Proceeds from sales of securities and other investments	721	1,026	2,812
Acquisition of Acceleron Pharma Inc., net of cash acquired	—	(11,174)	—
Acquisition of Pandion Therapeutics, Inc., net of cash acquired	—	(1,554)	—
Acquisition of VelosBio Inc., net of cash acquired	—	—	(2,696)
Acquisition of ArQule, Inc., net of cash acquired	—	—	(2,545)
Other acquisitions, net of cash acquired	(121)	(179)	(1,365)
Other	32	(91)	125
Net Cash Used in Investing Activities of Continuing Operations	(4,960)	(16,421)	(9,193)
Cash Flows from Financing Activities of Continuing Operations			
Net change in short-term borrowings	—	(3,986)	2,549
Payments on debt	(2,251)	(2,319)	(1,957)
Proceeds from issuance of debt	—	7,936	4,419
Distribution from Organon & Co.	—	9,000	—
Purchases of treasury stock	—	(840)	(1,281)
Dividends paid to stockholders	(7,012)	(6,610)	(6,215)
Proceeds from exercise of stock options	384	202	89
Other	(240)	(286)	(436)
Net Cash (Used in) Provided by Financing Activities of Continuing Operations	(9,119)	3,097	(2,832)
Cash Flows from Discontinued Operations			
Net cash provided by operating activities	—	987	2,636
Net cash used in investing activities	—	(134)	(250)
Net cash used in financing activities	—	(504)	—
Net Cash Flows Provided by Discontinued Operations	—	349	2,386
Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash	(410)	(133)	253
Net Increase (Decrease) in Cash, Cash Equivalents and Restricted Cash	4,606	14	(1,769)
Cash, Cash Equivalents and Restricted Cash at Beginning of Year (includes \$ 71, \$ 103 and \$ 258 of restricted cash at January 1, 2022, 2021 and 2020 included in Other current assets)	8,167	8,153	9,934
Less: Cash and cash equivalents related to discontinued operations	—	—	12
Cash, Cash Equivalents and Restricted Cash at End of Year (includes \$ 79, \$ 71 and \$ 103 of restricted cash at December 31, 2022, 2021 and 2020 included in Other current assets)	\$ 12,773	\$ 8,167	\$ 8,153

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, including biologic therapies, vaccines and animal health products. The Company's operations are principally managed on a product basis and include two operating segments, Pharmaceutical and Animal Health, both of which are reportable segments.

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

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

Spin-Off of Organon & Co.

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

2. Summary of Accounting Policies

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

Acquisitions — In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the acquisition at their respective fair values with limited exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are generally recognized at fair value. If fair value cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Accordingly, the Company may be required to value assets at fair value measures that do not reflect the Company's intended use of those assets. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in the Company's consolidated financial statements after the date of the acquisition. If the Company determines the assets acquired do not meet the definition of a business under the acquisition method of accounting, the transaction will be accounted for as an acquisition of assets rather than a business combination and, therefore, no

goodwill will be recorded. In an asset acquisition, acquired in-process research and development (IPR&D) with no alternative future use is charged to expense and contingent consideration is not recognized at the acquisition date.

Foreign Currency Translation — The net assets of international subsidiaries where the local currencies have been determined to be the functional currencies are translated into U.S. dollars using current exchange rates and results of operations are translated at average exchange rates. The U.S. dollar effects that arise from translating the net assets of these subsidiaries at changing rates are recorded in *Other Comprehensive Income (OCI)* and remain in *Accumulated other comprehensive loss (AOCL)* until either the sale or complete or substantially complete liquidation of the subsidiary. 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. human health 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 by the Company to be probable of obtaining 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 quoted prices for similar assets or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Changes in fair value that are not impairment related are reported net of taxes in *OCI*. The Company considers available evidence in evaluating potential impairments of its investments in marketable debt securities, including the extent to which fair value is less than cost, whether an allowance for credit loss is required, as well as adverse factors that could affect the value of the securities. An impairment has occurred if the Company does not expect to recover the entire amortized cost basis of the marketable debt security. If the Company does not intend to sell the impaired debt security, and it is not more likely than not it will be required to sell the debt security before the recovery of its amortized cost basis, the amount of the impairment recognized in earnings, recorded in *Other (income) expense, net* is limited to the portion attributed to credit loss. The remaining portion of the impairment related to other factors is recognized in *OCI*. Realized gains and losses for debt securities are included in *Other (income) expense, net*.

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

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

The vast majority of revenues from sales of products are recognized at a point in time when control of the goods is transferred to the customer, which the Company has determined is when title and risks and rewards of ownership transfer to the customer and the Company is entitled to payment. The Company recognizes revenue from the sales of vaccines to the Federal government for placement into vaccine stockpiles in accordance with Securities and Exchange Commission (SEC) Interpretation, *Commission Guidance Regarding Accounting for Sales of Vaccines*

and BioTerror Countermeasures to the Federal Government for Placement into the Pediatric Vaccine Stockpile or the Strategic National Stockpile. This interpretation allows companies to recognize revenue for sales of vaccines into U.S. government stockpiles even though these sales might not meet the criteria for revenue recognition under other accounting guidance. Some customers have bill-and-hold arrangements with the Company. Revenue for bill-and-hold arrangements is recognized when control transfers to the customer even though the customer does not yet have physical possession of the goods. Control transfers when the bill-and-hold arrangement has been requested by the customer, the product is identified as belonging to the customer and is ready for physical transfer, the product cannot be directed for use by anyone but the customer and, in certain circumstances, the customer has inspected and accepted the product at the Company's facility. For certain services in the Animal Health segment, revenue is recognized over time, generally ratably over the contract term as services are provided. These service revenues are not material.

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

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

The U.S. provision for aggregate customer discounts covering chargebacks and rebates was \$ 12.3 billion in 2022, \$ 12.3 billion in 2021 and \$ 11.4 billion in 2020. Chargebacks are discounts that occur when a contracted customer purchases through an intermediary wholesaler. The contracted customer generally purchases product from the wholesaler at its contracted price plus a mark-up. The wholesaler, in turn, charges the Company back for the difference between the price initially paid by the wholesaler and the contract price paid to the wholesaler by the customer. The provision for chargebacks is based on expected sell-through levels by the Company's wholesale customers to contracted customers, as well as estimated wholesaler inventory levels. Rebates are amounts owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers after the final dispensing of the product to a benefit plan participant. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. The Company uses historical customer segment utilization mix, sales forecasts, changes to product mix and price, inventory levels in the distribution channel, government pricing calculations and prior payment history in order to estimate the expected provision. Amounts accrued for aggregate customer discounts are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal and state agencies, and other customers to the amounts accrued. The accrued balances relative to the provisions for chargebacks and rebates included in *Accounts receivable and Accrued and other current liabilities* were \$ 178 million and \$ 2.7 billion, respectively, at December 31, 2022 and were \$ 207 million and \$ 2.6 billion, respectively, at December 31, 2021.

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

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

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

See Note 19 for disaggregated revenue disclosures.

Depreciation — Depreciation is provided over the estimated useful lives of the assets, principally using the straight-line method. For tax purposes, accelerated tax methods are used. The estimated useful lives primarily range from 25 to 40 years for *Buildings*, and from 3 to 15 years for *Machinery, equipment and office furnishings*. Depreciation expense was \$ 1.8 billion in 2022, \$ 1.6 billion in 2021 and \$ 1.7 billion in 2020.

Advertising and Promotion Costs — Advertising and promotion costs are expensed as incurred. The Company recorded advertising and promotion expenses of \$ 2.2 billion in 2022, \$ 2.0 billion in 2021 and \$ 1.8 billion in 2020.

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 — Intangibles acquired in a business combination include products and product rights, trade names and patents, licenses and other, which are initially recorded at fair value, assigned an estimated useful life, and amortized primarily on a straight-line basis over their estimated useful lives ranging from 2 to 24 years. The Company periodically evaluates whether current facts or circumstances indicate that the carrying values of its acquired intangibles may not be recoverable. If such circumstances are determined to exist, an estimate of the undiscounted future cash flows of these assets, or appropriate asset groupings, is compared to the carrying value to determine whether an impairment exists. If the asset is determined to be impaired, the loss is measured based on the difference between the carrying value of the intangible asset and its fair value, which is determined based on the net present value of estimated future cash flows.

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

Contingent Consideration — Certain of the Company's acquisitions involve the potential for future payment of consideration that is contingent upon the achievement of performance milestones, including product development milestones and royalty payments on future product sales. If the transaction is accounted for as a business combination, the fair value of contingent consideration liabilities is determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date, at each reporting period until the contingency is resolved, the contingent consideration liability is remeasured at current fair value with changes (either expense or income) recorded in earnings. Significant events that increase or decrease the probability of achieving development and regulatory milestones or that increase or decrease projected cash flows will result in corresponding increases or decreases in the fair values of the related contingent consideration obligations.

Research and Development — Research and development is expensed as incurred. Nonrefundable advance payments for goods and services that will be used in future research and development activities are

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

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

In addition, the terms of the collaboration agreements may require the Company to make payments based upon the achievement of certain developmental, regulatory approval or commercial milestones. Upfront and milestone payments payable by Merck to collaborative partners prior to regulatory approval are expensed as incurred and included in *Research and development expenses*. Payments due to collaborative partners upon or subsequent to regulatory approval are capitalized and amortized to *Cost of sales* over the estimated useful life of the corresponding intangible asset 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 determined to be probable of being achieved by the Company. 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, future employee termination costs to be incurred in conjunction with involuntary separations are accrued when such separations are probable and estimable. When accruing these costs, the Company will recognize the amount within a range of costs that is the best estimate within the range. When no amount within the range is a better estimate than any other amount, the Company recognizes the minimum amount within the range. Costs for one-time termination benefits in which the employee is required to render service until termination in order to receive the benefits are recognized ratably over the future service period.

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

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

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

Use of Estimates — The consolidated financial statements are prepared in conformity with accounting principles generally accepted in the U.S. (GAAP) and, accordingly, include certain amounts that are based on management's best estimates and judgments. Estimates are used when accounting for amounts recorded in connection with acquisitions, including initial fair value determinations of assets and liabilities in a business combination (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.

Recently Adopted Accounting Standards — In August 2020, the Financial Accounting Standards Board (FASB) issued amended guidance on the accounting for convertible instruments and contracts in an entity's own equity. The guidance removes the separation model for convertible debt instruments and preferred stock, amends requirements for conversion options to be classified in equity as well as amends diluted earnings per share (EPS) calculations for certain convertible debt instruments. The Company adopted the new guidance on January 1, 2022 using a modified retrospective approach. There was no impact to the Company's consolidated financial statements upon adoption.

In November 2021, the FASB issued new guidance to increase the transparency of transactions with a government that are accounted for by applying a grant or contribution accounting model by analogy. The guidance requires annual disclosures of such transactions to include the nature of the transactions and the significant terms and conditions, the accounting treatment and the impact to a company's financial statements. The Company adopted the new guidance on January 1, 2022 on a prospective basis. There was no material impact to the Company's consolidated financial statements upon adoption.

In March 2020, the FASB issued optional guidance to ease the potential burden in accounting for (or recognizing the effects of) reference rate reform on financial reporting and subsequently issued clarifying amendments. The guidance provides optional expedients and exceptions for accounting for contracts, hedging relationships, and other transactions that reference the London Interbank Offered Rate (LIBOR) or another reference rate expected to be discontinued because of reference rate reform. The Company adopted the optional guidance on July 1, 2022 on a prospective basis. There was no material impact to the Company's consolidated financial statements upon adoption.

In October 2021, the FASB issued amended guidance that requires acquiring entities to recognize and measure contract assets and liabilities in a business combination in accordance with existing revenue recognition guidance. The Company adopted the guidance effective January 1, 2023. The adoption of this guidance did not have an impact on the Company's consolidated financial statements for prior acquisitions; however, the impact in future periods will be dependent upon the contract assets and contract liabilities acquired in future business combinations.

Recently Issued Accounting Standard Not Yet Adopted — In June 2022, the FASB issued guidance related to the fair value measurement of an equity security subject to contractual restrictions that prohibit the sale of the equity security. The new guidance also introduces new disclosure requirements for equity securities subject to contractual sale restrictions that are measured at fair value. The amended guidance is effective for interim and annual periods in 2024 and is to be applied prospectively. Early adoption is permitted for both interim and annual periods. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

3. Spin-Off of Organon & Co.

On June 2, 2021, Merck completed the spin-off of Organon through a distribution of Organon's publicly traded stock to Company shareholders. In connection with the spin-off, each Merck shareholder received one-tenth of a share of Organon's common stock for each share of Merck common stock held by such shareholder. The distribution is expected to qualify and has been treated as tax free to Merck and its shareholders for U.S. federal income tax purposes. Indebtedness of \$ 9.5 billion principal amount, consisting of term loans and senior notes, was issued in 2021 in connection with the spin-off and assumed by Organon. Merck is no longer the obligor of any Organon debt or financing arrangements. Cash proceeds of \$ 9.0 billion were distributed by Organon to Merck in connection with the spin-off.

Also in connection with the spin-off, Merck and Organon entered into a separation and distribution agreement and also entered into various other agreements to effect the spin-off and provide a framework for the relationship between Merck and Organon after the spin-off, including a transition services agreement (TSA), manufacturing and supply agreements (MSAs), trademark license agreements, intellectual property license agreements, an employee matters agreement, a tax matters agreement and certain other commercial agreements. Under the TSA, Merck is providing Organon various services and, similarly, Organon is providing Merck various services. The provision of services under the TSA generally will terminate within 25 months following the spin-off; however, the provision of certain services has been extended to 35 months. Merck and Organon also entered into a series of interim operating agreements pursuant to which in various jurisdictions where Merck held licenses, permits and other rights in connection with marketing, import and/or distribution of Organon products prior to the separation, Merck is continuing to market, import and distribute such products until such time as the relevant licenses and permits are transferred to Organon. Under such interim operating agreements and in accordance with the separation and distribution agreement, Merck is continuing operations in the affected markets on behalf of Organon, with Organon receiving all of the economic benefits and burdens of such activities. Additionally, Merck and Organon entered into a number of MSAs pursuant to which Merck is (a) manufacturing and supplying certain active pharmaceutical ingredients for Organon, (b) manufacturing and supplying certain formulated pharmaceutical products for Organon, and (c) packaging and labeling certain finished pharmaceutical products for Organon. Similarly, Organon and Merck entered into a number of MSAs pursuant to which Organon is (a) manufacturing and supplying certain formulated pharmaceutical products for Merck, and (b) packaging and labeling certain finished pharmaceutical products for Merck. The terms of the MSAs range in initial duration from four years to ten years .

The amounts included in the consolidated statement of income for the above MSAs include sales of \$ 383 million and \$ 219 million in 2022 and 2021, respectively, and related cost of sales of \$ 404 million and \$ 195 million in 2022 and 2021, respectively. Amounts included in the consolidated statement of income for the TSAs were immaterial in 2022 and 2021. The amounts due from Organon under all of the above agreements were \$ 511 million and \$ 964 million at December 31, 2022 and 2021, respectively, and are reflected in *Other current assets*. The amounts due to Organon under these agreements were \$ 345 million and \$ 400 million at December 31, 2022 and 2021, respectively, and are included in *Accrued and other current liabilities*.

The results of the women's health, biosimilars and established brands businesses (previously included in the Pharmaceutical segment) that were contributed to Organon in the spin-off, as well as interest expense related to the debt issuance in 2021, have been reflected as discontinued operations in the Company's consolidated statement of income as *Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests* for periods prior to the spin-off on June 2, 2021. Merck incurred separation costs of \$ 556 million in 2021 and \$ 743 million in 2020 related to the spin-off of Organon, which are also included in *Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests*. These costs primarily relate to professional fees for separation activities within finance, tax, legal and information technology functions, as well as investment banking fees.

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

Years Ended December 31	2021 ⁽¹⁾	2020
Sales	\$ 2,512	\$ 6,476
Costs, Expenses and Other		
Cost of sales	789	1,867
Selling, general and administrative	877	1,513
Research and development	103	161
Restructuring costs	1	3
Other (income) expense, net	(15)	4
	1,755	3,548
Income from discontinued operations before taxes	757	2,928
Tax provision	50	369
Income from discontinued operations, net of taxes	707	2,559
Less: Income of discontinued operations attributable to noncontrolling interests	3	11
	\$ 704	\$ 2,548

⁽¹⁾ Reflects amounts through the June 2, 2021 spin-off date.

4. Acquisitions, Research Collaborations and Licensing 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.

Recently Completed Transactions

In February 2023, Merck and Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (Kelun-Biotech) closed a license and collaboration agreement expanding their relationship in which Merck gained exclusive rights for the research, development, manufacture and commercialization of up to seven investigational preclinical antibody drug conjugates (ADCs) for the treatment of cancer. Kelun-Biotech retained the right to research, develop, manufacture and commercialize certain licensed and option ADCs for Chinese mainland, Hong Kong and Macau. Merck will make an upfront payment of \$ 175 million, which will be recorded in *Research and development* expenses in 2023. In addition, Kelun-Biotech is eligible to receive future contingent development-related payments aggregating up to \$ 1.0 billion, \$ 2.8 billion in regulatory milestones, and \$ 5.5 billion in sales-based milestones if Kelun-Biotech does not retain Chinese mainland, Hong Kong and Macau rights for the option ADCs and all candidates achieve regulatory approval. In addition, Kelun-Biotech is eligible to receive tiered royalties ranging from a mid-single-digit rate to a low-double-digit rate on future net sales for any commercialized ADC product. Also, in connection with the agreement, Merck invested \$ 100 million in Kelun-Biotech's Series B preferred shares in January 2023.

In January 2023, Merck acquired Imago BioSciences, Inc. (Imago), a clinical stage biopharmaceutical company developing new medicines for the treatment of myeloproliferative neoplasms and other bone marrow diseases, for \$ 1.35 billion (including payments to settle share-based equity awards) and also incurred approximately \$ 60 million of transaction costs. Imago's lead candidate bomedemstat, MK-3543 (formerly IMG-7289), is an investigational orally available lysine-specific demethylase 1 inhibitor currently being evaluated in multiple Phase 2 clinical trials for the treatment of essential thrombocythemia, myelofibrosis, and polycythemia vera, in addition to other indications. The transaction was accounted for as an acquisition of an asset. Merck will record net assets of approximately \$ 200 million and *Research and development* expenses of \$ 1.2 billion in 2023 related to the transaction. There are no future contingent payments associated with the acquisition.

2022 Transactions

In October 2022, Merck and Royalty Pharma plc (Royalty Pharma) entered into a funding arrangement under which Royalty Pharma paid Merck \$ 50 million to co-fund Merck's development costs for a Phase 2b trial of MK-8189, an investigational oral phosphodiesterase 10A (PDE10A) inhibitor, which is being evaluated for the treatment of schizophrenia. As Royalty Pharma is sharing the risk of technical and regulatory success with Merck, the development funding was recognized by Merck as an obligation to perform contractual services. Accordingly, the payment received is being recognized by Merck as a reduction to *Research and development* expenses ratably over the estimated Phase 2b research period. Under the agreement, Royalty Pharma has no rights to MK-8189 and has no decision-making authority over the program. If Merck elects to advance MK-8189 into a Phase 3 study, Royalty Pharma has the option to provide additional funding of 50 % of the development costs up to \$ 375 million. Royalty Pharma is eligible to receive royalties on future sales. If Royalty Pharma elects to provide the additional funding noted above, Royalty Pharma becomes eligible to receive future regulatory milestone payments contingent upon certain marketing approvals, as well as a higher royalty rate. Merck will record the milestone payments as an expense within *Other (income), net* upon receipt of the related approvals.

In September 2022, Merck exercised its option to jointly develop and commercialize personalized therapeutic cancer vaccine mRNA-4157/V940 pursuant to the terms of an existing collaboration and license agreement with Moderna, Inc. (Moderna), which resulted in a \$ 250 million charge to *Research and development* expenses in 2022. mRNA-4157/V940 is currently being evaluated in combination with Keytruda (pembrolizumab), Merck's anti-PD-1 therapy, as adjuvant treatment for patients with stage III/IV melanoma following complete resection in a Phase 2 clinical trial being conducted by Moderna. Merck and Moderna will collaborate on development and commercialization and will share costs and any profits equally under this worldwide collaboration.

In August 2022, Merck and Orna Therapeutics (Orna), a biotechnology company pioneering a new investigational class of engineered circular RNA (orRNA) therapies, entered into a collaboration agreement to discover, develop, and commercialize multiple programs, including vaccines and therapeutics in the areas of infectious disease and oncology. Under the terms of the agreement, Merck made an upfront payment to Orna of \$ 150 million, which was recorded in *Research and development* expenses in 2022. In addition, Orna is eligible to receive future contingent development-related payments aggregating up to \$ 440 million, \$ 675 million in regulatory milestones, and \$ 2.4 billion in sales-based milestones associated with the progress of the multiple vaccine and therapeutic programs, as well as royalties ranging from a high-single-digit rate to a low-double-digit rate on any approved products derived from the collaboration. Merck also invested \$ 100 million in Orna's Series B preferred shares in 2022.

In July 2022, Merck and Orion Corporation (Orion) announced a global co-development and co-commercialization agreement for Orion's investigational candidate ODM-208 (MK-5684) and other drugs targeting cytochrome P450 11A1 (CYP11A1), an enzyme important in steroid production. MK-5684 is an oral, non-steroidal inhibitor of CYP11A1 currently being evaluated in a Phase 2 clinical trial for the treatment of patients with metastatic castration-resistant prostate cancer. Merck made an upfront payment to Orion of \$ 290 million, which was recorded in *Research and development* expenses in 2022. Orion is responsible for the manufacture of clinical and commercial supply of MK-5684. In addition, the contract provides both parties with an option to convert the initial co-development and co-commercialization agreement into a global exclusive license to Merck. If the option is exercised, Merck would assume full responsibility for all past development and commercialization expenses associated with the program since inception of the agreement, as well as all future development and commercialization expenses. In addition, Orion would be eligible to receive milestone payments associated with progress in the development and commercialization of MK-5684, as well as tiered double-digit royalties on sales if the product is approved.

Also in July 2022, Merck and Kelun-Biotech closed a license and collaboration agreement in which Merck gained exclusive worldwide rights for the development, manufacture and commercialization of an investigational ADC (MK-1200) for the treatment of solid tumors. Under the terms of the agreement, Merck and Kelun-Biotech will collaborate on the early clinical development of the investigational ADC. Merck made an upfront payment of \$ 35 million, which was recorded in *Research and development* expenses in 2022. Kelun-Biotech is also eligible to receive future contingent milestone payments aggregating up to \$ 82 million in developmental milestones, \$ 334 million in regulatory milestones, and \$ 485 million in sales-based milestones. The agreement also provides for Merck to pay tiered royalties ranging from a mid-single-digit rate to a low-double-digit rate on future net sales.

In May 2022, in connection with an existing arrangement, Merck exercised its option to obtain an exclusive license outside of Chinese mainland, Hong Kong, Macau and Taiwan for the development, manufacture and commercialization of Kelun-Biotech's trophoblast antigen 2 (TROP2)-targeting ADC programs, including its lead compound, SKB-264 (MK-2870), which is currently in Phase 2 clinical development. Under the terms of the agreement, Merck and Kelun-Biotech will collaborate on certain early clinical development plans, including evaluating the potential of MK-2870 as a monotherapy and in combination with Keytruda for advanced solid tumors. Upon option

exercise, Merck made a payment of \$ 30 million, which was recorded in *Research and development* expenses in 2022, and agreed to make additional payments of \$ 30 million upon completion of specified project activities and \$ 25 million upon technology transfer. Merck also agreed to make quarterly payments in 2022 and 2023 aggregating up to \$ 111 million to fund Kelun-Biotech's ongoing research and development activities, of which \$ 51 million was paid in 2022. In addition, Kelun-Biotech is eligible to receive future contingent milestone payments (which includes all program compounds) aggregating up to \$ 90 million in developmental milestones, \$ 290 million in first commercial sale milestones, and \$ 780 million in sales-based milestones. The agreement also provides for Merck to pay tiered royalties ranging from a mid-single-digit rate to a low-double-digit rate on future net sales.

2021 Transactions

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

In addition to sotatercept, Acceleron's portfolio includes Reblozyl (luspatercept), a first-in-class erythroid maturation recombinant fusion protein that is approved in the U.S., Europe, and certain other markets for the treatment of anemia in certain rare blood disorders and is also being evaluated for additional indications for hematology therapies. Reblozyl is being developed and commercialized through a global collaboration with BMS. In connection with this ongoing collaboration, Merck receives a 20 % sales royalty from BMS which could increase to a maximum of 24 % based on sales levels. This royalty will be reduced by 50 % upon the earlier of patent expiry or generic entry on an indication-by-indication basis in each market. Additionally, Merck received a contingent regulatory milestone payment of \$ 20 million in 2022 and remains eligible to receive up to \$ 80 million in sales-based milestones.

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

The estimated fair value of assets acquired and liabilities assumed from Acceleron (inclusive of measurement period adjustments) is as follows:

	November 19, 2021
Cash and cash equivalents	\$ 340
Investments	285
Identifiable intangible assets: ⁽¹⁾	
IPR&D - sotatercept	6,380
Products and product rights - Reblozyl (12 year useful life)	3,830
Deferred income tax liabilities, net	(1,814)
Other assets and liabilities, net	82
Total identifiable net assets	9,103
Goodwill ⁽²⁾	2,411
Consideration transferred	\$ 11,514

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

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

In April 2021, Merck acquired Pandion Therapeutics, Inc. (Pandion), a clinical-stage biotechnology company developing novel therapeutics designed to address the unmet needs of patients living with autoimmune diseases. Pandion's development work focused on advancing a pipeline of precision immune modulators targeting

critical immune control nodes. Total consideration paid of \$ 1.9 billion included \$ 147 million of costs primarily comprised of share-based compensation payments to settle equity awards. The transaction was accounted for as an acquisition of an asset. Merck recorded net assets of \$ 156 million (primarily cash) and *Research and development* expenses of \$ 1.7 billion in 2021 related to the transaction. There are no future contingent payments associated with the acquisition.

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

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

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

In December 2021, the U.S. Food and Drug Administration (FDA) placed full or partial clinical holds on investigational new drug applications for certain oral, implant and injectable formulations of islatravir based on observations of decreases in total lymphocyte and CD4+ T-cell counts in some participants receiving islatravir in clinical studies. In September 2022, Merck announced the Phase 2 clinical trial evaluating an investigational oral once-weekly combination treatment regimen of islatravir and lenacapavir in adults with HIV-1 infection who are virologically suppressed will resume under an amended protocol with a lower dose of islatravir. The investigational new drug application for the islatravir + lenacapavir once-weekly treatment regimen remains under a partial clinical hold for any studies that would use weekly oral islatravir doses higher than the doses considered for the revised clinical program. Additionally, Merck announced it will discontinue the development of once-monthly oral islatravir for pre-exposure prophylaxis (PrEP). The Company remains committed to developing compounds for long-acting HIV prevention and believes in the potential of the nucleoside reverse transcriptase translocation inhibitor (NRTI) mechanism.

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

2020 Transactions

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

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

In September 2020, Merck and Seagen Inc. (Seagen) announced an oncology collaboration to globally develop and commercialize Seagen's ladiratuzumab vedotin (MK-6440), an investigational ADC targeting LIV-1, which is currently in Phase 2 clinical trials. The companies will equally share profits worldwide. Under the terms of the agreement, Merck made an upfront payment of \$ 600 million and a \$ 1.0 billion equity investment in 5 million shares of Seagen common stock at a price of \$ 200 per share. Merck recorded \$ 616 million in *Research and development* expenses in 2020 related to this transaction reflecting the upfront payment as well as a \$ 16 million premium relating to the equity shares based on the price of Seagen common stock on the closing date. Seagen is also eligible to receive future contingent milestone payments of up to \$ 2.6 billion, including \$ 850 million in development milestones and \$ 1.75 billion in sales-based milestones.

Concurrent with the above transaction, Seagen granted Merck an exclusive license to commercialize Tukysa (tucatinib), a small molecule tyrosine kinase inhibitor, for the treatment of human epidermal growth factor receptor 2 (HER2)-positive cancers, in Asia, the Middle East and Latin America and other regions outside of the U.S., Canada and Europe. Merck will be responsible for marketing applications seeking approval in its territories. 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 is receiving tiered royalties ranging from 20 % to 33 % based on annual sales levels of Tukysa in Merck's territories.

Also 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 are being amortized over their estimated useful lives of 15 years. There are no future contingent payments associated with the acquisition.

Also in July 2020, Merck and Ridgeback Biotherapeutics LP (Ridgeback), a closely held biotechnology company, closed a collaboration agreement to develop *Lagevrio* (molnupiravir), an investigational oral antiviral COVID-19 medicine. See Note 5 for additional information related to this collaboration.

In June 2020, Merck acquired privately held Themis Bioscience GmbH (Themis), a company focused on vaccines (including a COVID-19 vaccine candidate, V591) and immune-modulation therapies for infectious diseases and cancer for \$ 366 million. The acquisition originally provided for Merck to make additional contingent payments. The transaction was accounted for as a business combination. The Company determined the fair value of the contingent consideration was \$ 85 million at the acquisition date utilizing a probability-weighted estimated cash flow stream using an appropriate discount rate dependent on the nature and timing of the milestone payments. Merck recognized intangible assets for IPR&D of \$ 113 million, cash of \$ 59 million, deferred tax assets of \$ 72 million and other net liabilities of \$ 32 million. The excess of the consideration transferred over the fair value of net assets acquired of \$ 239 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair values of the identifiable intangible assets related to IPR&D were determined using an income approach. 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. In 2022, the Company wrote off the remaining IPR&D intangible asset and related contingent consideration liability; the net impact to *Research and development expenses* was immaterial.

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

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

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

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

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

⁽¹⁾ The estimated fair value of nemtabrutinib was determined using an income approach. The future probability-weighted net cash flows were discounted to present value utilizing a discount rate of 12.5 %.

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

Merck recorded intangible asset impairment charges in 2022 and 2021 related to nemtabrutinib and in 2022 related to derazantinib (see Note 9).

5. Collaborative Arrangements

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

AstraZeneca

In 2017, Merck and AstraZeneca PLC (AstraZeneca) entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza (olaparib) for multiple cancer types. Independently, Merck and AstraZeneca will develop and commercialize Lynparza in combinations with their respective PD-1 and PD-L1 medicines, Keytruda and Imfinzi. The companies are also jointly developing and commercializing AstraZeneca's Koselugo (selumetinib) for multiple indications. Under the terms of the agreement, AstraZeneca and Merck will share the development and commercialization costs for Lynparza and Koselugo monotherapy and non-PD-L1/PD-1 combination therapy opportunities.

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

As part of the agreement, Merck made an upfront payment to AstraZeneca and also made payments over a multi-year period for certain license options. In addition, the agreement provides for contingent payments from Merck to AstraZeneca related to the successful achievement of sales-based and regulatory milestones.

In 2022, Merck determined it was probable that sales of Lynparza in the future would trigger a \$ 600 million sales-based milestone payment from Merck to AstraZeneca. Accordingly, Merck recorded a \$ 600 million liability (which remained accrued at December 31, 2022) and a corresponding increase to the intangible asset related to Lynparza. Merck also recognized \$ 250 million of cumulative amortization catch-up expense related to the recognition of this milestone in 2022. Merck made sales-based milestone payments to AstraZeneca aggregating \$ 400 million and \$ 550 million in 2022 and 2020, respectively. Potential future sales-based milestone payments of \$ 2.1 billion have not yet been accrued as they are not deemed by the Company to be probable at this time.

In 2022 and 2020, Lynparza received regulatory approvals triggering capitalized milestone payments of \$ 250 million and \$ 160 million, respectively, from Merck to AstraZeneca. A regulatory milestone of \$ 105 million that was accrued at December 31, 2022 was paid in January 2023. Potential future regulatory milestone payments of \$ 1.1 billion remain under the agreement.

The intangible asset balance related to Lynparza (which includes capitalized sales-based and regulatory milestone payments) was \$ 1.6 billion at December 31, 2022 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>	2022	2021	2020
Alliance revenue - Lynparza	\$ 1,116	\$ 989	\$ 725
Alliance revenue - KoseLugo	54	29	8
Total alliance revenue	\$ 1,170	\$ 1,018	\$ 733
Cost of sales ⁽¹⁾	492	167	247
Selling, general and administrative	185	178	160
Research and development	106	120	133
<i>December 31</i>	2022	2021	
Receivables from AstraZeneca included in <i>Other current assets</i>	\$ 303	\$ 271	
Payables to AstraZeneca included in <i>Trade accounts payable and Accrued and other current liabilities</i> ⁽²⁾	123	415	
Payables to AstraZeneca included in <i>Other Noncurrent Liabilities</i> ⁽²⁾	600	—	

⁽¹⁾ Represents amortization of capitalized milestone payments. Amounts in 2022 and 2020 include \$ 250 million and \$ 106 million, respectively, of cumulative amortization catch-up expense.

⁽²⁾ Includes accrued milestone payments.

Eisai

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

Under the agreement, Merck made an upfront payment to Eisai and also made payments over a multi-year period for certain option rights (of which the final \$ 125 million option payment was made in March 2021). In addition, the agreement provides for contingent payments from Merck to Eisai related to the successful achievement of sales-based and regulatory milestones.

Merck made sales-based milestone payments to Eisai aggregating \$ 600 million, \$ 200 million and \$ 500 million in 2022, 2021 and 2020, 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 2022, 2021 and 2020, Lenvima received regulatory approvals triggering capitalized milestone payments of \$ 50 million, \$ 75 million and \$ 10 million, respectively, from Merck to Eisai. There are no regulatory milestone payments remaining under the agreement.

The intangible asset balance related to Lenvima (which includes capitalized sales-based and regulatory milestone payments) was \$ 814 million at December 31, 2022 and is included in *Other Intangibles, Net*. The amount is being amortized over its estimated useful life through 2026 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

Years Ended December 31	2022	2021	2020
Alliance revenue - Lenvima	\$ 876	\$ 704	\$ 580
Cost of sales ⁽¹⁾	212	195	271
Selling, general and administrative	158	127	73
Research and development	136	173	185
 December 31	 2022	 2021	
Receivables from Eisai included in <i>Other current assets</i>	\$ 214	\$ 200	
Payables to Eisai included in <i>Accrued and other current liabilities</i> ⁽²⁾	—	625	

⁽¹⁾ Represents amortization of capitalized milestone payments.

⁽²⁾ Represents accrued milestone payments.

Bayer AG

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

In addition, the agreement provided for contingent payments from Merck to Bayer related to the successful achievement of sales-based milestones. Merck made sales-based milestone payments to Bayer of \$ 400 million and \$ 375 million in 2022 and 2020, respectively. There are no sales-based milestone payments remaining under the agreement.

The intangible asset balances related to Adempas (which includes the acquired intangible asset balance, as well as capitalized sales-based milestone payments attributed to Adempas) and Verquvo (which reflects the portion of the final sales-based milestone payment that was attributed to Verquvo) were \$ 633 million and \$ 57 million, respectively, at December 31, 2022 and are included in *Other Intangibles, Net*. The assets are being amortized over their estimated useful lives (through 2027 for Adempas and through 2031 for Verquvo) as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

Years Ended December 31	2022	2021	2020
Alliance revenue - Adempas/Verquvo	\$ 341	\$ 342	\$ 281
Net sales of Adempas recorded by Merck	238	252	220
Net sales of Verquvo recorded by Merck	22	7	—
Total sales	\$ 601	\$ 601	\$ 501
 Cost of sales ⁽¹⁾	 210	 424	 196
Selling, general and administrative	153	126	47
Research and development	75	53	63
 December 31	 2022	 2021	
Receivables from Bayer included in <i>Other current assets</i>	\$ 143	\$ 114	
Payables to Bayer included in <i>Accrued and other current Liabilities</i> ⁽²⁾	80	472	

⁽¹⁾ Includes amortization of intangible assets. Amount in 2021 includes \$ 153 million of cumulative amortization catch-up expense.

⁽²⁾ Amount as of December 31, 2021 includes accrued milestone payment.

Ridgeback Biotherapeutics LP

In July 2020, Merck and Ridgeback, a closely held biotechnology company, entered into a collaboration agreement to develop *Lagevrio*, an investigational orally available antiviral candidate for the treatment of patients with COVID-19. Merck gained exclusive worldwide rights to develop and commercialize *Lagevrio* and related molecules. Following initial authorizations in certain markets in the fourth quarter of 2021, *Lagevrio* has since received multiple additional authorizations worldwide.

Under the terms of the agreement, Ridgeback received an upfront payment and is eligible to receive future contingent payments dependent upon the achievement of certain developmental and regulatory approval milestones. The agreement also provides for Merck to reimburse Ridgeback for a portion of certain third-party contingent milestone payments and royalties on net sales, which is part of the profit-sharing calculation. Merck is the principal on sales transactions, recognizing sales and related costs, with profit-sharing amounts recorded within *Cost of sales*. Profits from the collaboration are split equally between the partners. Reimbursements from Ridgeback for its share of research and development costs (deducted from Ridgeback's share of profits) are reflected as decreases to *Research and development expenses*.

Summarized financial information related to this collaboration is as follows:

Years Ended December 31	2022	2021	2020
Net sales of <i>Lagevrio</i>	\$ 5,684	\$ 952	\$ —
Cost of sales ⁽¹⁾⁽²⁾	3,038	502	17
Selling, general and administrative ⁽²⁾	147	37	6
Research and development ⁽²⁾⁽³⁾	88	137	349
<i>December 31</i>	2022	2021	
Payables to Ridgeback included in <i>Accrued and other current liabilities</i> ⁽⁴⁾	\$ 348	\$ 283	

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

⁽²⁾ Expenses in all periods now include an allocation for overhead charges.

⁽³⁾ Amount in 2020 includes upfront payment.

⁽⁴⁾ Includes accrued royalty and milestone payments.

Bristol Myers Squibb

Reblozyl (luspatercept-aamt) is a first-in-class erythroid maturation recombinant fusion protein obtained as part of Merck's November 2021 acquisition of Acceleron that is being developed and commercialized through a global collaboration with Bristol Myers Squibb (BMS). Reblozyl is approved in the U.S., Europe, and certain other markets for the treatment of anemia in certain rare blood disorders and is also being evaluated for additional indications for hematology therapies. BMS is the principal on sales transactions for Reblozyl; however, Merck co-promotes Reblozyl (and will co-promote all future products approved under this collaboration) in North America, which is reimbursed by BMS. Merck receives a 20 % sales royalty from BMS which could increase to a maximum of 24 % based on sales levels. This royalty will be reduced by 50 % upon the earlier of patent expiry or generic entry on an indication-by-indication basis in each market. Additionally, Merck is eligible to receive future contingent sales-based milestone payments of up to \$ 80 million. Merck recorded alliance revenue of \$ 166 million in 2022, which includes royalties of \$ 146 million and the receipt of a regulatory approval milestone payment of \$ 20 million, compared with alliance revenue of \$ 17 million in 2021.

6. Restructuring

In 2019, Merck approved a global restructuring program (Restructuring Program) as part of a worldwide initiative focused on further optimizing the Company's manufacturing and supply network, as well as reducing its global real estate footprint. This program is a continuation of the Company's plant rationalization and builds on prior restructuring programs. The actions currently contemplated under the Restructuring Program are expected to be substantially completed by the end of 2023, with the cumulative pretax costs to be incurred by the Company to implement the program estimated to be approximately \$ 3.7 billion. The Company estimates that approximately 70 % of the cumulative pretax costs will result in cash outlays, primarily related to employee separation expense and facility shut-down costs. Approximately 30 % of the cumulative pretax costs will be non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested.

The Company recorded total pretax costs of \$ 666 million in 2022, \$ 868 million in 2021 and \$ 880 million in 2020 related to restructuring program activities. Since inception of the Restructuring Program through December 31, 2022, Merck has recorded total pretax accumulated costs of approximately \$ 3.3 billion. The Company expects to record charges of approximately \$ 400 million in 2023 related to the Restructuring Program. For segment reporting, restructuring charges are unallocated expenses.

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

	Separation Costs	Accelerated Depreciation	Other	Total
Year Ended December 31, 2022				
Cost of sales	\$ —	\$ 72	\$ 133	\$ 205
Selling, general and administrative	—	19	75	94
Research and development	—	29	1	30
Restructuring costs	212	—	125	337
	\$ 212	\$ 120	\$ 334	\$ 666
Year Ended December 31, 2021				
Cost of sales	\$ —	\$ 52	\$ 108	\$ 160
Selling, general and administrative	—	12	7	19
Research and development	—	27	1	28
Restructuring costs	451	—	210	661
	\$ 451	\$ 91	\$ 326	\$ 868
Year Ended December 31, 2020				
Cost of sales	\$ —	\$ 143	\$ 32	\$ 175
Selling, general and administrative	—	44	3	47
Research and development	—	81	2	83
Restructuring costs	385	—	190	575
	\$ 385	\$ 268	\$ 227	\$ 880

Separation costs are associated with actual headcount reductions, as well as involuntary 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 program. 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 2022, 2021 and 2020 includes asset abandonment, facility shut-down and other related costs, as well as pretax gains and losses resulting from the sales of facilities and related assets. Additionally, other activity includes certain employee-related costs associated with pension and other postretirement benefit plans (see Note 14) and share-based compensation.

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

	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2021	\$ 567	\$ —	\$ 19	\$ 586
Expenses	451	91	326	868
(Payments) receipts, net	(422)	—	(186)	(608)
Non-cash activity	—	(91)	(118)	(209)
Restructuring reserves December 31, 2021	596	—	41	637
Expenses	212	120	334	666
(Payments) receipts, net	(329)	—	(120)	(449)
Non-cash activity	—	(120)	(221)	(341)
Restructuring reserves December 31, 2022 ⁽¹⁾	\$ 479	\$ —	\$ 34	\$ 513

⁽¹⁾ The remaining cash outlays are expected to be largely completed by the end of 2025.

7. Financial Instruments

Derivative Instruments and Hedging Activities

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

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

Foreign Currency Risk Management

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

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

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

The Company manages operating activities and net asset positions at each local subsidiary in order to mitigate the effects of exchange on monetary assets and liabilities. 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 Company also uses a balance sheet risk management program to mitigate the exposure of such assets and liabilities from the effects of volatility in foreign exchange. Merck principally utilizes forward exchange contracts to offset the effects of exchange in developed country currencies, primarily the euro, Japanese yen, British pound, Canadian dollar, Australian dollar and Swiss franc. For exposures in developing country currencies, including the Chinese renminbi,

the Company will enter into forward contracts to offset the effects of exchange on exposures when it is deemed economical to do so based on a cost-benefit analysis that considers the magnitude of the exposure, the volatility of the exchange rate and the cost of the hedging instrument. The 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 six months. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

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

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

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 <i>Other (income) expense, net</i> for Amounts Excluded from Effectiveness Testing		
	2022	2021	2020	2022	2021	2020
<i>Net Investment Hedging Relationships</i>						
Foreign exchange contracts	\$ (48)	\$ (49)	\$ 26	\$ (1)	\$ (13)	\$ (19)
Euro-denominated notes	(162)	(296)	385	—	—	—

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

Interest Rate Risk Management

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

In 2022, nine interest rate swap contracts with a total notional amount of \$ 2.25 billion matured. These swaps effectively converted the Company's \$ 1.0 billion, 2.4 % fixed-rate notes and \$ 1.25 billion, 2.35 % fixed-rate notes due 2022 to variable rate debt.

The interest rate swap contracts were 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 were 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 is not currently a party to any interest rate swaps.

The table below presents the location of amounts recorded in 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 Included in the Carrying Amount	
	2022	2021	2022	2021
<i>Balance Sheet Line Item in which Hedged Item is Included</i>				
Loans payable and current portion of long-term debt	\$ —	\$ 2,263	\$ —	\$ 13

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:

		2022			2021		
		Fair Value of Derivative		U.S. Dollar Notional	Fair Value of Derivative		U.S. Dollar Notional
		Asset	Liability		Asset	Liability	
<i>Derivatives Designated as Hedging Instruments</i>							
Interest rate swap contracts	Other current assets	\$ —	\$ —	\$ —	\$ 14	\$ —	\$ 2,250
Foreign exchange contracts	Other current assets	220	—	4,824	271	—	6,778
Foreign exchange contracts	Other Assets	27	—	1,609	43	—	1,551
Foreign exchange contracts	Accrued and other current liabilities	—	101	2,691	—	24	1,623
Foreign exchange contracts	Other Noncurrent Liabilities	—	1	91	—	1	43
		\$ 247	\$ 102	\$ 9,215	\$ 328	\$ 25	\$ 12,245
<i>Derivatives Not Designated as Hedging Instruments</i>							
Foreign exchange contracts	Other current assets	\$ 186	\$ —	\$ 8,540	\$ 221	\$ —	\$ 10,073
Foreign exchange contracts	Accrued and other current liabilities	—	307	10,926	—	96	10,640
		\$ 186	\$ 307	\$ 19,466	\$ 221	\$ 96	\$ 20,713
		\$ 433	\$ 409	\$ 28,681	\$ 549	\$ 121	\$ 32,958

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:

	2022		2021	
	Asset	Liability	Asset	Liability
Gross amounts recognized in the consolidated balance sheet	\$ 433	\$ 409	\$ 549	\$ 121
Gross amounts subject to offset in master netting arrangements not offset in the consolidated balance sheet	(220)	(220)	(110)	(110)
Cash collateral received/posted	(66)	(19)	(164)	—
Net amounts	\$ 147	\$ 170	\$ 275	\$ 11

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

Years Ended December 31	2022	2021	2020	2022	2021	2020	2022	2021	2020
<i>Financial Statement Caption in which Effects of Fair Value or Cash Flow Hedges are Recorded</i>									
Sales									
(Gain) loss on fair value hedging relationships:									
Interest rate swap contracts				(13)	(40)	40	—	—	—
Hedged items	—	—	—						
Derivatives designated as hedging instruments	—	—	—	4	1	(76)	—	—	—
Impact of cash flow hedging relationships:									
Foreign exchange contracts									
Amount of gain (loss) recognized in OCI on derivatives	—	—	—	—	—	—	684	333	(383)
Increase (decrease) in Sales as a result of AOCL reclassifications	773	(194)	(6)	—	—	—	(773)	194	6
Interest rate contracts									
Amount of gain recognized in Other (income) expense, net on derivatives	—	—	—	(2)	(2)	(4)	—	—	—
Amount of loss recognized in OCI on derivatives	—	—	—	—	—	—	(2)	(2)	(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		
			2022	2021	2020
Foreign exchange contracts ⁽¹⁾	Foreign exchange contracts	Other (income) expense, net	\$ (49)	\$ 313	\$ (12)
Foreign exchange contracts ⁽²⁾		Sales	(37)	9	13
Interest rate contracts ⁽³⁾		Other (income) expense, net	—	—	9
Forward contract related to Seagen common stock		Research and development	—	—	15

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

⁽²⁾ These derivative contracts serve as economic hedges of forecasted transactions.

⁽³⁾ These derivative contracts serve as economic hedges against rising treasury rates.

At December 31, 2022, the Company estimates \$ 104 million of pretax net unrealized gains on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from AOCL to Sales. The amount ultimately reclassified to Sales may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.

Investments in Debt and Equity Securities

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

	2022					2021				
	Amortized Cost	Gross Unrealized		Fair Value	Amortized Cost	Gross Unrealized		Fair Value		
		Gains	Losses			Gains	Losses			
Commercial paper	\$ 498	\$ —	\$ —	\$ 498	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
U.S. government and agency securities	68	—	—	68	80	—	—	—	—	80
Corporate notes and bonds	3	—	—	3	4	—	—	—	—	4
Foreign government bonds	—	—	—	—	2	—	—	—	—	2
Total debt securities	569	—	—	569	86	—	—	—	—	86
Publicly traded equity securities ⁽¹⁾				1,284						1,647
Total debt and publicly traded equity securities				\$ 1,853						\$ 1,733

⁽¹⁾ Unrealized net losses of \$ 462 million were recorded in Other (income) expense, net in 2022 on equity securities still held at December 31, 2022. Unrealized net losses of \$ 232 million were recorded in Other (income) expense, net in 2021 on equity securities still held at December 31, 2021.

At December 31, 2022 and 2021, the Company also had \$ 832 million and \$ 596 million, respectively, of equity investments without readily determinable fair values included in *Other Assets*. The Company records unrealized gains on these equity investments based on favorable observable price changes from transactions involving similar investments of the same investee and records unrealized losses based on unfavorable observable price changes, which are included in *Other (income) expense, net*. During 2022, the Company recorded unrealized gains of \$ 56 million and unrealized losses of \$ 12 million related to certain of these equity investments still held at December 31, 2022. During 2021, the Company recorded unrealized gains of \$ 110 million and unrealized losses of \$ 1 million related to certain of these investments still held at December 31, 2021. Cumulative unrealized gains and cumulative unrealized losses based on observable price changes for investments in equity investments without readily determinable fair values still held at December 31, 2022 were \$ 289 million and \$ 19 million, respectively.

At December 31, 2022, 2021 and 2020, the Company also had \$ 598 million, \$ 1.7 billion and \$ 800 million, respectively, recorded in *Other Assets* for equity securities held through ownership interests in investment funds. Losses (gains) recorded in *Other (income) expense, net* relating to these investment funds were \$ 1.0 billion, \$(1.4) billion and \$(583) million for the years ended December 31, 2022, 2021 and 2020, respectively.

Fair Value Measurements

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

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

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

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

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

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

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

	Fair Value Measurements Using				Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
	2022				2021			
Assets								
Investments								
Commercial paper	\$ —	\$ 498	\$ 498	\$ 498	\$ —	\$ —	\$ —	\$ —
Foreign government bonds	—	—	—	—	—	2	—	2
Publicly traded equity securities	1,015	—	—	1,015	368	—	—	368
	1,015	498	—	1,513	368	2	—	370
Other assets ⁽¹⁾								
U.S. government and agency securities	68	—	—	68	80	—	—	80
Corporate notes and bonds	3	—	—	3	4	—	—	4
Publicly traded equity securities	269	—	—	269	1,279	—	—	1,279
	340	—	—	340	1,363	—	—	1,363
Derivative assets ⁽²⁾								
Forward exchange contracts	—	218	—	218	—	351	—	351
Purchased currency options	—	215	—	215	—	184	—	184
Interest rate swaps	—	—	—	—	—	14	—	14
	—	433	—	433	—	549	—	549
Total assets	\$ 1,355	\$ 931	\$ —	\$ 2,286	\$ 1,731	\$ 551	\$ —	\$ 2,282
Liabilities								
Other liabilities								
Contingent consideration	\$ —	\$ 456	\$ 456	\$ 456	\$ —	\$ 777	\$ —	\$ 777
Derivative liabilities ⁽²⁾								
Forward exchange contracts	—	402	—	402	—	120	—	120
Written currency options	—	7	—	7	—	1	—	1
	—	409	—	409	—	121	—	121
Total liabilities	\$ —	\$ 409	\$ 456	\$ 865	\$ —	\$ 121	\$ 777	\$ 898

⁽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, 2022 and 2021, Cash and cash equivalents included \$ 11.3 billion and \$ 6.8 billion of cash equivalents, respectively, (which would be considered Level 2 in the fair value hierarchy).

Contingent Consideration

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

	2022	2021
Fair value January 1	\$ 777	\$ 841
Changes in estimated fair value ⁽¹⁾	(146)	57
Payments	(119)	(109)
Other	(56)	(12)
Fair value December 31 ⁽²⁾	\$ 456	\$ 777

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

⁽²⁾ At December 31, 2022 and 2021, \$ 368 million and \$ 620 million, respectively, of the liabilities relate to the termination of the Sanofi Pasteur MSD joint venture in 2016. As part of the termination, Merck recorded a liability for contingent future royalty payments of 11.5 % on net sales of all Merck products that were previously sold by the joint venture through December 31, 2024. The fair value of this liability is determined utilizing the estimated amount and timing of projected cash flows using a risk-adjusted discount rate to present value the cash flows. Balance at December 31, 2022 includes \$ 122 million recorded as a current liability for amounts expected to be paid within the next 12 months.

The payments of contingent consideration in both years relate to the Sanofi Pasteur MSD liabilities described above.

Other Fair Value Measurements

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

The estimated fair value of loans payable and long-term debt (including current portion) at December 31, 2022, was \$ 26.7 billion compared with a carrying value of \$ 30.7 billion and at December 31, 2021, was \$ 35.7 billion compared with a carrying value of \$ 33.1 billion. Fair value was estimated using recent observable market prices and would be considered Level 2 in the fair value hierarchy.

Concentrations of Credit Risk

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

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

The Company's customers with the largest accounts receivable balances are: McKesson Corporation, AmerisourceBergen Corporation and Cardinal Health, Inc., which represented approximately 21 %, 20 % and 13 %, respectively, of total accounts receivable at December 31, 2022. 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 \$ 2.5 billion and \$ 2.8 billion of accounts receivable as of December 31, 2022 and 2021, 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, 2022 and 2021, the Company had collected \$ 67 million and \$ 62 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 2023 and 2022, respectively. The net cash flows related 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 various counterparties was \$ 19 million at December 31, 2022. Cash collateral received by the Company from various counterparties was \$ 66 million and \$ 164 million at December 31, 2022 and 2021, respectively. The obligation to return such collateral is recorded in *Accrued and other current liabilities*.

8. Inventories

Inventories at December 31 consisted of:

	2022	2021
Finished goods	\$ 1,841	\$ 1,747
Raw materials and work in process	7,063	6,220
Supplies	238	196
Total (approximates current cost)	9,142	8,163
Decrease to LIFO cost	(293)	(16)
	\$ 8,849	\$ 8,147
Recognized as:		
Inventories	\$ 5,911	\$ 5,953
Other Assets	2,938	2,194

Inventories valued under the LIFO method comprised approximately \$ 3.4 billion and \$ 3.3 billion at December 31, 2022 and 2021, respectively. Amounts recognized as *Other Assets* are comprised almost entirely of raw materials and work in process inventories. At December 31, 2022 and 2021, these amounts included \$ 2.4 billion and \$ 1.9 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included \$ 516 million and \$ 256 million at December 31, 2022 and 2021, respectively, of inventories produced in preparation for product launches.

9. Goodwill and Other Intangibles

The following table summarizes goodwill activity by segment:

	Pharmaceutical	Animal Health	Total
Balance January 1, 2021	\$ 15,614	\$ 3,268	\$ 18,882
Acquisitions	2,431	5	2,436
Other ⁽¹⁾	(48)	(6)	(54)
Balance December 31, 2021 ⁽²⁾	17,997	3,267	21,264
Other ⁽¹⁾	(61)	1	(60)
Balance December 31, 2022 ⁽²⁾	\$ 17,936	\$ 3,268	\$ 21,204

⁽¹⁾ Includes cumulative translation adjustments on goodwill balances.

⁽²⁾ Accumulated goodwill impairment losses were \$ 531 million at both December 31, 2022 and 2021.

The additions to goodwill in the Pharmaceutical segment in 2021 were primarily related to the acquisition of Acceleron (see Note 4).

Other acquired intangibles at December 31 consisted of:

	2022			2021		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Products and product rights	\$ 23,555	\$ 16,745	\$ 6,810	\$ 23,671	\$ 15,776	\$ 7,895
IPR&D	7,661	—	7,661	9,281	—	9,281
Trade names	2,879	635	2,244	2,882	493	2,389
Licenses and other	7,651	4,097	3,554	6,604	3,236	3,368
	\$ 41,746	\$ 21,477	\$ 20,269	\$ 42,438	\$ 19,505	\$ 22,933

Some of the more significant acquired intangibles included in products and product rights, on a net basis, related to human health marketed products at December 31, 2022 were Reblozyl, \$ 3.5 billion; Zerbaxa, \$ 406 million; Sivextro, \$ 122 million; Gardasil/Gardasil 9, \$ 120 million; and Bridion, \$ 97 million. Additionally, the Company had \$ 4.6 billion of net acquired intangibles related to animal health at December 31, 2022, of which \$ 2.3 billion related to products and product rights and \$ 2.2 billion was attributable to trade names, primarily related to Allflex. At December 31, 2022, IPR&D primarily relates to MK-7962 (sotatercept), \$ 6.4 billion, obtained through the acquisition of Acceleron in 2021 (see Note 4); MK-7264 (gefapixant), \$ 832 million, obtained through the acquisition of Afferent Pharmaceuticals in 2016; and MK-1026 (nemtabrutinib), \$ 418 million, obtained through the acquisition of ArQule in

2020 (see below and Note 4). Some of the more significant net intangible assets included in licenses and other above at December 31, 2022 include Lynparza, \$ 1.6 billion, related to a collaboration with AstraZeneca; Lenvima, \$ 814 million, related to a collaboration with Eisai; and Adempas, \$ 633 million, related to a collaboration with Bayer. See Note 5 for additional information related to the intangible assets associated with these collaborations.

In 2020, the Company recorded an impairment charge of \$ 1.6 billion within *Cost of sales* related to Zerbaxa (ceftolozane and tazobactam) for injection, a combination antibacterial and beta-lactamase inhibitor for the treatment of certain bacterial infections. In December 2020, the Company temporarily suspended sales of Zerbaxa, and subsequently issued a product recall, following the identification of product sterility issues. The recall constituted a triggering event requiring the evaluation of the Zerbaxa intangible asset for impairment. The Company revised its cash flow forecasts for Zerbaxa utilizing certain assumptions around the return to market timeline and anticipated uptake in sales thereafter. These revised cash flow forecasts indicated that the Zerbaxa intangible asset value was not fully recoverable on an undiscounted cash flows basis. The Company utilized market participant assumptions to determine its best estimate of the fair value of the intangible asset related to Zerbaxa that, when compared with its related carrying value, resulted in the impairment charge noted above. The Company also wrote-off inventory of \$ 120 million to *Cost of sales* in 2020 related to the Zerbaxa recall. A phased resupply of Zerbaxa was initiated in the fourth quarter of 2021 and completed during 2022.

IPR&D that the Company acquires through business combinations represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. Amounts capitalized as IPR&D are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each IPR&D project, the Company will make a separate determination as to the then-useful life of the asset and begin amortization.

In 2022, the Company recorded \$ 1.7 billion of intangible impairment charges within *Research and development expenses*, of which \$ 1.6 billion represents IPR&D impairment charges related to nemtabrutinib (MK-1026), a novel, oral BTK inhibitor currently being evaluated for the treatment of B-cell malignancies that was obtained through the 2020 acquisition of ArQule (see Note 4). Following discussions with regulatory authorities in the third quarter, the development period for nemtabrutinib was extended, which constituted a triggering event that required the evaluation of the nemtabrutinib intangible asset for impairment. The Company estimated the current fair value of nemtabrutinib utilizing an income approach which calculates the present value of projected future cash flows. The market participant assumptions used to derive the forecasted cash flows were updated to reflect a delay in the anticipated launch date for nemtabrutinib, which resulted in lower cumulative revenue forecasts and a reduction in the estimated fair value. The revised estimated fair value of nemtabrutinib when compared with its related carrying value resulted in a \$ 807 million impairment charge recorded in the third quarter of 2022. In December 2022, regulatory authorities provided additional feedback with respect to clinical study design that led to a further reassessment of the development plan for nemtabrutinib, which is expected to result in changes to the clinical study design, and corresponding delays in the anticipated approval and launch timelines, which constituted a triggering event. Utilizing an income approach, the forecasted cash flows were updated to reflect a decline in forecasted revenue coupled with an increase in development cost forecasts, which reduced projected cash flows lowering the estimated current fair value of nemtabrutinib. The revised estimated fair value of nemtabrutinib when compared with its then-related carrying value resulted in a \$ 780 million impairment charge. The remaining IPR&D intangible asset related to nemtabrutinib is \$ 418 million. If the assumptions used to estimate the fair value of nemtabrutinib prove to be incorrect and the development of nemtabrutinib does not progress as anticipated thereby adversely affecting projected future cash flows, the Company may record an additional impairment charge in the future and such charge could be material. The Company also recorded an \$ 80 million intangible asset impairment charge related to derazantinib resulting from the termination of the out-licensing agreement and the decision by Merck not to pursue development of derazantinib.

In 2021, the Company recorded a \$ 275 million IPR&D impairment charge related to nemtabrutinib. As part of Merck's annual impairment assessment of IPR&D intangible assets, the Company estimated the current fair value of nemtabrutinib utilizing projected future cash flows. The market participant assumptions used to derive the forecasted cash flows were updated to reflect the current competitive landscape for nemtabrutinib, including increased expected development costs for additional clinical trial data needed to develop nemtabrutinib, as well as a delay in the anticipated launch date for nemtabrutinib, which collectively reduced the projected future cash flows and estimated fair value. Additionally, the discount rate utilized to determine the current fair value of the asset was reduced to 8.5 % to reflect the current risk profile of the asset. The revised estimated fair value of nemtabrutinib when compared with its related carrying value resulted in the IPR&D impairment charge noted above.

In 2020, the Company recorded a \$ 90 million IPR&D impairment charge related to a decision to discontinue the development program for COVID-19 vaccine candidate V591 following Merck's review of findings from a Phase 1 clinical study for the vaccine. In the study, V591 was generally well tolerated, but the immune responses were inferior to those seen following natural infection and those reported for other SARS-CoV-2/COVID-19 vaccines. The discontinuation of this development program also resulted in a reversal of the related liability for contingent consideration of \$ 45 million.

The IPR&D projects that remain in development are subject to the inherent risks and uncertainties in drug development and it is possible that the Company will not be able to successfully develop and complete the IPR&D programs and profitably commercialize the underlying product candidates.

The Company may recognize additional non-cash impairment charges in the future related to other marketed products or pipeline programs and such charges could be material.

Aggregate amortization expense primarily recorded within *Cost of sales* was \$ 2.1 billion in 2022, \$ 1.6 billion in 2021 and \$ 1.8 billion in 2020. The estimated aggregate amortization expense for each of the next five years is as follows: 2023, \$ 1.8 billion; 2024, \$ 1.7 billion; 2025, \$ 1.6 billion; 2026, \$ 1.5 billion; 2027, \$ 1.3 billion.

10. Loans Payable, Long-Term Debt and Leases

Loans Payable

Loans payable at December 31, 2022 included \$ 1.7 billion of notes due in 2023 and \$ 197 million of long-dated notes that are subject to repayment at the option of the holders. Loans payable at December 31, 2021 included \$ 2.3 billion of notes due in 2022 and \$ 149 million of long-dated notes that are subject to repayment at the option of the holders. The weighted-average interest rate of commercial paper borrowings was 0.65 % and 0.08 % for the years ended December 31, 2022 and 2021, respectively.

Long-Term Debt

Long-term debt at December 31 consisted of:

	2022	2021
2.75 % notes due 2025	\$ 2,496	\$ 2,495
2.15 % notes due 2031	1,986	1,986
2.75 % notes due 2051	1,979	1,979
3.70 % notes due 2045	1,978	1,977
3.40 % notes due 2029	1,738	1,736
1.70 % notes due 2027	1,494	1,493
2.90 % notes due 2061	1,483	1,484
4.00 % notes due 2049	1,471	1,470
4.15 % notes due 2043	1,239	1,239
1.45 % notes due 2030	1,237	1,235
2.45 % notes due 2050	1,213	1,212
1.875 % euro-denominated notes due 2026	1,060	1,123
0.75 % notes due 2026	995	993
1.90 % notes due 2028	994	994
3.90 % notes due 2039	985	984
2.35 % notes due 2040	984	983
2.90 % notes due 2024	749	748
6.50 % notes due 2033	711	715
0.50 % euro-denominated notes due 2024	531	563
1.375 % euro-denominated notes due 2036	527	559
2.50 % euro-denominated notes due 2034	526	558
3.60 % notes due 2042	492	491
6.55 % notes due 2037	408	409
5.75 % notes due 2036	339	338
5.95 % debentures due 2028	307	306
5.85 % notes due 2039	271	271
6.40 % debentures due 2028	250	250
6.30 % debentures due 2026	135	135
2.80 % notes due 2023	—	1,749
Other	167	215
	\$ 28,745	\$ 30,690

Other (as presented in the table above) includes borrowings at variable rates that resulted in effective interest rates of 1.40 % and zero for 2022 and 2021, 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. 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, 2022, the Company was in compliance with these covenants.

The aggregate maturities of long-term debt for each of the next five years are as follows: 2023, \$ 1.7 billion; 2024, \$ 1.3 billion; 2025, \$ 2.5 billion; 2026, \$ 2.2 billion; 2027, \$ 1.5 billion. Interest payments related to these debt obligations are as follows: 2023, \$ 882 million; 2024, \$ 845 million; 2025, \$ 778 million; 2026, \$ 751 million; 2027, \$ 720 million.

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

Leases

The Company has operating leases primarily for manufacturing facilities, research and development facilities, corporate offices, employee housing, vehicles and certain equipment. The Company determines if an arrangement is a lease at inception. When evaluating contracts for embedded leases, the Company exercises judgment to determine if there is an explicit or implicit identified asset in the contract and if Merck controls the use of that asset. Embedded leases, primarily associated with contract manufacturing organizations, are immaterial. The lease term includes options to extend or terminate the lease when it is reasonably certain that Merck will exercise that option. Real estate leases for facilities have an average remaining lease term of seven years , which include options to extend the leases for up to four years where applicable. Vehicle leases are generally in effect for four years . The Company elected to exclude short-term leases (leases with an initial term of 12 months or less) from the lease assets and liabilities on the balance sheet.

Lease expense for operating lease payments is recognized on a straight-line basis over the term of the lease. Operating lease assets and liabilities are recognized based on the present value of lease payments over the lease term. Since the Company's leases do not have a readily determinable implicit discount rate, the Company uses its incremental borrowing rate to calculate the present value of lease payments by asset class. On a quarterly basis, an updated incremental borrowing rate is determined based on the average remaining lease term of each asset class and the Company's pretax cost of debt for that same term. The updated rates for each asset class are applied prospectively to new leases. The Company does not separate lease components (e.g. payments for rent, real estate taxes and insurance costs) from non-lease components (e.g. common-area maintenance costs) in the event that the agreement contains both. Merck includes both the lease and non-lease components for purposes of calculating the right-of-use asset and related lease liability (if the non-lease components are fixed). For vehicle leases and employee housing, the Company applies a portfolio approach to account for the operating lease assets and liabilities.

Certain of the Company's lease agreements contain variable lease payments that are adjusted periodically for inflation or for actual operating expense true-ups compared with estimated amounts; however, these amounts are immaterial. Sublease income and activity related to sale and leaseback transactions are immaterial. Merck's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

Operating lease cost was \$ 334 million in 2022, \$ 343 million in 2021 and \$ 340 million in 2020. Cash paid for amounts included in the measurement of operating lease liabilities was \$ 335 million in 2022, \$ 340 million in 2021 and \$ 334 million in 2020. Operating lease assets obtained in exchange for lease obligations were \$ 57 million in 2022, \$ 117 million in 2021 and \$ 473 million in 2020.

Supplemental balance sheet information related to operating leases is as follows:

<i>December 31</i>	2022	2021
Assets		
Other Assets ⁽¹⁾	\$ 1,346	\$ 1,586
Liabilities		
Accrued and other current liabilities	281	304
Other Noncurrent Liabilities	1,013	1,225
	\$ 1,294	\$ 1,529
Weighted-average remaining lease term (years)	7.0	7.0
Weighted-average discount rate	3.1 %	2.6 %

⁽¹⁾ Includes prepaid leases that have no related lease liability.

Maturities of operating leases liabilities are as follows:

2023	\$ 323	323
2024		258
2025		224
2026		157
2027		126
Thereafter		404
Total lease payments		1,492
Less: Imputed interest		198
		\$ 1,294

At December 31, 2022, the Company had entered into additional real estate operating leases that had not yet commenced; the obligations associated with these leases total \$ 232 million.

11. Contingencies and Environmental Liabilities

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property, and commercial litigation, as well as certain additional matters including governmental and environmental matters. In the opinion of the Company, it is unlikely that the resolution of these matters will be material to the Company's financial condition, results of operations or cash flows.

Given the nature of the litigation discussed below and the complexities involved in these matters, the Company is unable to reasonably estimate a possible loss or range of possible loss for such matters until the Company knows, among other factors, (i) what claims, if any, will survive dispositive motion practice, (ii) the extent of the claims, including the size of any potential class, particularly when damages are not specified or are indeterminate, (iii) how the discovery process will affect the litigation, (iv) the settlement posture of the other parties to the litigation and (v) any other factors that may have a material effect on the litigation.

The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. For product liability claims, a portion of the overall accrual is actuarially determined and considers such factors as past experience, number of claims reported and estimates of claims incurred but not yet reported. Individually significant contingent losses are accrued when probable and reasonably estimable. Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable.

The Company's decision to obtain insurance coverage is dependent on market conditions, including cost and availability, existing at the time such decisions are made. The Company has evaluated its risks and has determined that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and, as such, has no insurance for most product liabilities.

Product Liability Litigation

Gardasil/Gardasil 9

As previously disclosed, Merck is a defendant in product liability lawsuits in the U.S. involving *Gardasil* (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant) and *Gardasil* 9 (Human Papillomavirus 9-valent Vaccine, Recombinant). As of December 31, 2022, approximately 70 cases were filed and pending against Merck in either federal or state court. In these actions, plaintiffs allege, among other things, that they suffered various personal injuries after vaccination with *Gardasil* or *Gardasil* 9, with postural orthostatic tachycardia syndrome as a predominate alleged injury. In August 2022, the Judicial Panel on Multidistrict Litigation ordered that *Gardasil/Gardasil* 9 product liability cases pending in federal courts nationwide be transferred to Judge Robert J. Conrad in the Western District of North Carolina for coordinated pre-trial proceedings. There are fewer than 15 product liability cases pending outside the U.S., including one purported class action in Colombia.

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, from time to time, the Company's subsidiaries in China receive inquiries regarding their operations from various Chinese governmental agencies. Some of these inquiries may be related to matters involving other multinational pharmaceutical companies, as well as Chinese entities doing business with such companies. The Company's policy is to cooperate with these authorities and to provide responses as appropriate.

As previously disclosed, from time to time, the Company receives inquiries and is the subject of preliminary investigation activities from competition and other governmental authorities in markets outside the U.S. These authorities may include regulators, administrative authorities, and law enforcement and other similar officials, and these preliminary investigation activities may include site visits, formal or informal requests or demands for documents or materials, inquiries or interviews and similar matters. Certain of these preliminary inquiries or activities may lead to the commencement of formal proceedings. Should those proceedings be determined adversely to the Company, monetary fines and/or remedial undertakings may be required.

Commercial and Other Litigation

Zetia Antitrust Litigation

As previously disclosed, Merck, MSD, Schering Corporation, Schering-Plough Corporation, and MSP Singapore Company LLC (collectively, the Merck Defendants) are defendants in a number of lawsuits filed in 2018 on behalf of direct and indirect purchasers of Zetia (ezetimibe) alleging violations of federal and state antitrust laws, as well as other state statutory and common law causes of action. The cases were consolidated in a federal multidistrict litigation (the Zetia MDL) before Judge Rebecca Beach Smith in the Eastern District of Virginia.

In November 2019, the direct purchaser plaintiffs and the indirect purchaser plaintiffs filed motions for class certification. In August 2020, the district court granted in part the direct purchasers' motion for class certification and certified a class of 35 direct purchasers. In August 2021, the Fourth Circuit vacated the district court's class certification order and remanded for further proceedings consistent with the court's ruling. In September 2021, the direct purchaser plaintiffs filed a renewed motion for class certification. On January 25, 2022, the magistrate judge recommended that the district court deny the motion for class certification. On February 8, 2022, the direct purchaser plaintiffs filed objections to the recommendation. On April 13, 2022, the district court denied the direct purchaser plaintiffs' renewed motion for class certification. In August 2021, the district court granted certification of a class of indirect purchasers.

In 2020 and 2021, United Healthcare Services, Inc., Humana Inc., Centene Corporation and others, and Kaiser Foundation Health Plan, Inc. (collectively, the Insurer Plaintiffs), each filed a lawsuit in a jurisdiction outside of the Eastern District of Virginia against the Merck Defendants and others, making similar allegations as those made in the Zetia MDL, as well as additional allegations about Vytorin. These cases have been transferred to the Eastern District of Virginia to proceed with the Zetia MDL.

On February 9, 2022, the Insurer Plaintiffs filed amended complaints. On March 2, 2022, the Merck Defendants, jointly with other defendants, moved to dismiss certain aspects of the Insurer Plaintiffs' complaints, including any claims for Vytorin damages. That motion to dismiss the Vytorin-related claims is still pending.

In April 2022, the direct purchaser plaintiffs moved for an order setting a deadline for direct purchasers of Zetia not currently parties to the case to file cases against defendants in order for those cases to be coordinated for trial with the existing direct purchaser plaintiffs and other Zetia MDL plaintiff groups. The court granted that motion, setting a deadline of June 30, 2022 for unnamed direct purchasers to file claims. On June 30, 2022, 23 new entities, many related, brought new complaints against defendants or otherwise sought to intervene.

On February 10, 2023, the district court denied the Merck Defendants' and Glenmark defendants' motions for summary judgment. In the cases filed by direct purchaser plaintiffs, retailer plaintiffs, and indirect purchaser plaintiffs, plaintiffs seek up to a maximum of \$ 12.7 billion in damages after trebling. The court has scheduled trial for these plaintiffs (all plaintiffs other than the Insurer Plaintiffs) for April 17, 2023.

Bravecto Litigation

As previously disclosed, in January 2020, the Company was served with a complaint in the U.S. District Court for the District of New Jersey. Following motion practice, the plaintiffs filed a second amended complaint on July 1, 2021, seeking to certify a nationwide class action of purchasers or users of *Bravecto* (fluralaner) products in the U.S. or its territories between May 1, 2014 and July 1, 2021. Plaintiffs contend *Bravecto* causes neurological events in dogs and cats and alleges violations of the New Jersey Consumer Fraud Act, Breach of Warranty, Product Liability, and related theories. The Company moved to dismiss or, alternatively, to strike the class allegations from the second amended complaint, and that motion is pending. A similar case was filed in Quebec, Canada in May 2019. The Superior Court certified a class of dog owners in Quebec who gave *Bravecto* Chew to their dogs between February 16, 2017 and November 2, 2018 whose dogs experienced one of the conditions in the post-marketing adverse reactions section of the labeling approved on November 2, 2018. The Company and plaintiffs each appealed the class certification decision. The Court of Appeal of Quebec heard the appeal on February 7, 2022 and took the matter under advisement.

340B Program Litigation

Merck has filed a complaint in the U.S. District Court for the District of Columbia to challenge the letter Merck received from the Health Resources and Services Administration (HRSA) in May 2022 regarding Merck's 340B Program integrity initiative. HRSA's letter to Merck asserts that Merck is in violation of the 340B statute. HRSA further claims that continued failure to provide the 340B price to covered entities using contract pharmacies may result in civil monetary penalties for each instance of alleged overcharging, in addition to repayment for any instance of overcharging. The letter is very similar to letters HRSA has sent to other manufacturers, which letters have been held to be unlawful by multiple federal courts. Merck disagrees with HRSA's assertion. Merck remains committed to the 340B Program and to providing 340B discounts to eligible covered entities. Merck's 340B Program integrity initiative is consistent with the requirements of the 340B statute and is intended to ensure the integrity and sustainability of the 340B statute by reducing prohibited duplicate discounts and diversion and putting patients back at the center of the program. Merck continues to offer all of the Company's covered outpatient drugs to all 340B covered entities for purchase at or below the 340B ceiling price. On September 13, 2022, the court stayed the case pending the D.C. Circuit's ruling in *Novartis Pharmaceuticals Corp. v. Johnson and United Therapeutics Corp. v. Johnson*.

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 proceeded into discovery, which is now complete, and the parties have filed and briefed cross-motions for summary judgment, which are currently pending before the court.

Merck KGaA Litigation

As previously disclosed, in January 2016, to protect its long-established brand rights in the U.S., the Company filed a lawsuit against Merck KGaA, Darmstadt, Germany (KGaA), historically operating as the EMD Group in the U.S., alleging it improperly uses the name "Merck" in the U.S. KGA has filed suit against the Company in a number of jurisdictions outside of the U.S. alleging, among other things, unfair competition, trademark infringement

and/or corporate name infringement. In certain of those jurisdictions, KGaA also alleges breach of the parties' coexistence agreement. The litigation is ongoing in the U.S. with no trial date set, and also ongoing in jurisdictions outside of the U.S.

Patent Litigation

From time to time, generic manufacturers of pharmaceutical products file abbreviated New Drug Applications (NDAs) with the FDA seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned by the Company. To protect its patent rights, the Company may file patent infringement lawsuits against such generic companies. Similar lawsuits defending the Company's patent rights may exist in other countries. The Company intends to vigorously defend its patents, which it believes are valid, against infringement by companies attempting to market products prior to the expiration of such patents. As with any litigation, there can be no assurance of the outcomes, which, if adverse, could result in significantly shortened periods of exclusivity for these products and, with respect to products acquired through acquisitions accounted for as business combinations, potentially significant intangible asset impairment charges.

Bridion — As previously disclosed, between January and November 2020, the Company received multiple Paragraph IV Certification Letters under the Hatch-Waxman Act notifying the Company that generic drug companies have filed applications to the FDA seeking pre-patent expiry approval to sell generic versions of *Bridion* (sugammadex) Injection. In March, April and December 2020, the Company filed patent infringement lawsuits in the U.S. District Courts for the District of New Jersey and the Northern District of West Virginia against those generic companies. All actions in the District of New Jersey have been consolidated. These lawsuits, which assert one or more patents covering sugammadex and methods of using sugammadex, automatically stay FDA approval of the generic applications until June 2023 or until adverse court decisions, if any, whichever may occur earlier. The West Virginia case was jointly dismissed with prejudice on August 8, 2022 in favor of proceeding in New Jersey. The remaining defendants in the New Jersey action have stipulated to infringement of the asserted claims and have stated they are withdrawing all remaining claims and defenses other than a defense seeking to shorten the patent term extension of the sugammadex patent to December 2022. The U.S. District Court for the District of New Jersey held a one-day trial on December 19, 2022 on this remaining patent term extension calculation defense. The court ordered a post-trial briefing on this defense and held closing arguments on February 3, 2023.

The Company has settled with five generic companies providing that these generic companies can bring their generic versions of *Bridion* to the market in January 2026 (which may be delayed by any applicable pediatric exclusivity) or earlier under certain circumstances. The Company has agreed to stay the lawsuit filed against two generic companies, which in exchange agreed to be bound by a judgment on the merits of the consolidated action in the District of New Jersey. One of the generic companies in the consolidated action requested dismissal of the action against it and the Company did not oppose this request, which was subsequently granted by the court. The Company does not expect this company to bring its generic version of *Bridion* to the market before January 2026 or later, depending on any applicable pediatric exclusivity, unless the Company receives an adverse court decision.

Januvia, Janumet, Janumet XR — As previously disclosed, the FDA granted pediatric exclusivity with respect to *Januvia* (sitagliptin), *Janumet* (sitagliptin/metformin HCl), and *Janumet XR* (sitagliptin and metformin HCl extended-release), which provides a further six months of exclusivity in the U.S. beyond the expiration of all patents listed in the FDA's Orange Book. Adding this exclusivity to the term of the key patent protection extended exclusivity on these products to January 2023. 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 that expires in May 2027, including pediatric exclusivity (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 where its term plus the pediatric exclusivity ends in 2029. The Company also filed a patent infringement lawsuit against Mylan in the Northern District of West Virginia. The Judicial Panel on Multidistrict Litigation entered an order transferring the Company's lawsuit against Mylan to the U.S. District Court for the District of Delaware for coordinated and consolidated pretrial proceedings with the other cases pending in that district.

Prior to the beginning of the scheduled October 2021 trial in the U.S. District Court for the District of Delaware on invalidity issues, the Company settled with all defendants scheduled to participate in that trial. In the Company's case against Mylan, a bench trial was held in December 2021 in the U.S. District Court for the Northern District of West Virginia, and the closing arguments were held on April 13, 2022. On September 21, 2022, the District

Court for the Northern District of West Virginia issued a decision in the Company's favor, upholding all asserted patent claims. Mylan (now Viatris) has appealed to the U.S. Court of Appeals for the Federal Circuit.

In total, the Company has settled with 22 generic companies providing that these generic companies can bring their generic versions of *Januvia* and *Janumet* to the market in May 2026 or earlier under certain circumstances, and their generic versions of *Janumet XR* to the market in July 2026 or earlier under certain circumstances.

Additionally, in 2019, Mylan filed a petition for *inter partes* review (IPR) at the U.S. Patent and Trademark Office (USPTO) seeking invalidity of some, but not all, of the claims of the 2027 salt/polymorph patent. The USPTO instituted IPR proceedings in May 2020, finding a reasonable likelihood that the challenged claims are not valid. A trial was held in February 2021 and a final decision was rendered in May 2021, holding that all of the challenged claims were not invalid. Mylan appealed the USPTO's decision to the U.S. Court of Appeals for the Federal Circuit, and a hearing was held on August 2, 2022. On September 29, 2022, the U.S. Court of Appeals for the Federal Circuit ruled in the Company's favor, upholding the USPTO's decision. Mylan submitted a combined petition for panel rehearing and rehearing en banc, for which the Company was invited by the court to provide a response. On February 3, 2023, the court issued a per curiam decision denying both rehearing requests.

In March 2021, the Company filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Cadila Healthcare Ltd. (collectively, Zydus). In that lawsuit, the Company alleged infringement of the 2027 salt/polymorph patent based on the filing of Zydus's NDA seeking approval of its sitagliptin tablets. In December 2022, the parties reached settlement that included dismissal of the case without prejudice enabling Zydus to seek final approval of a non-automatically substitutable product containing a different form of sitagliptin than that used in *Januvia*, *Janumet* and *Janumet XR*.

As a result of these favorable court rulings and settlement agreements related to the later expiring patent directed to the specific sitagliptin salt form of the products, the Company expects that these products will not lose market exclusivity in the U.S. until May 2026. However, certain of the rulings are currently being appealed, and an unfavorable court decision would likely cause the products to lose exclusivity toward the end of 2023.

Generic companies have sought revocation of the Supplementary Protection Certificate (SPC) for *Janumet* in a number of European countries. In February 2022, a Finnish court referred certain questions to the Court of Justice of the European Union that could determine the validity of the *Janumet* SPCs in Europe, for which there will be an oral hearing on March 8, 2023. In first instance decisions, the *Janumet* SPC has been found invalid in Germany and Romania, and has been upheld in Czech Republic and Sweden. Appeals are pending in Germany, Czech Republic and Sweden. The Company has filed for injunctive relief in Belgium, Czech Republic, Finland, France, Greece, Hungary, Ireland, Portugal, Switzerland and Slovakia. An *ex parte* preliminary injunction was granted in Finland, which has been subsequently maintained in *inter partes* proceedings, Czech Republic and Switzerland, and an *inter partes* preliminary injunction has been granted in Ireland. A preliminary injunction was granted in France and the validity of the SPC and the associated patent were held to be *prima facie* valid. Preliminary injunctions have been refused in Portugal, Greece, Belgium and Hungary. In Belgium, the Company has filed a main infringement action against generic companies and a request for preliminary measures in that action has been refused.

Lynparza — In December 2022, AstraZeneca Pharmaceuticals LP received a Paragraph IV Certification Letter under the Hatch-Waxman Act notifying AstraZeneca that Natco Pharma Limited (Natco) has filed an application to the FDA seeking pre-patent expiry approval to sell generic versions of Lynparza (olaparib) tablet. In February 2023, AstraZeneca and the Company filed a patent infringement lawsuit in the U.S. District Court for the District of New Jersey/Delaware against Natco. This lawsuit, which asserts one or more patents covering olaparib, automatically stays FDA approval of the generic application until June 2025 or until an adverse court decision, if any, whichever may occur earlier.

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, 2022 and 2021 of approximately \$ 230 million 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 \$ 39 million and \$ 40 million at December 31, 2022 and 2021, respectively. These liabilities are undiscounted, do not consider potential recoveries from other parties and will be paid out over the periods of remediation for the applicable sites, which are expected to occur primarily over the next 15 years. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed approximately \$ 35 million in the aggregate. Management also does not believe that these expenditures should result in a material adverse effect on the Company's financial condition, results of operations or liquidity for any year.

12. Equity

The Merck certificate of incorporation authorizes 6,500,000,000 shares of common stock and 20,000,000 shares of preferred stock.

Capital Stock

A summary of common stock and treasury stock transactions (shares in millions) is as follows:

	2022		2021		2020	
	Common Stock	Treasury Stock	Common Stock	Treasury Stock	Common Stock	Treasury Stock
Balance January 1	3,577	1,049	3,577	1,047	3,577	1,038
Purchases of treasury stock	—	—	—	11	—	16
Issuances ⁽¹⁾	—	(10)	—	(9)	—	(7)
Balance December 31	3,577	1,039	3,577	1,049	3,577	1,047

⁽¹⁾ Issuances primarily reflect activity under share-based compensation plans.

13. Share-Based Compensation Plans

The Company has share-based compensation plans under which the Company grants restricted stock units (RSUs) and performance share units (PSUs) to certain management level employees. In addition, employees

and non-employee directors may be granted options to purchase shares of Company common stock at the fair market value at the time of grant. These plans were approved by the Company's shareholders.

At December 31, 2022, 87 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 2022, 2021 and 2020 was \$ 541 million, \$ 498 million and \$ 475 million, respectively. The amounts in 2021 and 2020 include \$ 479 million and \$ 441 million, respectively, related to continuing operations. Income tax benefits for share-based compensation expense recognized in 2022, 2021 and 2020 were \$ 78 million, \$ 69 million and \$ 65 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 2022, 2021 and 2020 was \$ 87.10 , \$ 75.99 and \$ 77.67 per option, respectively. The weighted average fair value of options granted in 2022, 2021 and 2020 was \$ 15.45 , \$ 9.80 and \$ 9.93 per option, respectively, and were determined using the following assumptions:

<i>Years Ended December 31</i>	2022	2021	2020
Expected dividend yield	3.1 %	3.1 %	3.1 %
Risk-free interest rate	3.0 %	1.0 %	0.4 %
Expected volatility	22.5 %	20.9 %	22.1 %
Expected life (years)	5.9	5.9	5.8

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, 2022	18,572	\$ 65.27		
Granted	2,326	87.10		
Exercised	(6,317)	60.77		
Forfeited	(862)	73.11		
Outstanding December 31, 2022	13,719	\$ 70.55	6.5	\$ 554
Vested and expected to vest December 31, 2022	13,199	\$ 70.09	6.4	\$ 539
Exercisable December 31, 2022	8,730	\$ 65.24	5.4	\$ 399

Additional information pertaining to stock option plans is provided in the table below:

Years Ended December 31	2022	2021	2020
Total intrinsic value of stock options exercised	\$ 225	\$ 106	\$ 51
Fair value of stock options vested	30	27	25
Cash received from the exercise of stock options	384	202	89

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, 2022	11,790	\$ 74.88	1,966	\$ 77.13
Granted	7,170	87.12	951	88.52
Vested	(5,150)	75.40	(725)	87.87
Forfeited	(1,110)	78.65	(171)	77.58
Nonvested December 31, 2022	12,700	\$ 81.25	2,021	\$ 78.60
Expected to vest December 31, 2022	11,254	\$ 80.96	1,895	\$ 78.26

At December 31, 2022, there was \$ 813 million of total pretax unrecognized compensation expense related to nonvested stock options, RSU and PSU awards which will be recognized over a weighted average period of 1.9 years. For segment reporting, share-based compensation costs are unallocated expenses.

14. Pension and Other Postretirement Benefit Plans

The Company has defined benefit pension plans covering eligible employees in the U.S. and in certain of its international subsidiaries. In addition, the Company provides medical benefits, principally to its eligible U.S. retirees and their dependents, through its other postretirement benefit plans. The Company uses December 31 as the year-end measurement date for all of its pension plans and other postretirement benefit plans.

Net Periodic Benefit Cost

The net periodic benefit cost (credit) for pension and other postretirement benefit plans (including certain costs reported as part of discontinued operations) consisted of the following components:

Years Ended December 31	Pension Benefits						Other Postretirement Benefits			
	2022	2021	2020	2022	2021	2020	2022	2021	2020	
Service cost	\$ 372	\$ 403	\$ 360	\$ 283	\$ 328	\$ 297	\$ 48	\$ 48	\$ 52	
Interest cost	457	404	431	145	123	136	46	45	57	
Expected return on plan assets	(753)	(755)	(774)	(383)	(416)	(414)	(86)	(79)	(75)	
Amortization of unrecognized prior service cost	(32)	(38)	(49)	(14)	(16)	(18)	(57)	(63)	(73)	
Net loss (gain) amortization	128	298	303	96	142	127	(43)	(42)	(18)	
Termination benefits	2	56	10	1	5	3	—	37	2	
Curtailments	12	16	10	—	(26)	—	(1)	(29)	(4)	
Settlements	239	216	13	1	8	15	—	—	—	
Net periodic benefit cost (credit)	\$ 425	\$ 600	\$ 304	\$ 129	\$ 148	\$ 146	\$ (93)	\$ (83)	\$ (59)	

Net periodic benefit cost (credit) for pension and other postretirement benefit plans in 2021 includes expenses for curtailments, settlements and termination benefits provided to certain employees in connection with the spin-off of Organon.

In connection with restructuring actions (see Note 6), termination charges were recorded in 2022, 2021 and 2020 on pension and other postretirement benefit plans related to expanded eligibility for certain employees exiting Merck. Also, in connection with these restructuring activities, curtailments and settlements were recorded on certain pension plans. An increase in lump sum payments to U.S. pension plan participants also contributed to the settlements recorded during 2022 and 2021.

The components of net periodic benefit cost (credit) other than the service cost component are included in *Other (income) expense, net* (see Note 15), with the exception of certain amounts for termination benefits, curtailments and settlements, which are recorded in *Restructuring costs* if the event giving rise to the termination benefits, curtailment or settlement is related to restructuring actions or in *Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests* if related to the spin-off of Organon (each as noted above).

Obligations and Funded Status

Summarized information about the changes in plan assets and benefit obligations, the funded status and the amounts recorded at December 31 is as follows:

	Pension Benefits				Other Postretirement Benefits	
	U.S.		International		2022	2021
	2022	2021	2022	2021		
Fair value of plan assets January 1	\$ 13,067	\$ 12,672	\$ 12,195	\$ 12,009	\$ 1,292	\$ 1,221
Actual return on plan assets	(3,129)	1,250	(2,793)	891	(306)	118
Company contributions	293	305	155	189	46	33
Effects of exchange rate changes	—	—	(848)	(671)	—	—
Benefits paid	(219)	(219)	(250)	(233)	(90)	(86)
Settlements	(918)	(941)	(16)	(55)	—	—
Spin-off of Organon	—	—	—	(55)	—	—
Other	—	—	30	120	5	6
Fair value of plan assets December 31	\$ 9,094	\$ 13,067	\$ 8,473	\$ 12,195	\$ 947	\$ 1,292
Benefit obligation January 1	\$ 13,999	\$ 14,613	\$ 11,575	\$ 12,458	\$ 1,541	\$ 1,607
Service cost	372	403	283	328	48	48
Interest cost	457	404	145	123	46	45
Actuarial (gains) losses ⁽¹⁾	(3,851)	(332)	(3,283)	(240)	(392)	(103)
Benefits paid	(219)	(219)	(250)	(233)	(90)	(86)
Effects of exchange rate changes	—	—	(732)	(678)	(1)	(1)
Plan amendments	—	—	4	4	—	—
Curtailments	12	15	—	(38)	—	(12)
Termination benefits	2	56	1	5	—	37
Settlements	(918)	(941)	(16)	(55)	—	—
Spin-off of Organon	—	—	—	(118)	—	—
Other	—	—	28	19	5	6
Benefit obligation December 31	\$ 9,854	\$ 13,999	\$ 7,755	\$ 11,575	\$ 1,157	\$ 1,541
Funded status December 31	\$ (760)	\$ (932)	\$ 718	\$ 620	\$ (210)	\$ (249)
Recognized as:						
Other Assets	\$ 5	\$ 9	\$ 1,052	\$ 1,395	\$ —	\$ —
Accrued and other current liabilities	(59)	(64)	(19)	(22)	(8)	(8)
Other Noncurrent Liabilities	(706)	(877)	(315)	(753)	(202)	(241)

⁽¹⁾ Actuarial (gains) losses primarily reflect changes in discount rates.

At December 31, 2022 and 2021, the accumulated benefit obligation was \$ 17.2 billion and \$ 24.9 billion, respectively, for all pension plans, of which \$ 9.7 billion and \$ 13.8 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	
	2022	2021	2022	2021
Pension plans with a projected benefit obligation in excess of plan assets				
Projected benefit obligation	\$ 9,186	\$ 13,013	\$ 2,779	\$ 2,507
Fair value of plan assets	8,421	12,072	2,445	1,731
Pension plans with an accumulated benefit obligation in excess of plan assets				
Accumulated benefit obligation	\$ 9,081	\$ 12,916	\$ 1,226	\$ 2,462
Fair value of plan assets	8,421	12,072	948	1,723

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, 2022 and 2021, \$ 765 million and \$ 943 million, respectively, or approximately 4 % of the Company's pension investments were categorized as Level 3 assets.

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

The fair values of the Company's pension plan assets at December 31 by asset category are as follows:

	Fair Value Measurements Using					Fair Value Measurements Using				
	Level 1	Level 2	Level 3	NAV ⁽¹⁾	Total	Level 1	Level 2	Level 3	NAV ⁽¹⁾	Total
	2022					2021				
U.S. Pension Plans										
Cash and cash equivalents	\$ 49	\$ —	\$ —	\$ 98	\$ 147	\$ 3	\$ —	\$ —	\$ 289	\$ 292
<i>Investment funds</i>										
Developed markets equities	211	—	—	2,443	2,654	236	—	—	3,799	4,035
Emerging markets equities	—	—	—	707	707	—	—	—	919	919
Real estate	—	—	—	131	131	—	—	—	—	—
<i>Equity securities</i>										
Developed markets	1,956	—	—	—	1,956	2,915	—	—	—	2,915
<i>Fixed income securities</i>										
Government and agency obligations	—	1,934	—	—	1,934	—	2,870	—	—	2,870
Corporate obligations	—	1,438	—	—	1,438	—	2,005	—	—	2,005
Mortgage and asset-backed securities	—	22	—	—	22	—	23	—	—	23
<i>Other investments</i>										
Derivatives	—	101	—	—	101	—	—	—	—	—
Other	—	—	4	—	4	2	—	6	—	8
Plan assets at fair value	\$ 2,216	\$ 3,495	\$ 4	\$ 3,379	\$ 9,094	\$ 3,156	\$ 4,898	\$ 6	\$ 5,007	\$ 13,067
International Pension Plans										
Cash and cash equivalents	\$ 57	\$ 8	\$ —	\$ 13	\$ 78	\$ 82	\$ 10	\$ —	\$ 18	\$ 110
<i>Investment funds</i>										
Developed markets equities	375	2,957	—	90	3,422	531	4,292	—	121	4,944
Government and agency obligations	177	2,656	—	130	2,963	240	4,025	—	171	4,436
Emerging markets equities	52	—	—	59	111	137	—	—	72	209
Corporate obligations	8	9	—	129	146	9	8	—	171	188
Other fixed income obligations	10	7	—	4	21	15	8	—	3	26
Real estate	—	1	—	10	11	—	1	—	16	17
<i>Equity securities</i>										
Developed markets	263	—	—	—	263	369	—	—	—	369
<i>Fixed income securities</i>										
Government and agency obligations	—	448	—	—	448	3	591	—	3	597
Corporate obligations	—	157	—	—	157	—	223	—	2	225
Mortgage and asset-backed securities	—	69	—	—	69	—	90	—	—	90
<i>Other investments</i>										
Insurance contracts ⁽²⁾	—	18	761	1	780	—	44	937	1	982
Other	1	3	—	—	4	1	1	—	—	2
Plan assets at fair value	\$ 943	\$ 6,333	\$ 761	\$ 436	\$ 8,473	\$ 1,387	\$ 9,293	\$ 937	\$ 578	\$ 12,195

⁽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, 2022 and 2021.

⁽²⁾ The plans' Level 3 investments in insurance contracts are generally valued using a crediting rate that approximates market returns and invest in underlying securities whose market values are unobservable and determined using pricing models, discounted cash flow methodologies, or similar techniques.

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The table below provides a summary of the changes in fair value, including transfers in and/or out, of all financial assets measured at fair value using significant unobservable inputs (Level 3) for the Company's pension plan assets:

	2022				2021			
	Insurance Contracts	Real Estate	Other	Total	Insurance Contracts	Real Estate	Other	Total
U.S. Pension Plans								
Balance January 1	\$ —	\$ —	\$ 6	\$ 6	\$ —	\$ —	\$ 7	\$ 7
Actual return on plan assets:								
Relating to assets still held at December 31	—	—	(3)	(3)	—	—	(5)	(5)
Relating to assets sold during the year	—	—	2	2	—	—	7	7
Purchases and sales, net	—	—	(1)	(1)	—	—	(3)	(3)
Balance December 31	\$ —	\$ —	\$ 4	\$ 4	\$ —	\$ —	\$ 6	\$ 6
International Pension Plans								
Balance January 1	\$ 937	\$ —	\$ —	\$ 937	\$ 935	\$ —	\$ —	\$ 935
Actual return on plan assets:								
Relating to assets still held at December 31	(147)	—	—	(147)	(34)	—	—	(34)
Purchases and sales, net	(39)	—	—	(39)	(42)	—	—	(42)
Transfers into Level 3	10	—	—	10	78	—	—	78
Balance December 31	\$ 761	\$ —	\$ —	\$ 761	\$ 937	\$ —	\$ —	\$ 937

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
	2022	2021	2022	2021	2022	2021	2022			2022	2021	2022	2021	2022	2021			
Cash and cash equivalents	\$ 2	\$ —	\$ —	\$ 8	\$ 10	\$ 279	24	—	—	\$ —	\$ —	\$ 28	\$ —	\$ —	\$ 39			
<i>Investment funds</i>																		
Developed markets equities	22	—	—	257	279	279	24	—	—	—	—	378	—	—	402			
Emerging markets equities	—	—	—	74	74	74	—	—	—	—	—	92	—	—	92			
Real estate	—	—	—	14	14	14	—	—	—	—	—	—	—	—	—			
Government and agency obligations	1	—	—	—	1	1	1	—	—	—	—	—	—	—	1			
<i>Equity securities</i>																	—	
Developed markets	206	—	—	—	206	206	290	—	—	—	—	—	—	—	—	290		
<i>Fixed income securities</i>																		
Government and agency obligations	—	212	—	—	212	212	—	275	—	—	—	—	—	—	—	275		
Corporate obligations	—	137	—	—	137	137	—	191	—	—	—	—	—	—	—	191		
Mortgage and asset-backed securities	—	2	—	—	2	2	—	2	—	—	—	—	—	—	—	2		
<i>Other Investments</i>																		
Derivatives	—	12	—	—	12	12	—	—	—	—	—	—	—	—	—	—	—	
Plan assets at fair value	\$ 231	\$ 363	\$ —	\$ 353	\$ 947	\$ 947	\$ 326	\$ 468	\$ 498	\$ —	\$ —	\$ 1,292						

⁽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, 2022 and 2021.

The Company has established investment guidelines for its U.S. pension and other postretirement plans to create an asset allocation that is expected to deliver a rate of return sufficient to meet the long-term obligation of each plan, given an acceptable level of risk. The target investment portfolio of the Company's U.S. pension and other postretirement benefit plans is allocated 25 % to 40 % in U.S. equities, 10 % to 20 % in international equities, 35 % to 45 % in fixed-income investments, and up to 8 % in cash and other investments. The portfolio's equity weighting is consistent with the long-term nature of the plans' benefit obligations. The expected annual standard deviation of

returns of the target portfolio, which approximates 10 %, reflects both the equity allocation and the diversification benefits among the asset classes in which the portfolio invests. For international pension plans, the targeted investment portfolio varies based on the duration of pension liabilities and local government rules and regulations. Although a significant percentage of plan assets are invested in U.S. equities, concentration risk is mitigated through the use of strategies that are diversified within management guidelines.

Expected Contributions

Contributions during 2023 are expected to be approximately \$ 270 million for U.S. pension plans, approximately \$ 150 million for international pension plans and approximately \$ 20 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
2023	\$ 627	\$ 271	\$ 84
2024	634	257	86
2025	650	262	87
2026	676	283	89
2027	694	297	90
2028 — 2032	3,948	1,704	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 gain/loss amounts reflect differences between expected and actual returns on plan assets as well as the effects of changes in actuarial assumptions. Net gain/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						
	2022	2021	2020	2022	2021	2020	2022	2021	2020	
Net (loss) gain arising during the period	\$ (42)	\$ 813	\$ (472)	\$ 116	\$ 772	\$ (424)	\$ —	\$ 156	\$ 199	
Prior service (cost) credit arising during the period	—	—	—	(4)	(4)	64	—	—	—	
	\$ (42)	\$ 813	\$ (472)	\$ 112	\$ 768	\$ (360)	\$ —	\$ 156	\$ 199	
Net loss (gain) amortization included in benefit cost	\$ 128	\$ 298	\$ 303	\$ 96	\$ 142	\$ 127	\$ (43)	\$ (42)	\$ (18)	
Prior service credit amortization included in benefit cost	(32)	(38)	(49)	(14)	(16)	(18)	(57)	(63)	(73)	
Settlements and curtailments	251	232	23	1	(18)	15	(1)	(29)	(4)	
	\$ 347	\$ 492	\$ 277	\$ 83	\$ 108	\$ 124	\$ (101)	\$ (134)	\$ (95)	

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		
	2022	2021	2020	2022	2021	2020
Net periodic benefit cost						
Discount rate	3.00 %	2.70 %	3.40 %	1.50 %	1.10 %	1.50 %
Expected rate of return on plan assets	6.70 %	6.70 %	7.30 %	3.70 %	3.80 %	4.40 %
Salary growth rate	4.60 %	4.60 %	4.20 %	2.90 %	2.80 %	2.80 %
Interest crediting rate	5.00 %	4.70 %	4.90 %	3.00 %	3.00 %	2.80 %
Benefit obligation						
Discount rate	5.50 %	3.00 %	2.70 %	3.90 %	1.50 %	1.10 %
Salary growth rate	4.60 %	4.60 %	4.60 %	3.20 %	2.90 %	2.80 %
Interest crediting rate	5.30 %	5.00 %	4.70 %	3.30 %	3.00 %	3.00 %

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 2023, the expected rate of return for the Company's U.S. pension and other postretirement benefit plans will be 7.00 %, as compared to 6.70 % in 2022.

The health care cost trend rate assumptions for other postretirement benefit plans are as follows:

December 31	2022	2021
Health care cost trend rate assumed for next year	7.8 %	6.4 %
Rate to which the cost trend rate is assumed to decline	4.5 %	4.5 %
Year that the trend rate reaches the ultimate trend rate	2038	2032

Savings Plans

The Company also maintains defined contribution savings plans in the U.S. The Company matches a percentage of each employee's contributions consistent with the provisions of the plan for which the employee is eligible. Total employer contributions to these plans in 2022, 2021 and 2020 were \$ 175 million, \$ 158 million and \$ 158 million, respectively.

15. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

Years Ended December 31	2022	2021	2020
Interest income	\$ (157)	\$ (36)	\$ (59)
Interest expense	962	806	831
Exchange losses	237	297	145
Loss (income) from investments in equity securities, net ⁽¹⁾	1,419	(1,940)	(1,338)
Net periodic defined benefit plan (credit) cost other than service cost	(279)	(212)	(339)
Other, net	(681)	(256)	(130)
	\$ 1,501	\$ (1,341)	\$ (890)

⁽¹⁾ Includes net realized and unrealized gains and losses from investments in equity securities either owned directly or through ownership interests in investment funds. Unrealized gains and losses from investments that are directly owned are determined at the end of the reporting period, while gains and losses from ownership interests in investment funds are accounted for on a one quarter lag. The Company estimates gains of approximately \$ 140 million will be recorded in the first quarter of 2023 from ownership interests in investment funds.

Interest paid was \$ 937 million in 2022, \$ 779 million in 2021 and \$ 822 million in 2020.

16. Taxes on Income

A reconciliation between the effective tax rate for income from continuing operations and the U.S. statutory rate is as follows:

	2022		2021		2020	
	Amount	Tax Rate	Amount	Tax Rate	Amount	Tax Rate
U.S. statutory rate applied to income from continuing operations before taxes	\$ 3,453	21.0 %	\$ 2,915	21.0 %	\$ 1,231	21.0 %
Differential arising from:						
Foreign earnings	(1,835)	(11.1)	(1,446)	(10.4)	(965)	(16.5)
GILTI and the foreign-derived intangible income deduction	462	2.8	(75)	(0.5)	349	6.0
State taxes	(110)	(0.7)	2	—	57	1.0
R&D tax credit	(81)	(0.5)	(81)	(0.6)	(108)	(1.8)
Tax settlements	(10)	(0.1)	(275)	(2.0)	(13)	(0.2)
Valuation allowances	108	0.7	102	0.7	37	0.6
Restructuring	11	0.1	61	0.4	105	1.8
Acquisition of VelosBio	—	—	(9)	(0.1)	559	9.5
Acquisition of Pandion	—	—	356	2.6	—	—
Acquisition of OncoImmune	—	—	—	—	97	1.7
Other	(80)	(0.5)	(29)	(0.1)	(9)	(0.2)
	\$ 1,918	11.7 %	\$ 1,521	11.0 %	\$ 1,340	22.9 %

Where applicable, the impact of changes in uncertain tax positions is reflected in the reconciling items above.

The Company's remaining transition tax liability under the Tax Cuts and Jobs Act (TCJA) of 2017, which has been reduced by payments and the utilization of foreign tax credits, was \$ 2.2 billion at December 31, 2022, of which \$ 732 million is included in *Income taxes payable* and the remainder of \$ 1.5 billion is included in *Other Noncurrent Liabilities*. As a result of the transition tax under the TCJA, the Company is no longer indefinitely reinvested with respect to its undistributed earnings from foreign subsidiaries and has provided a deferred tax liability for foreign withholding taxes that would apply. The Company remains indefinitely reinvested with respect to its financial statement basis in excess of tax basis of its foreign subsidiaries. A determination of the deferred tax liability with respect to this basis difference is not practicable.

The foreign earnings tax rate differentials in the tax rate reconciliation above primarily reflect the impacts of operations in jurisdictions with different tax rates than the U.S., particularly Ireland and Switzerland, as well as Singapore and Puerto Rico which operate under tax incentive grants (which begin to expire in 2025), thereby yielding

a favorable impact on the effective tax rate compared with the U.S. statutory rate of 21%. The Company has an additional Cantonal tax holiday in Switzerland that provides for a tax rate reduction and is effective through 2032.

Income from continuing operations before taxes consisted of:

Years Ended December 31	2022	2021	2020
Domestic	\$ 1,011	\$ 1,854	\$ (3,814)
Foreign	15,433	12,025	9,677
	\$ 16,444	\$ 13,879	\$ 5,863

Taxes on income from continuing operations consisted of:

Years Ended December 31	2022	2021	2020
<i>Current provision</i>			
Federal	\$ 2,265	\$ 74	\$ 893
Foreign	1,164	1,273	969
State	57	(13)	44
	3,486	1,334	1,906
<i>Deferred provision</i>			
Federal	(1,510)	240	(605)
Foreign	71	(77)	64
State	(129)	24	(25)
	(1,568)	187	(566)
	\$ 1,918	\$ 1,521	\$ 1,340

Deferred income taxes at December 31 consisted of:

	2022		2021	
	Assets	Liabilities	Assets	Liabilities
Product intangibles and licenses	\$ —	\$ 2,575	\$ —	\$ 3,207
R&D capitalization	1,341	—	274	—
Inventory related	43	423	119	370
Accelerated depreciation	—	657	—	589
Equity investments	—	92	—	335
Pensions and other postretirement benefits	372	284	487	338
Compensation related	335	—	301	—
Unrecognized tax benefits	91	—	75	—
Net operating losses and other tax credit carryforwards	912	—	867	—
Other	511	267	434	180
Subtotal	3,605	4,298	2,557	5,019
Valuation allowance	(599)	—	(287)	—
Total deferred taxes	\$ 3,006	\$ 4,298	\$ 2,270	\$ 5,019
Net deferred income taxes		\$ 1,292		\$ 2,749
<i>Recognized as:</i>				
Other Assets	\$ 503		\$ 692	
Deferred Income Taxes		\$ 1,795		\$ 3,441

The Company has net operating loss (NOL) carryforwards in several jurisdictions. As of December 31, 2022, \$ 349 million of deferred tax assets on NOL carryforwards relate to foreign jurisdictions. Valuation allowances of \$ 345 million have been established on these foreign NOL carryforwards and other foreign deferred tax assets. In addition, the Company has \$ 563 million of deferred tax assets relating to various U.S. tax credit carryforwards and

NOL carryforwards. Valuation allowances of \$ 247 million have been established on these U.S. tax credit carryforwards and NOL carryforwards.

Income taxes paid in 2022, 2021 and 2020 (including amounts attributable to discontinued operations in 2021 and 2020) were \$ 3.2 billion, \$ 2.4 billion and \$ 2.7 billion, respectively. Income taxes paid consisted of:

<i>Years Ended December 31</i>	2022	2021	2020
Domestic ⁽¹⁾	\$ 1,891	\$ 1,211	\$ 977
Foreign	1,348	1,201	1,763
	\$ 3,239	\$ 2,412	\$ 2,740

⁽¹⁾ Includes TCJA transition tax payments.

Tax benefits relating to stock option exercises were \$ 45 million in 2022, \$ 21 million in 2021 and \$ 12 million in 2020.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	2022	2021	2020
Balance January 1	\$ 1,529	\$ 1,537	\$ 1,225
Additions related to current year positions	344	306	298
Additions related to prior year positions	48	63	110
Reductions for tax positions of prior years ⁽¹⁾	(40)	(230)	(4)
Settlements ⁽¹⁾	(6)	(46)	(70)
Lapse of statute of limitations	(40)	(58)	(22)
Spin-off of Organon	—	(43)	—
Balance December 31	\$ 1,835	\$ 1,529	\$ 1,537

⁽¹⁾ Amount in 2021 reflects a settlement with the IRS discussed below.

If the Company were to recognize the unrecognized tax benefits of \$ 1.8 billion at December 31, 2022, the income tax provision would reflect a favorable net impact of \$ 1.8 billion.

The Company is under examination by numerous tax authorities in various jurisdictions globally. The Company believes that it is reasonably possible that the total amount of unrecognized tax benefits as of December 31, 2022 could decrease by up to approximately \$ 31 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 \$ 54 million in 2022, \$(37) million in 2021 and \$ 16 million in 2020. These amounts reflect the beneficial impacts of various tax settlements, including the settlement discussed below. Liabilities for accrued interest and penalties were \$ 256 million and \$ 192 million as of December 31, 2022 and 2021, respectively.

In 2021, the Internal Revenue Service (IRS) concluded its examinations of Merck's 2015-2016 U.S. federal income tax returns. As a result, the Company was required to make a payment of \$ 190 million (of which \$ 172 million related to continuing operations and \$ 18 million related to discontinued operations). The Company's reserves for unrecognized tax benefits for the years under examination exceeded the adjustments relating to this examination period and therefore the Company recorded a \$ 236 million net tax benefit in 2021 (of which \$ 207 million related to continuing operations and \$ 29 million related to discontinued operations). This net benefit reflects reductions in reserves for unrecognized tax benefits and other related liabilities for tax positions relating to the years that were under examination.

The IRS is currently conducting examinations of the Company's tax returns for the years 2017 and 2018. In addition, various state and foreign tax examinations are in progress and for these jurisdictions, the Company's income tax returns are open for examination for the period 2003 through 2022.

17. Earnings per Share

The calculations of earnings per share (shares in millions) are as follows:

Years Ended December 31	2022	2021	2020
Net Income from Continuing Operations Attributable to Merck & Co., Inc.	\$ 14,519	\$ 12,345	\$ 4,519
Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests	—	704	2,548
Net Income Attributable to Merck & Co., Inc.	\$ 14,519	\$ 13,049	\$ 7,067
Average common shares outstanding	2,532	2,530	2,530
Common shares issuable ⁽¹⁾	10	8	11
Average common shares outstanding assuming dilution	2,542	2,538	2,541
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders:			
Income from Continuing Operations	\$ 5.73	\$ 4.88	\$ 1.79
Income from Discontinued Operations	—	0.28	1.01
Net Income	\$ 5.73	\$ 5.16	\$ 2.79
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders:			
Income from Continuing Operations	\$ 5.71	\$ 4.86	\$ 1.78
Income from Discontinued Operations	—	0.28	1.00
Net Income	\$ 5.71	\$ 5.14	\$ 2.78

⁽¹⁾ Issuable primarily under share-based compensation plans.

In 2022, 2021 and 2020, 2 million, 9 million and 5 million, respectively, of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

18. Other Comprehensive Income (Loss)

Changes in each component of other comprehensive income (loss) are as follows:

	Derivatives	Investments	Employee Benefit Plans	Foreign Currency Translation Adjustment	Accumulated Other Comprehensive Loss
Balance January 1, 2020, net of taxes	\$ 31	\$ 18	\$ (4,261)	\$ (1,981)	\$ (6,193)
Other comprehensive income (loss) before reclassification adjustments, pretax	(383)	3	(633)	64	(949)
Tax	84	—	120	89	293
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(299)	3	(513)	153	(656)
Reclassification adjustments, pretax	2 ⁽¹⁾	(21) ⁽²⁾	306 ⁽³⁾	—	287
Tax	—	—	(72)	—	(72)
Reclassification adjustments, net of taxes	2	(21)	234	—	215
Other comprehensive income (loss), net of taxes	(297)	(18)	(279)	153	(441)
Balance at December 31, 2020, net of taxes	(266)	—	(4,540)	(1,828)	(6,634)
Other comprehensive income (loss) before reclassification adjustments, pretax	333	—	1,737	(304)	1,766
Tax	(75)	—	(332)	(119)	(526)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	258	—	1,405	(423)	1,240
Reclassification adjustments, pretax	192 ⁽¹⁾	—	466 ⁽³⁾	—	658
Tax	(40)	—	(102)	—	(142)
Reclassification adjustments, net of taxes	152	—	364	—	516
Other comprehensive income (loss), net of taxes	410	—	1,769	(423)	1,756
Spin-off of Organon (see Note 3)	—	—	28	421	449
Balance at December 31, 2021, net of taxes	144	—	(2,743) ⁽⁴⁾	(1,830)	(4,429)
Other comprehensive income (loss) before reclassification adjustments, pretax	684	—	70	(584)	170
Tax	(143)	—	12	(19)	(150)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	541	—	82	(603)	20
Reclassification adjustments, pretax	(775) ⁽¹⁾	—	329 ⁽³⁾	—	(446)
Tax	163	—	(76)	—	87
Reclassification adjustments, net of taxes	(612)	—	253	—	(359)
Other comprehensive income (loss), net of taxes	(71)	—	335	(603)	(339)
Balance at December 31, 2022, net of taxes	\$ 73	\$ —	\$ (2,408) ⁽⁴⁾	\$ (2,433)	\$ (4,768)

⁽¹⁾ Primarily relates to foreign currency cash flow hedges that were reclassified from AOCL to Sales.

⁽²⁾ Represents net realized gains on the sales of available-for-sale debt securities that were reclassified from AOCL to Other (income) expense, net.

⁽³⁾ Includes net amortization of prior service cost, actuarial gains and losses, settlements and curtailments included in net periodic benefit cost (see Note 14).

⁽⁴⁾ Includes pension plan net loss of \$ 3.1 billion and \$ 3.6 billion at December 31, 2022 and 2021, respectively, and other postretirement benefit plan net gain of \$ 446 million and \$ 473 million at December 31, 2022 and 2021, respectively, as well as pension plan prior service credit of \$ 152 million and \$ 190 million at December 31, 2022 and 2021, respectively, and other postretirement benefit plan prior service credit of \$ 135 million and \$ 181 million at December 31, 2022 and 2021, respectively.

19. Segment Reporting

The Company's operations are principally managed on a product basis and include two operating segments, Pharmaceutical and Animal Health, both of which are reportable segments.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. A large component of pediatric and adolescent vaccine sales are made to the U.S. Centers for Disease Control and Prevention Vaccines for Children program, which is funded by the U.S. government. Additionally, the Company sells vaccines to the Federal government for placement into vaccine stockpiles.

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

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

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Sales of the Company's products were as follows:

Years Ended December 31	2022			2021			2020		
	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	Total
Pharmaceutical:									
Oncology									
Keytruda	\$ 12,686	\$ 8,251	\$ 20,937	\$ 9,765	\$ 7,421	\$ 17,186	\$ 8,352	\$ 6,028	\$ 14,380
Alliance revenue - Lynparza ⁽¹⁾	584	532	1,116	515	473	989	417	308	725
Alliance revenue - Lenvima ⁽¹⁾	579	297	876	417	287	704	359	220	580
Alliance revenue - Reblozyl ⁽²⁾	123	43	166	—	17	17	—	—	—
Vaccines									
Gardasil/Gardasil 9	2,065	4,832	6,897	1,881	3,792	5,673	1,755	2,184	3,938
ProQuad/M-M-R II/Varivax	1,724	518	2,241	1,629	506	2,135	1,378	500	1,878
RotaTeq	508	275	783	473	334	807	486	311	797
Pneumovax 23	346	256	602	547	346	893	727	359	1,087
Vaqta	95	78	173	100	79	179	103	67	170
Hospital Acute Care									
Bridion	922	762	1,685	762	770	1,532	583	615	1,198
Prevymis	188	240	428	153	218	370	119	162	281
Difidicid	241	22	263	166	10	175	102	7	110
Primaxin	1	238	239	2	258	259	2	248	251
Noxafil	51	187	238	60	199	259	42	287	329
Invanz	4	185	189	(5)	207	202	9	202	211
Cancidas	6	168	174	4	208	212	7	207	213
Zerbaxa	89	79	169	4	(5)	(1)	74	56	130
Cardiovascular									
Alliance revenue - Adempas/Verquvo ⁽³⁾	329	12	341	312	30	342	259	22	281
Adempas	—	238	238	—	252	252	—	220	220
Virology									
Lagevrio	1,523	4,161	5,684	632	320	952	—	—	—
Isentress/Isentress HD	274	359	633	294	474	769	326	531	857
Neuroscience									
Belsomra	79	179	258	78	241	318	81	247	327
Immunology									
Simponi	—	706	706	—	825	825	—	838	838
Remicade	—	207	207	—	299	299	—	330	330
Diabetes									
Januvia	1,248	1,565	2,813	1,404	1,920	3,324	1,470	1,836	3,306
Janumet	355	1,344	1,700	367	1,597	1,964	477	1,494	1,971
Other pharmaceutical ⁽⁴⁾	969	1,282	2,249	841	1,275	2,118	882	1,321	2,202
Total Pharmaceutical segment sales	24,989	27,016	52,005	20,401	22,353	42,754	18,010	18,600	36,610
Animal Health:									
Livestock	710	2,590	3,300	667	2,628	3,295	612	2,327	2,939
Companion Animals	1,112	1,138	2,250	1,091	1,182	2,273	872	892	1,764
Total Animal Health segment sales	1,822	3,728	5,550	1,758	3,810	5,568	1,484	3,219	4,703
Other segment sales ⁽⁵⁾	—	—	—	—	—	—	23	—	23
Total segment sales	26,811	30,744	57,555	22,159	26,163	48,322	19,517	21,819	41,336
Other ⁽⁶⁾	395	1,333	1,728	266	116	382	71	111	182
	\$ 27,206	\$ 32,077	\$ 59,283	\$ 22,425	\$ 26,279	\$ 48,704	\$ 19,588	\$ 21,930	\$ 41,518

U.S. plus international may not equal total due to rounding.

⁽¹⁾ Alliance revenue for Lynparza and Lenvima represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs (see Note 5).

⁽²⁾ Alliance revenue for Reblozyl represents royalties and, for 2022, also includes a payment received related to the achievement of a regulatory approval milestone (see Note 5).

⁽³⁾ Alliance revenue for Adempas/Verquvo represents Merck's share of profits from sales in Bayer's marketing territories, which are product sales net of cost of sales and commercialization costs (see Note 5).

⁽⁴⁾ Other pharmaceutical primarily reflects sales of other human health pharmaceutical products, including products within the franchises not listed separately.

⁽⁵⁾ Represents sales for the Healthcare Services segment. All the businesses in the Healthcare Services segment were fully divested by the first quarter of 2020.

⁽⁶⁾ Other is primarily comprised of miscellaneous corporate revenue, including revenue hedging activities which increased (decreased) sales by \$ 810 million, \$(203) million and \$(19) million in 2022, 2021 and 2020, respectively, as well as revenue from third-party manufacturing arrangements (including sales to Organon). Other for 2022, 2021 and 2020 also includes \$ 165 million, \$ 218 million and \$ 54 million, respectively, related to upfront and milestone payments received by Merck for out-licensing arrangements.

Consolidated sales by geographic area where derived are as follows:

Years Ended December 31	2022	2021	2020
United States	\$ 27,206	\$ 22,425	\$ 19,588
Europe, Middle East and Africa	14,493	13,341	11,547
China	5,191	4,378	2,751
Japan	3,629	2,726	2,602
Asia Pacific (other than China and Japan)	3,614	2,407	2,113
Latin America	2,582	2,206	1,890
Other	2,568	1,221	1,027
	\$ 59,283	\$ 48,704	\$ 41,518

A reconciliation of segment profits to *Income from Continuing Operations Before Taxes* is as follows:

Years Ended December 31	2022	2021	2020
Segment profits:			
Pharmaceutical segment	\$ 36,852	\$ 30,977	\$ 26,106
Animal Health segment	1,963	1,950	1,669
Other segments	—	—	1
Total segment profits	38,815	32,927	27,776
Other profits	1,160	156	75
Unallocated:			
Interest income	157	36	59
Interest expense	(962)	(806)	(831)
Amortization	(2,085)	(1,636)	(1,817)
Depreciation	(1,642)	(1,414)	(1,519)
Research and development	(13,011)	(11,692)	(12,911)
Restructuring costs	(337)	(661)	(575)
Other unallocated, net	(5,651)	(3,031)	(4,394)
	\$ 16,444	\$ 13,879	\$ 5,863

Pharmaceutical segment profits are comprised of segment sales less standard costs, as well as selling, general and administrative expenses directly incurred by the segment. Animal Health segment profits are comprised of segment sales, less all cost of sales, as well as selling, general and administrative expenses and research and development costs directly incurred by the segment. For internal management reporting presented to the chief operating decision maker, Merck does not allocate the remaining cost of sales not included in segment profits as described above, research and development expenses incurred in Merck Research Laboratories, the Company's research and development division that focuses on human health-related activities, or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. In addition, costs related to restructuring activities, as well as the amortization of intangible assets and purchase accounting adjustments are not allocated to segments.

Other profits are primarily comprised of miscellaneous corporate profits, as well as operating profits related to third-party manufacturing arrangements.

Other unallocated, net, includes expenses from corporate and manufacturing cost centers, goodwill and other intangible asset impairment charges, gains or losses on sales of businesses, expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration, and other miscellaneous income or expense items.

Equity income/loss from affiliates and depreciation included in segment profits is as follows:

	Pharmaceutical	Animal Health	All Other	Total
Year Ended December 31, 2022				
Included in segment profits:				
Equity income from affiliates	\$ 39	\$ —	\$ —	\$ 39
Depreciation	\$ 5	\$ 177	\$ —	\$ 182
<i>Year Ended December 31, 2021</i>				
Included in segment profits:				
Equity income from affiliates	\$ 11	\$ —	\$ —	\$ 11
Depreciation	\$ 6	\$ 158	\$ —	\$ 164
<i>Year Ended December 31, 2020</i>				
Included in segment profits:				
Equity loss from affiliates	\$ 6	\$ —	\$ —	\$ 6
Depreciation	\$ 6	\$ 143	\$ 1	\$ 150

Property, plant and equipment, net, by geographic area where located is as follows:

December 31	2022	2021	2020
United States	\$ 12,891	\$ 11,759	\$ 10,394
Europe, Middle East and Africa	6,993	6,081	5,314
Asia Pacific (other than China and Japan)	966	857	737
Latin America	225	199	169
China	207	220	216
Japan	135	159	166
Other	5	4	4
	\$ 21,422	\$ 19,279	\$ 17,000

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, 2022 and 2021, 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, 2022, 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, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022 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, 2022, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

U.S. Rebate Accruals - Medicaid, Managed Care and Medicare Part D

As described in Note 2 to the consolidated financial statements, the Company records certain variable consideration including discounts, which are estimated at the time of sale generally using the expected value method. Amounts accrued for aggregate customer discounts are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal and state agencies, and other customers to the amounts accrued. Certain of these discounts representing a portion of the accrual take the form of rebates, which are amounts owed based upon definitive contractual agreements or legal requirements with private sector (Managed Care) and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product to a benefit plan participant. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. Management uses historical customer segment utilization mix, sales forecasts, changes to product mix and price, inventory levels in the distribution channel, government pricing calculations and prior payment history in order to estimate the expected provision. The accrued balance relative to the provision for rebates included in accrued and other current liabilities was \$2.7 billion as of December 31, 2022, of which the majority relates to U.S. rebate accruals - Medicaid, Managed Care and Medicare Part D.

The principal considerations for our determination that performing procedures relating to U.S. rebate accruals - Medicaid, Managed Care and Medicare Part D is a critical audit matter are the significant judgment by management due to the significant measurement uncertainty involved in developing the rebate accruals, as the accruals are based on assumptions developed using pricing information and historical customer segment utilization mix, and a high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating evidence related to these assumptions.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to U.S. rebate accruals - Medicaid, Managed Care and Medicare Part D, including management's controls over the assumptions used to estimate the corresponding rebate accruals. These procedures also included, among others (i) developing an independent estimate of the rebate accruals by utilizing third party data on historical customer segment utilization mix in the U.S., pricing information, the terms of the specific rebate programs, and the historical trend of actual rebate claims paid, (ii) comparing the independent estimate to the rebate accruals recorded by management, and (iii) testing rebate claims paid, including evaluating those claims for consistency with the contractual terms of the Company's rebate agreements.

The logo for PricewaterhouseCoopers LLP, featuring the company name in a stylized, cursive font.

PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 24, 2023

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 2022, 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, 2022. 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, 2022.

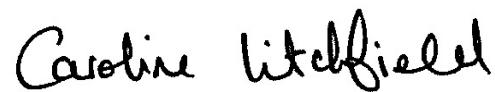
Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls

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, 2022, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.



Robert M. Davis
Chairman, President and Chief Executive Officer



Caroline Litchfield
Executive Vice President and Chief Financial Officer

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The required information on directors and nominees is incorporated by reference from the discussion under Proposal 1, Election of Directors of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 23, 2023. Information on executive officers is set forth in Part I of this document on page [40](#).

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 23, 2023.

The Company has a Code of Conduct — *Our Values and Standards* applicable to all employees, including the principal executive officer, principal financial officer, principal accounting officer and Controller. The Code of Conduct is available on the Company's website at merck.com/company-overview/culture-and-values/code-of-conduct/values-and-standards. The Company intends to disclose future amendments to certain provisions of the Code of Conduct, and waivers of the Code of Conduct granted to executive officers and directors, if any, on the website within four business days following the date of any amendment or waiver. Every Merck employee is responsible for adhering to business practices that are in accordance with the law and with ethical principles that reflect the highest standards of corporate and individual behavior.

The required information on the identification of the audit committee and the audit committee financial expert is incorporated by reference from the discussion under the heading "Board Meetings and Committees" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 23, 2023.

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, "CEO Pay Ratio," "Pay vs. Performance" table, "Grants of Plan-Based Awards" table, "Outstanding Equity Awards" table, "Option Exercises and Stock Vested" table, "Pension Benefits" table, "Nonqualified Deferred Compensation" table, and "Potential Payments Upon Termination or a Change in Control", including the discussion under the subheadings "Separation" and "Change in Control," as well as all footnote information to the various tables, of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 23, 2023.

The required information on director compensation is incorporated by reference from the discussion under the heading "Director Compensation" and related "2022 Schedule of Director Fees" table and "2022 Director Compensation" table of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 23, 2023.

The required information under the headings "Compensation and Management Development Committee Interlocks and Insider Participation" and "Compensation and Management Development Committee Report" is incorporated by reference from the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 23, 2023.

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 23, 2023.

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, 2022. 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⁾	13,719,333 ⁽²⁾	\$ 70.55	86,776,452
Equity compensation plans not approved by security holders	—	—	—
Total	13,719,333	\$ 70.55	86,776,452

⁽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 12,700,042 shares of restricted stock units and 1,980,608 performance share units (assuming maximum payouts) under the Merck Sharp & Dohme 2010 and 2019 Incentive Stock Plans. Also excludes 182,601 shares of phantom stock deferred under the MSD Employee Deferral Program and 487,534 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 23, 2023.

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 23, 2023.

Item 14. Principal Accountant Fees and Services.

The information required for this item is incorporated by reference from the discussion under Proposal 4. Ratification of Appointment of Independent Registered Public Accounting Firm for 2023 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 23, 2023.

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, 2022, 2021 and 2020

Consolidated statement of comprehensive income for the years ended December 31, 2022, 2021 and 2020

Consolidated balance sheet as of December 31, 2022 and 2021

Consolidated statement of equity for the years ended December 31, 2022, 2021 and 2020

Consolidated statement of cash flows for the years ended December 31, 2022, 2021 and 2020

Notes to consolidated financial statements

Report of PricewaterhouseCoopers LLP, independent registered public accounting firm (PCAOB ID 238)

2. Financial Statement Schedules

Schedules are omitted because they are either not required or not applicable.

Financial statements of affiliates carried on the equity basis have been omitted because, considered individually or in the aggregate, such affiliates do not constitute a significant subsidiary.

3. Exhibits

Exhibit Number	Description
3.1	— Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) — Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
3.2	— By-Laws of Merck & Co., Inc. (effective March 22, 2022) — Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed March 25, 2022 (No. 1-6571)
4.1	— Indenture, dated as of April 1, 1991, between Merck Sharp & Dohme Corp. (f/k/a Schering Corporation) and U.S. Bank Trust National Association (as successor to Morgan Guaranty Trust Company of New York), as Trustee (the 1991 Indenture) — Incorporated by reference to Exhibit 4 to MSD's Registration Statement on Form S-3 (No. 33-39349)
4.2	— First Supplemental Indenture to the 1991 Indenture, dated as of October 1, 1997 — Incorporated by reference to Exhibit 4(b) to MSD's Registration Statement on Form S-3 filed September 25, 1997 (No. 333-36383)
4.3	— Second Supplemental Indenture to the 1991 Indenture, dated November 3, 2009 — Incorporated by reference to Exhibit 4.3 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
4.4	— Third Supplemental Indenture to the 1991 Indenture, dated May 1, 2012 — Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the period ended March 31, 2012 (No. 1-6571)
4.5	— Indenture, dated November 26, 2003, between Merck & Co., Inc. (f/k/a Schering-Plough Corporation) and The Bank of New York as Trustee (the 2003 Indenture) — Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed November 28, 2003 (No. 1-6571)
4.6	— Second Supplemental Indenture to the 2003 Indenture (including Form of Note), dated November 26, 2003 — Incorporated by reference to Exhibit 4.3 to Schering-Plough's Current Report on Form 8-K filed November 28, 2003 (No. 1-6571)
4.7	— Third Supplemental Indenture to the 2003 Indenture (including Form of Note), dated September 17, 2007 — Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed September 17, 2007 (No. 1-6571)
4.8	— Fifth Supplemental Indenture to the 2003 Indenture, dated November 3, 2009 — Incorporated by reference to Exhibit 4.4 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
4.9	— Indenture, dated as of January 6, 2010, between Merck & Co., Inc. and U.S. Bank Trust National Association, as Trustee — Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed December 10, 2010 (No. 1-6571)
4.10	— Description of the Registrant's Common Stock - Incorporated by reference to Exhibit 4.10 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2020 filed February 25, 2021 (No. 1-6571)
4.11	— Description of the Registrant's 1.125% Notes due 2021, 1.875% Notes due 2026, and 2.500% Notes due 2034 - Incorporated by reference to Exhibit 4.11 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2020 filed February 25, 2021 (No. 1-6571)
4.12	— Description of the Registrant's 0.500% Notes due 2024 and 1.375% Notes due 2036 - Incorporated by reference to Exhibit 4.12 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2020 filed February 25, 2021 (No. 1-6571)

- *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 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 \(No. 1-6571\)](#)
- *10.5 — [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 \(No. 1-6571\)](#)
- *10.6 — [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 \(No. 1-6571\)](#)
- *10.7 — [Form of stock option terms for 2017 annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan - Filed herewith](#)
- *10.8 — [Form of stock option terms for 2019 annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan - Filed herewith](#)
- *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 reference to Exhibit 10.12 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2017 filed February 27, 2018 \(No. 1-6571\)](#)
- *10.10 — [Form of stock option terms for 2016 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.19 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2016 filed February 28, 2017 \(No. 1-6571\)](#)

- *10.11 — [Merck & Co., Inc. 2019 Incentive Stock Plan - Incorporated by reference to Appendix C to Merck & Co., Inc.'s Schedule 14A filed April 8, 2019 \(No. 1-6571\) and to the Registration Statement on Form S-8 filed August 12, 2019 to register 111,000,000 shares under the 2019 Incentive Stock Plan \(File No. 333-233226\)](#)
- *10.12 — [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 \(No. 1-6571\)](#)
- *10.13 — [Merck & Co., Inc. U.S. Separation Benefits Plan \(amended and restated as of January 1, 2019\) as further amended by Amendments 2019-1 \(as of December 19, 2019\), 2020-1 \(as of February 25, 2020\), 2020-2 \(as of December 10, 2020\), 2021-1 \(as of March 31, 2021\), 2021-2 \(as of December 16, 2021\), 2022-1 \(as of December 14, 2022\) and 2022-2 \(as of December 13, 2021\) - Filed herewith](#)
- *10.14 — [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 \(No. 1-3305\)](#)
- *10.15 — [Merck & Co., Inc. Plan for Deferred Payment of Directors' Compensation \(Amended and Restated effective as of January 1, 2022\) - Incorporated by reference to Exhibit 10.17 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2021 filed February 25, 2022 \(No. 1-6571\)](#)
- 10.16 — [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 \(No. 1-6571\)†](#)
- 10.17 — [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 \(No. 1-6571\)†](#)
- *10.18 — [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 \(No. 1-6571\)](#)
- *10.19 — [Form of stock option terms for 2021 annual non-qualified option grants under the Merck & Co., Inc. 2019 Incentive Stock Plan - Incorporated by reference to Exhibit 10.23 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2020 filed February 25, 2021 \(No. 1-6571\)](#)
- *10.20 — [Form of restricted stock unit terms for 2021 annual grants under the Merck & Co., Inc. 2019 Incentive Stock Plan - Incorporated by reference to Exhibit 10.24 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2020 filed February 25, 2021 \(No. 1-6571\)](#)
- *10.21 — [Form of stock option terms for 2022 annual non-qualified option grants under the Merck & Co., Inc. 2019 Incentive Stock Plan - Incorporated by reference to Exhibit 10.24 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2021 filed February 25, 2022 \(No. 1-6571\)](#)
- *10.22 — [Form of restricted stock unit terms for 2022 annual grants under the Merck & Co., Inc. 2019 Incentive Stock Plan - Incorporated by reference to Exhibit 10.25 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2021 filed February 25, 2022 \(No. 1-6571\)](#)
- *10.23 — [2019 terms for CEO annual non-qualified option grant under the Merck & Co., Inc. 2010 Incentive Stock Plan - Filed herewith](#)
- *10.24 — [Form of restricted stock unit terms for 2019 annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan - Filed herewith](#)
- *10.25 — [Form of stock option terms for 2020 annual non-qualified option grants under the Merck & Co., Inc. 2019 Incentive Stock Plan — Filed herewith](#)
- *10.26 — [2020 terms for CEO annual non-qualified option grant under the Merck & Co., Inc. 2019 Incentive Stock Plan — Filed herewith](#)
- *10.27 — [Form of restricted stock unit terms for 2020 annual grants under the Merck & Co., Inc. 2019 Incentive Stock Plan - Filed herewith](#)
- *10.28 — [2020 Performance Share Unit terms for grants under the Merck & Co., Inc. 2019 Incentive Stock Plan — Filed herewith](#)

- *10.29 — [2020 CEO Performance Share Unit terms for grant under the Merck & Co., Inc. 2019 Incentive Stock Plan — Filed herewith](#)
- *10.30 — [2021 CEO annual non-qualified option terms for grant under the Merck & Co., Inc. 2019 Incentive Stock Plan — Filed herewith](#)
- *10.31 — [2021 Performance Share Unit terms for grants under the Merck & Co., Inc. 2019 Incentive Stock Plan — Filed herewith](#)
- *10.32 — [2021 CEO Performance Share Unit terms for grant under the Merck & Co., Inc. 2019 Incentive Stock Plan — Filed herewith](#)
- *10.33 — [Terms for Restricted Stock Unit Grants under the Merck & Co., Inc. 2019 Incentive Stock Plan - Filed herewith](#)
- *10.34 — [Restricted stock unit terms for May 3, 2022 and August 3, 2022 grants to Executive Chairman under the Merck & Co., Inc. 2019 Incentive Stock Plan — Filed herewith](#)
- *10.35 — [Restricted stock unit terms for August 3, 2022 grant to Chirfi Guindo under the Merck & Co., Inc. 2019 Incentive Stock Plan - Filed herewith](#)
- *10.36 — [Performance share unit terms for August 3, 2022 grant to Chirfi Guindo under the Merck & Co., Inc. 2019 Incentive Stock Plan - Filed herewith](#)
- *10.37 — [Offer Letter between Merck & Co., Inc. and Chirfi Guindo, dated June 8, 2022 - Filed herewith](#)
 - 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 101:

- 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 24, 2023

MERCK & CO., INC.

By: ROBERT M. DAVIS
(Chairman, Chief Executive Officer and President)
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
ROBERT M. DAVIS	Chairman, Chief Executive Officer and President; Principal Executive Officer	February 24, 2023
CAROLINE LITCHFIELD	Executive Vice President and Chief Financial Officer; Principal Financial Officer	February 24, 2023
RITA A. KARACHUN	Senior Vice President Finance-Global Controller; Principal Accounting Officer	February 24, 2023
DOUGLAS M. BAKER, JR.	Director	February 24, 2023
MARY ELLEN COE	Director	February 24, 2023
PAMELA J. CRAIG	Director	February 24, 2023
THOMAS H. GLOCER	Director	February 24, 2023
RISA J. LAVIZZO-MOUREY	Director	February 24, 2023
STEPHEN L. MAYO	Director	February 24, 2023
PAUL B. ROTHMAN	Director	February 24, 2023
PATRICIA F. RUSSO	Director	February 24, 2023
CHRISTINE E. SEIDMAN	Director	February 24, 2023
INGE G. THULIN	Director	February 24, 2023
KATHY J. WARDEN	Director	February 24, 2023
PETER C. WENDELL	Director	February 24, 2023

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)