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

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

FORM 10-K

(MARK ONE)

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

For the Fiscal Year Ended December 31, 2021

OR

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

For the transition period from _____ to _____

Commission File No. 1-6571

Merck & Co., Inc.

2000 Galloping Hill Road
Kenilworth New Jersey 07033
(908) 740-4000

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Documents Incorporated by Reference:

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

Table of Contents

		Page
	Part I	
Item 1.	Business	1
Item 1A.	Risk Factors	27
	Cautionary Factors that May Affect Future Results	41
Item 1B.	Unresolved Staff Comments	43
Item 2.	Properties	43
Item 3.	Legal Proceedings	43
Item 4.	Mine Safety Disclosures	43
	Executive Officers of the Registrant	44
	Part II	
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	46
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	48
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	78
Item 8.	Financial Statements and Supplementary Data	79
	(a) Financial Statements	79
	Notes to Consolidated Financial Statements	83
	Report of Independent Registered Public Accounting Firm	140
	(b) Supplementary Data	142
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	143
Item 9A.	Controls and Procedures	143
	Management's Report	143
Item 9B.	Other Information	144
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	144
	Part III	
Item 10.	Directors, Executive Officers and Corporate Governance	145
Item 11.	Executive Compensation	145
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	146
Item 13.	Certain Relationships and Related Transactions, and Director Independence	146
Item 14.	Principal Accountant Fees and Services	146
	Part IV	
Item 15.	Exhibits and Financial Statement Schedules	147
Item 16.	Form 10-K Summary	151
	Signatures	152

PART I

Item 1. Business.

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

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

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

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

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

Spin-Off of Organon & Co.

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

Product Sales

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

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

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

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

Pharmaceutical

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

Oncology

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

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

Vaccines

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

Hospital Acute Care

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

Immunology

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

Neuroscience

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

Virology

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

Cardiovascular

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

Diabetes

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

Animal Health

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

Livestock Products

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

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

Companion Animal Products

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

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

2021 Product Approvals and Authorizations

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

Product	Date	Approval
Keytruda	January 2021	European Commission (EC) approved *Keytruda* as monotherapy for the first-line treatment of adult patients with MSI-H or dMMR CRC.
	March 2021	EC approved *Keytruda* as monotherapy for the treatment of adult and pediatric patients aged 3 years and older with relapsed or refractory cHL who have failed autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT is not a treatment option.
	March 2021	U.S. Food and Drug Administration (FDA) approved *Keytruda* in combination with platinum- and fluoropyrimidine-based chemotherapy for the treatment of patients with locally advanced or metastatic esophageal or GEJ (tumors with epicenter 1 to 5 centimeters above the GEJ) carcinoma that is not amenable to surgical resection or definitive chemoradiation.
	May 2021	FDA approved *Keytruda*, in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of patients with locally advanced unresectable or metastatic HER2-positive gastric or GEJ adenocarcinoma.
	June 2021	China's National Medical Products Administration (NMPA) approved *Keytruda* as a monotherapy for the first-line treatment of patients with unresectable or metastatic MSI-H or dMMR CRC that is KRAS, NRAS and BRAF all wild-type.

Keytruda	June 2021	EC approved *Keytruda* in combination with platinum- and fluoropyrimidine-based chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic carcinoma of the esophagus or HER2-negative GEJ adenocarcinoma in adults whose tumors express PD-L1 (Combined Positive Score [CPS] ≥10).
	July 2021	FDA approved *Keytruda* as monotherapy for the treatment of patients with locally advanced cSCC that is not curable by surgery or radiation.
	July 2021	FDA approved *Keytruda* plus Lenvima for the treatment of patients with advanced endometrial carcinoma that is not MSI-H or dMMR, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.
	July 2021	FDA approved *Keytruda* for the treatment of patients with high-risk, early-stage TNBC in combination with chemotherapy as neoadjuvant treatment, then continued as single agent as adjuvant treatment after surgery.
	August 2021	FDA approved *Keytruda* for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for any platinum-containing chemotherapy.
	August 2021	Japan Pharmaceuticals and Medical Devices Agency (PMDA) approved *Keytruda* for the treatment of patients with PD-L1-positive, hormone receptor-negative and HER2-negative, inoperable or recurrent breast cancer.
	August 2021	PMDA approved *Keytruda* for the treatment of patients with unresectable, advanced or recurrent MSI-H CRC.
	August 2021	FDA approved *Keytruda* plus Lenvima for the first-line treatment of adult patients with advanced RCC.
	September 2021	NMPA approved *Keytruda* in combination with platinum- and fluoropyrimidine-based chemotherapy for first-line treatment of patients with locally advanced, unresectable or metastatic carcinoma of the esophageal or GEJ.
	October 2021	FDA approved *Keytruda* in combination with chemotherapy, with or without bevacizumab, for the treatment of patients with persistent, recurrent or metastatic cervical cancer whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test.
	October 2021	EC approved *Keytruda* in combination with chemotherapy for the first-line treatment of locally recurrent unresectable or metastatic TNBC in adults whose tumors express PD-L1 (CPS ≥1) and who have not received prior chemotherapy for metastatic disease.
	November 2021	FDA approved *Keytruda* for the adjuvant treatment of patients with RCC at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.
	November 2021	EC approved *Keytruda* plus Lenvima as a first-line treatment for adult patients with advanced RCC.

Keytruda	November 2021	EC approved *Keytruda* plus Lenvima for the treatment of advanced or recurrent endometrial carcinoma in adults who have disease progression on or following prior treatment with a platinum-containing therapy in any setting and who are not candidates for curative surgery or radiation.
	November 2021	PMDA approved *Keytruda* in combination with chemotherapy (5-fluorouracil plus cisplatin) for the first-line treatment of patients with radically unresectable, advanced or recurrent esophageal carcinoma.
	December 2021	FDA approved *Keytruda* as a monotherapy for the adjuvant treatment of adult and pediatric (12 years and older) patients with stage IIB or IIC melanoma following complete resection. The FDA also expanded the indication for *Keytruda* as adjuvant treatment for stage III melanoma following complete resection to include pediatric patients (12 years and older).
	December 2021	Japan's Ministry of Health, Labor and Welfare (MHLW) approved *Keytruda* in combination with Lenvima for the treatment of patients with unresectable, advanced or recurrent endometrial carcinoma that progressed after cancer chemotherapy.
Lynparza[(1)]	June 2021	NMPA approved Lynparza as monotherapy for the treatment of adult patients with germline or somatic *BRCA*-mutated metastatic castration-resistant prostate cancer who have progressed following prior treatment that included a new hormonal agent (abiraterone, enzalutamide).
molnupiravir[(2)]	December 2021	FDA granted Emergency Use Authorization (EUA) for molnupiravir to treat mild to moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by the FDA are not accessible or clinically appropriate.
	December 2021	MHLW granted molnupiravir Special Approval for Emergency for the treatment of infectious disease caused by SARS-CoV-2.
Vaxneuvance	July 2021	FDA approved *Vaxneuvance* for active immunization for the prevention of invasive disease caused by *Streptococcus* pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in adults 18 years of age and older.
	December 2021	EC approved *Vaxneuvance* for active immunization for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in individuals 18 years of age and older.
Verquvo[(3)]	January 2021	FDA approved Verquvo to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient intravenous (IV) diuretics in adults with symptomatic chronic HF and ejection fraction less than 45%.
	July 2021	EC approved Verquvo for the treatment of symptomatic chronic heart failure in adult patients with reduced ejection fraction who are stabilized after a recent decompensation event requiring IV therapy.
Welireg	August 2021	FDA approved *Welireg* for adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated RCC, central nervous system hemangioblastomas, or pancreatic neuroendocrine tumors, not requiring immediate surgery.

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

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

(3) Being jointly developed and commercialized in a worldwide collaboration with Bayer AG.

Competition and the Health Care Environment

Competition

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

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

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

Health Care Environment and Government Regulation

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

United States

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

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

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

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

Legislative Changes

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

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

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

Regulatory Changes

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

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

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

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

European Union

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

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

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

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

Brexit

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

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

Japan

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

China

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

Emerging Markets

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

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

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

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

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

Regulation

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

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

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

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

Access to Medicines

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

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

Privacy and Data Protection

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

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

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

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

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

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

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

Distribution

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

Patents, Trademarks and Licenses

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

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

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

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

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

N/A: Currently no marketing approval.

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

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

(3) Eligible for 6 months Pediatric Exclusivity.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Research and Development

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

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

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

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

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

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

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

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

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

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

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

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

Research and Development Update

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Phase 2	Phase 3 (Phase 3 entry date)	Under Review
Cancer MK-0482[2] Non-Small-Cell Lung MK-1026 (nemtabrutinib) Hematological Malignancies MK-1308 (quavonlimab)[2] Non-Small-Cell Lung MK-1308A (quavonlimab+pembrolizumab) Advanced Solid Tumors Colorectal Hepatocellular Melanoma Small-Cell-Lung MK-2140 (zilovertamab vedotin) Breast Hematological Malignancies Non-Small-Cell Lung MK-3475 *Keytruda* Advanced Solid Tumors MK-4280 (favezelimab)[2] Hematological Malignancies Non-Small-Cell Lung MK-4280A (favezelimab+pembrolizumab) Renal Cell Small-Cell Lung MK-4830[2] Non-Small-Cell Lung Renal Cell Small-Cell Lung MK-5890[2] Non-Small-Cell Lung Small-Cell Lung MK-6440 (ladiratuzumab vedotin)[1][3] Breast Esophageal Gastric Head and Neck Melanoma Non-Small-Cell Lung Prostate Small-Cell Lung MK-6482 *Welireg*[3] Biliary Colorectal Hepatocellular Pancreatic Rare cancers Von Hippel-Lindau Disease-Associated Tumors (EU) MK-7119 Tukysa[1] Advanced Solid Tumors Biliary Bladder Cervical Colorectal Endometrial Gastric Non-Small-Cell Lung MK-7339 Lynparza[1][3] Advanced Solid Tumors MK-7684 (vibostolimab)[2] Melanoma MK-7684A (vibostolimab+pembrolizumab) Biliary Breast Cervical Endometrial Esophageal Head and Neck Hematological Malignancies Hepatocellular Prostate MK-7902 Lenvima[1][2] Biliary Glioblastoma Pancreatic Prostate Small-Cell Lung V937 Breast Cutaneous Squamous Cell Head and Neck Melanoma Solid Tumors **Cardiovascular** MK-2060 **Chikungunya Virus Vaccine** V184 **HIV-1 Infection** MK-8591B (islatravir+MK-8507)[4] MK-8591D (islatravir+lenacapavir)[1][4] **Nonalcoholic Steatohepatitis (NASH)** MK-3655 MK-6024 **Overgrowth Syndrome** MK-7075 (miransertib) **Pneumococcal Vaccine Adult** V116 **Pulmonary Arterial Hypertension** MK-5475 **Schizophrenia** MK-8189 **Treatment Resistant Depression** MK-1942	**Antiviral COVID-19** MK-4482 (molnupiravir) (May 2021)[1][5] (U.S) **Cancer** MK-1308A (quavonlimab+pembrolizumab) Renal Cell (April 2021) MK-3475 *Keytruda* Biliary (September 2019) Cutaneous Squamous Cell (August 2019) (EU) Gastric (May 2015) (EU) Hepatocellular (May 2016) (EU) Mesothelioma (May 2018) Ovarian (December 2018) Prostate (May 2019) Small-Cell Lung (May 2017) MK-3475 (pembrolizumab subcutaneous) Non-Small-Cell Lung (August 2021) MK-4280A (favezelimab+pembrolizumab) Colorectal (November 2021) MK-6482 *Welireg*[3] Renal Cell (February 2020) MK-7119 Tukysa[1] Breast (October 2019) MK-7339 Lynparza[1][3] Colorectal (August 2020) Non-Small-Cell Lung (June 2019) Small-Cell Lung (December 2020) MK-7684A (vibostolimab+pembrolizumab) Non-Small-Cell Lung (April 2021) MK-7902 Lenvima[1][2] Colorectal (April 2021) Esophageal (July 2021) Gastric (December 2020) Head and Neck (February 2020) Melanoma (March 2019) Non-Small-Cell Lung (March 2019) **HIV-1 Infection** MK-8591A (doravirine+islatravir) (February 2020)[4] **HIV-1 Prevention** MK-8591 (islatravir) (February 2021)[4] **Pulmonary Arterial Hypertension** MK-7962 (sotatercept) (January 2021) **Respiratory Syncytial Virus** MK-1654 (clesrovimab) (November 2021)	**New Molecular Entities/Vaccines** **Antiviral COVID-19** MK-4482 (molnupiravir)[1] (EU) **Cough** MK-7264 (gefapixant) (U.S.)[6] (EU) **Pneumococcal Vaccine Adult** V114 (JPN) **Certain Supplemental Filings** **Cancer** MK-3475 *Keytruda* • Adjuvant Treatment of Stage IIB or IIC Melanoma (KEYNOTE-716) (EU) • Adjuvent Renal Cell Cancer (KEYNOTE-564) (JPN) • MSI-H or dMMR Endometrial Cancer (KEYNOTE-158) (U.S.) • MSI-H or dMMR Six Tumor Basket (KEYNOTE-158) (EU) • High-Risk Early-Stage Triple-Negative Breast Cancer (KEYNOTE-522) (EU) (JPN) • Tumor Mutational Burden-High (KEYNOTE-158) (JPN) • Cervical Cancer (KEYNOTE-826) (EU) (JPN) MK-7339 Lynparza[1] • *BRCA*-Mutated HER2-Negative Adjuvant Breast Cancer (OlympiA) (U.S.) (EU) • First-Line Metastatic Prostate Cancer (PROpel) (EU) MK-7902 Lenvima[1][2] • First-Line Metastatic Hepatocellular Carcinoma (KEYNOTE-524) (U.S.)[7] • Advanced Unresectable Renal Cell Carcinoma (KEYNOTE-581) (JPN)[8]

Footnotes:

[1] Being developed in a collaboration.

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

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

[4] On FDA clinical hold.

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

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

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

[8] Approved on February 25, 2022.

Human Capital

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

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

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

Talent Acquisition

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

Global Diversity and Inclusion

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

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

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

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

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

[1] *As of 12/31. As self-identified to the Company.*
[2] *Prior period data has not been restated to adjust for the Organon Spin-Off.*
[3] *"Executive role" is defined as an individual holding an Executive Vice President title.*
[4] *"Management role" is defined as all managers with direct reports other than executives as defined in note 3.*

Compensation and Benefits

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

Employee Wellbeing

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

COVID-19 Response

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

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

Engaging Employees

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

Talent Management and Development

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

Environmental Matters

Environmental Sustainability

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

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

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

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

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

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

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

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

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

Environmental Regulation and Remediation

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

Geographic Area Information

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

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

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

Available Information

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

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

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

Item 1A. Risk Factors.

Summary Risk Factors

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

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

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

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

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

Risk Factors

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

Risks Related to the Company's Business

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The Company expects pricing pressures to continue in the future.

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

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

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

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

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

The Company faces intense competition from lower cost generic products.

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

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

The Company faces intense competition from competitors' products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Pharmaceutical products can develop unexpected safety or efficacy concerns.

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

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

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

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

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

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

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

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

Risks Relating to Government Regulation and Legal Proceedings

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Technology

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

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

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

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

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

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

Social media and mobile messaging platforms present risks and challenges.

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

Cautionary Factors that May Affect Future Results

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

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

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

- Competition from generic and/or biosimilar products as the Company's products lose patent protection.

- Increased "brand" competition in therapeutic areas important to the Company's long-term business performance.

- The difficulties and uncertainties inherent in new product development. The outcome of the lengthy and complex process of new product development is inherently uncertain. A drug candidate can fail at any stage of the process and one or more late-stage product candidates could fail to receive regulatory approval. New product candidates may appear promising in development but fail to reach the market because of efficacy or safety concerns, the inability to obtain necessary regulatory approvals, the difficulty or excessive cost to manufacture and/or the infringement of patents or intellectual property rights of others. Furthermore, the sales of new products may prove to be disappointing and fail to reach anticipated levels.

- Pricing pressures, both in the U.S. and abroad, including rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and health care reform, pharmaceutical reimbursement and pricing in general.

- The impact of the global COVID-19 pandemic and any future pandemic, epidemic, or similar public health threat, on the Company's business, operations and financial performance.

- Changes in government laws and regulations, including laws governing intellectual property, and the enforcement thereof affecting the Company's business.

- Efficacy or safety concerns with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales.

- Significant changes in customer relationships or changes in the behavior and spending patterns of purchasers of health care products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing health care insurance coverage.

- Legal factors, including product liability claims, antitrust litigation and governmental investigations, including tax disputes, environmental concerns and patent disputes with branded and generic competitors, any of which could preclude commercialization of products or negatively affect the profitability of existing products.

- Cyber-attacks on the Company's or third-party providers' information technology systems, which could disrupt the Company's operations.

- Lost market opportunity resulting from delays and uncertainties in the approval process of the FDA and foreign regulatory authorities.

- Increased focus on privacy issues in countries around the world, including the U.S., the EU, and China. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect directly the Company's business, including recently enacted laws in a majority of states in the U.S. requiring security breach notification.

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

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

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

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

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

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

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

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

Item 3. Legal Proceedings.

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

Item 4. Mine Safety Disclosures.

Not Applicable.

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

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

Name	Age	Offices and Business Experience
Robert M. Davis	55	Chief Executive Officer and President (since July 2021); Executive Vice President, Global Services, and Chief Financial Officer (since April 2016)
Sanat Chattopadhyay	62	Executive Vice President and President, Merck Manufacturing Division (since March 2016)
Richard R. DeLuca, Jr.	59	Executive Vice President and President, Merck Animal Health (since September 2011)
Cristal Downing	53	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
Kenneth C. Frazier	67	Executive Chairman (since July 2021); Prior to that, Chairman, President and Chief Executive Officer
Julie L. Gerberding	65	Executive Vice President and Chief Patient Officer, Population Health and Sustainability (since July 2016)
Rita A. Karachun	58	Senior Vice President Finance - Global Controller (since March 2014)
Michael A. Klobuchar	46	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); Prior to that, Vice President, Global Business and Financial Planning
Lisa LeCointe-Cephas	40	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	59	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); Prior to that, Chief Scientific Officer and Associate Vice President, University of Utah Health Sciences
Caroline Litchfield	53	Executive Vice President and Chief Financial Officer (since April 2021); Senior Vice President, Corporate Treasurer (January 2018-March 2021); Prior to that, Senior Vice President, Global Human Health
Steven C. Mizell	61	Executive Vice President, Chief Human Resources Officer (since December 2016)
David M. Williams	53	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); Prior to that, Associate Vice President and Chief Information Officer, Merck Animal Health
Jennifer Zachary	44	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

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

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

PART II

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

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

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

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

Issuer Purchases of Equity Securities

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

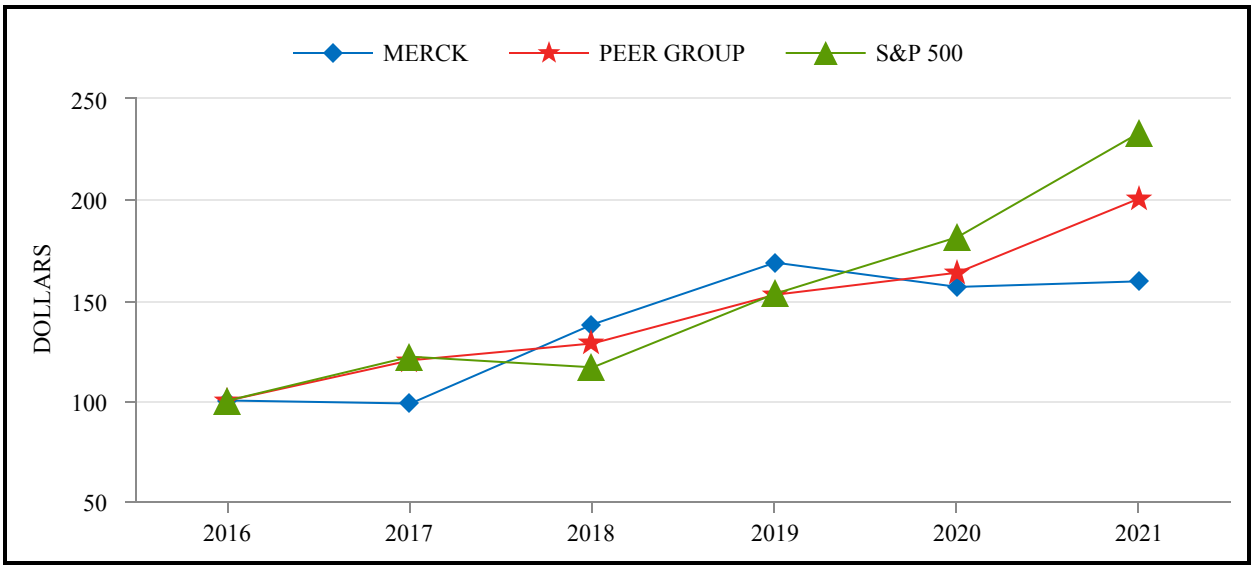
(1) *All shares purchased during the period were made as part of a plan approved by the Board of Directors in October 2018 to purchase up to $10 billion in Merck shares for its treasury.*

Performance Graph

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

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

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



	2016	2017	2018	2019	2020	2021
MERCK	100.0	98.5	137.9	168.6	156.5	159.3
PEER GROUP	100.0	120.0	128.4	152.6	163.6	200.6
S&P 500	100.0	121.8	116.5	153.1	181.3	233.3

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

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

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

Description of Merck's Business

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

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

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

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

Spin-Off of Organon & Co.

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

Overview

Financial Highlights

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

** Calculation not meaningful.*

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

Executive Summary

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

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

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

In 2021, Merck received over 30 approvals and filed over 20 New Drug Applications (NDAs) and supplemental Biologics License Applications (BLAs) across the U.S., the EU, Japan and China. During 2021, the Company received numerous regulatory approvals within oncology. *Keytruda* received approval for additional indications in the U.S. and/or internationally as monotherapy in the therapeutic areas of breast, colorectal, cutaneous squamous cell, esophageal, melanoma and renal cell cancers, as well as in combination with chemotherapy in the therapeutic areas of breast, cervical, gastric or gastroesophageal junction cancers. *Keytruda* was also approved in combination with Lenvima both for the treatment of certain adult patients with endometrial cancer and for the treatment of renal cell cancer. Lenvima is being developed in collaboration with Eisai Co., Ltd. (Eisai). Lynparza, which is being developed in collaboration with AstraZeneca PLC (AstraZeneca), received approval in China as monotherapy for the treatment of certain adult patients with metastatic castration resistant prostate cancer. Additionally, the U.S. Food and Drug Administration (FDA) approved *Welireg* (belzutifan), an oral hypoxia-inducible factor-2 alpha (HIF-2α) inhibitor, for the treatment of adult patients with von Hippel-Lindau (VHL)

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

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

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

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

The Company's Phase 3 oncology programs include:

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

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

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

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

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

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

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

COVID-19 Update

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

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

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

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

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

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

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

Pricing

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

Operating Results

Sales

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

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

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

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

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

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

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

Pharmaceutical Segment

Oncology

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

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

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

Global sales of *Keytruda* grew 20% in 2021 driven by higher demand as the Company continues to launch *Keytruda* with multiple new indications globally, although the COVID-19 pandemic had a dampening effect on growing demand by negatively affecting the number of new patients starting treatment. Sales in the U.S. continue to build across the multiple approved indications, in particular for the treatment of advanced NSCLC as monotherapy, and in combination with chemotherapy for both nonsquamous and squamous metastatic NSCLC, along with continued uptake in the TNBC, RCC, HNSCC, MSI-H cancer, and esophageal cancer indications. *Keytruda* sales growth in international markets reflects continued uptake predominately for the NSCLC, HNSCC and RCC indications, particularly in Europe. Sales growth in 2021 was partially offset by lower pricing in Europe, China and Japan. Global sales of *Keytruda* grew 30% in 2020 driven by higher demand globally, particularly in the U.S. and Europe, although the COVID-19 pandemic had an unfavorable effect on growing demand. Sales growth in 2020 was partially offset by lower pricing in Japan and Europe.

Keytruda received numerous regulatory approvals in 2021 summarized below.

Date	Approval
January 2021	EC approval as a first-line treatment in adult patients with MSI-H or dMMR colorectal cancer based on the KEYNOTE-177 study.
March 2021	EC approval of an expanded label as monotherapy for the treatment of adult and pediatric patients aged 3 years and older with relapsed or refractory cHL who have failed autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT is not a treatment option based on the KEYNOTE-204 and KEYNOTE-087 trials.
March 2021	FDA approval in combination with platinum- and fluoropyrimidine-based chemotherapy for the treatment of certain patients with locally advanced or metastatic esophageal or GEJ carcinoma that is not amenable to surgical resection or definitive chemoradiation based on the KEYNOTE-590 trial.
May 2021	FDA approval in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive gastric or GEJ adenocarcinoma based on the KEYNOTE-811 trial.
May 2021	EC approval of the 400 mg every six weeks (Q6W) dosing regimen to indications where *Keytruda* is administered in combination with other anticancer agents.
June 2021	China's National Medical Products Administration (NMPA) approval as a first-line treatment of adult patients with MSI-H or dMMR colorectal cancer that is KRAS, NRAS and BRAF all wild-type based on the KEYNOTE-177 study.
June 2021	EC approval in combination with chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic carcinoma of the esophagus or HER2-negative GEJ adenocarcinoma in adults whose tumors express PD-L1 based on the KEYNOTE-590 trial.
July 2021	FDA approval as monotherapy for the treatment of patients with locally advanced cSCC that is not curable by surgery or radiation based on the KEYNOTE-629 trial.
July 2021	FDA approval of *Keytruda* plus Lenvima for the treatment of patients with advanced endometrial carcinoma that is not 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-775/ Study 309 trial.
July 2021	FDA approval of *Keytruda* for treatment of patients with high-risk, early-stage TNBC in combination with chemotherapy as neoadjuvant treatment and then continued as single agent as adjuvant treatment after surgery based on the KEYNOTE-522 trial.
August 2021	FDA approval of *Keytruda* plus Lenvima for the first-line treatment of adult patients with advanced RCC based on the KEYNOTE-581 trial/Study 307 trial.
August 2021	Japan's Pharmaceuticals and Medical Devices Agency (PMDA) approval for the treatment of patients with unresectable, advanced or recurrent MSI-H colorectal cancer based on the KEYNOTE-177 trial.
August 2021	Japan's PMDA approval for the treatment of patients with PD-L1-positive, hormone receptor-negative and HER2-negative, inoperable or recurrent breast cancer based on the KEYNOTE-355 trial.
September 2021	China's NMPA approval in combination with chemotherapy for the first-line treatment of patients with locally advanced, unresectable or metastatic carcinoma of the esophagus or GEJ based on the KEYNOTE-590 trial.
October 2021	FDA approval in combination with chemotherapy, with or without bevacizumab, for the treatment of patients with persistent, recurrent or metastatic cervical cancer based on the KEYNOTE-826 trial.
October 2021	EC approval in combination with chemotherapy for the first-line treatment of locally recurrent unresectable or metastatic TNBC in adults whose tumors express PD-L1 and who have not received prior chemotherapy for metastatic disease based on the KEYNOTE-355 trial.
November 2021	FDA approval for the adjuvant treatment of patients with RCC at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions based on the KEYNOTE-564 trial.

November 2021	EC approval of *Keytruda* plus Lenvima for the first-line treatment of adult patients with advanced RCC based on the CLEAR (Study 307)/KEYNOTE-581 trial.
November 2021	EC approval of *Keytruda* plus Lenvima for the treatment of advanced or recurrent endometrial carcinoma in adults who have disease progression on or following prior treatment with a platinum-containing therapy in any setting and who are not candidates for curative surgery or radiation based on the KEYNOTE-775/Study 309 trial.
November 2021	Japan's PMDA approval in combination with chemotherapy (5-fluorouracil plus cisplatin) for the first-line treatment of patients with radically unresectable, advanced or recurrent esophageal carcinoma in combination with chemotherapy based on the KEYNOTE-590 trial.
December 2021	FDA approval for the adjuvant treatment of adult and pediatric (12 years and older) patients with stage IIB or IIC melanoma following complete resection based on the KEYNOTE-716 trial; FDA expanded the indication for the adjuvant treatment of stage III melanoma following complete resection to include pediatric patients (12 years and older).
December 2021	Japan's MHLW approval of *Keytruda* in combination with Lenvima for the treatment of patients with unresectable, advanced or recurrent endometrial carcinoma that progressed after cancer chemotherapy based on the KEYNOTE-775/Study 309 trial.

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

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

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

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

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

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

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

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

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

Vaccines

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

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

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

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

Worldwide sales of *M-M-R* II, a vaccine to help protect against measles, mumps and rubella, grew 3% in 2021 primarily due to higher sales in the U.S. reflecting the ongoing COVID-19 pandemic recovery inclusive of higher public sector mix of business. Lower demand in Europe partially offset *M-M-R* II sales growth in 2021. Global sales of *M-M-R* II declined 31% in 2020 driven primarily by lower demand in the U.S. resulting from fewer

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

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

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

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

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

Hospital Acute Care

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

** Calculation not meaningful.*

Global sales of *Bridion*, for the reversal of two types of neuromuscular blocking agents used during surgery, grew 28% in 2021 due to higher demand globally, particularly in the U.S. and Europe, attributable to the COVID-19 pandemic recovery, as well as increased usage of neuromuscular blockade reversal agents and *Bridion*'s growing share within the class. *Bridion* was also approved by the FDA in June 2021 for pediatric patients aged 2 years and older undergoing surgery. Worldwide sales of *Bridion* grew 6% in 2020 due to higher demand globally,

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

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

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

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

Immunology

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

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

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

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

Virology

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

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

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

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

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

Cardiovascular

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

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

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

Diabetes

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

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

Animal Health Segment

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

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

Costs, Expenses and Other

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

** Calculation not meaningful.*

Cost of Sales

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

Gross margin was 72.0% in 2021 compared with 67.2% in 2020. The gross margin improvement in 2021 reflects lower impairments and amortization of intangible assets (noted above), as well as the favorable effects of product mix and lower inventory write-offs. Partially offsetting the gross margin improvement in 2021 were higher manufacturing costs, the impact of molnupiravir (which has a lower gross margin due to profit sharing with Ridgeback as discussed in Note 5 to the consolidated financial statements), and higher compensation and benefit costs. Gross margin was 67.2% in 2020 compared with 69.3% in 2019. The gross margin decline in 2020 reflects the unfavorable effects of higher impairments and amortization of intangible assets, pricing pressure, a charge related to the discontinuation of COVID-19 vaccine development programs, and higher inventory write-offs related to the recall of *Zerbaxa* (noted above), partially offset by the favorable effects of product mix and lower restructuring costs.

Selling, General and Administrative

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

Research and Development

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

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

Restructuring Costs

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

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

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

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

Other (Income) Expense, Net

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

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

Segment Profits

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

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

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

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

Taxes on Income

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

Net Income (Loss) Attributable to Noncontrolling Interests

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

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

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

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

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

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

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

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

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

Acquisition and Divestiture-Related Costs

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

Restructuring Costs

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

Income and Losses from Investments in Equity Securities

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

Certain Other Items

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

Research and Development

Research Pipeline

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

Acquisitions, Research Collaborations and License Agreements

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

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

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

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

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

Acquired In-Process Research and Development

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

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

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

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

Capital Expenditures

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

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

Analysis of Liquidity and Capital Resources

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

Selected Data

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Financial Instruments Market Risk Disclosures

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

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

Foreign Currency Risk Management

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

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

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

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

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

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

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

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

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

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

Interest Rate Risk Management

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

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

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

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

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

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

Critical Accounting Estimates

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

Acquisitions and Dispositions

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

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

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

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

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

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

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

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

Revenue Recognition

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Inventories Produced in Preparation for Product Launches

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

Contingencies and Environmental Liabilities

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

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

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

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

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

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

Share-Based Compensation

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

Pensions and Other Postretirement Benefit Plans

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

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

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

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

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

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

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

Restructuring Costs

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

Impairments of Long-Lived Assets

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

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

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

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

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

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

Taxes on Income

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

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

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

Recently Issued Accounting Standards

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

Cautionary Factors That May Affect Future Results

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

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

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

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

Item 8. Financial Statements and Supplementary Data.

(a) Financial Statements

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

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

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

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

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

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

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

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

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

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

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

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

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

	2021	2020	2019
Cash Flows from Operating Activities of Continuing Operations			
Net income from continuing operations	**$ 12,358**	$ 4,523	$ 5,606
Adjustments to reconcile net income from continuing operations to net cash provided by operating activities of continuing operations:			
Amortization	**1,636**	1,817	1,695
Depreciation	**1,578**	1,669	1,615
Intangible asset impairment charges	**302**	1,718	1,040
Income from investments in equity securities, net	**(1,940)**	(1,338)	(170)
Charge for the acquisition of Pandion Therapeutics, Inc.	**1,556**	—	—
Charge for the acquisition of VelosBio Inc.	**—**	2,660	—
Charge for the acquisition of Peloton Therapeutics, Inc.	**—**	—	993
Deferred income taxes	**187**	(566)	(560)
Share-based compensation	**479**	441	388
Other	**805**	1,294	354
Net changes in assets and liabilities:			
Accounts receivable	**(2,033)**	(1,002)	92
Inventories	**(674)**	(895)	(473)
Trade accounts payable	**405**	684	443
Accrued and other current liabilities	**277**	(1,152)	413
Income taxes payable	**(540)**	814	(1,889)
Noncurrent liabilities	**484**	(617)	(733)
Other	**(1,758)**	(2,433)	70
Net Cash Provided by Operating Activities of Continuing Operations	**13,122**	7,617	8,884
Cash Flows from Investing Activities of Continuing Operations			
Capital expenditures	**(4,448)**	(4,429)	(3,369)
Purchase of Seagen Inc. common stock	**—**	(1,000)	—
Purchases of securities and other investments	**(1)**	(95)	(3,202)
Proceeds from sales of securities and other investments	**1,026**	2,812	8,622
Acquisition of Acceleron Pharma Inc., net of cash acquired	**(11,174)**	—	—
Acquisition of Pandion Therapeutics, Inc., net of cash acquired	**(1,554)**	—	—
Acquisition of VelosBio Inc., net of cash acquired	**—**	(2,696)	—
Acquisition of ArQule, Inc., net of cash acquired	**—**	(2,545)	—
Acquisition of Antelliq Corporation, net of cash acquired	**—**	—	(3,620)
Acquisition of Peloton Therapeutics, Inc., net of cash acquired	**—**	—	(1,040)
Other acquisitions, net of cash acquired	**(179)**	(1,365)	(294)
Other	**(91)**	125	374
Net Cash Used in Investing Activities of Continuing Operations	**(16,421)**	(9,193)	(2,529)
Cash Flows from Financing Activities of Continuing Operations			
Net change in short-term borrowings	**(3,986)**	2,549	(3,710)
Payments on debt	**(2,319)**	(1,957)	—
Proceeds from issuance of debt	**7,936**	4,419	4,958
Distribution from Organon & Co.	**9,000**	—	—
Purchases of treasury stock	**(840)**	(1,281)	(4,780)
Dividends paid to stockholders	**(6,610)**	(6,215)	(5,695)
Proceeds from exercise of stock options	**202**	89	361
Other	**(286)**	(436)	5
Net Cash Provided by (Used in) Financing Activities of Continuing Operations	**3,097**	(2,832)	(8,861)
Discontinued Operations			
Net cash provided by operating activities	**987**	2,636	4,556
Net cash used in investing activities	**(134)**	(250)	(100)
Net cash used in financing activities	**(504)**	—	—
Net Cash Flows Provided by Discontinued Operations	**349**	2,386	4,456
Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash	**(133)**	253	17
Net Increase (Decrease) in Cash, Cash Equivalents and Restricted Cash	**14**	(1,769)	1,967
Cash, Cash Equivalents and Restricted Cash at Beginning of Year (includes $103 of restricted cash at January 1, 2021 included in Other Assets - see Note 7)	**8,153**	9,934	7,967
Less: Cash and cash equivalents related to discontinued operations	**—**	12	—
Cash, Cash Equivalents and Restricted Cash at End of Year (includes $71 of restricted cash at December 31, 2021 included in Other Assets - see Note 7)	**$ 8,167**	$ 8,153	$ 9,934

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

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

1. Nature of Operations

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

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

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

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

Spin-Off of Organon & Co.

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

2. Summary of Accounting Policies

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

See Note 19 for disaggregated revenue disclosures.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3. Spin-Off of Organon & Co.

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

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

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

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

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

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

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

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

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

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

As a result of the spin-off of Organon, Merck distributed net liabilities of $5.1 billion as of June 2, 2021 consisting of debt of $9.4 billion (described above), goodwill of $1.4 billion, property, plant and equipment of $981 million, cash of $929 million, inventory of $815 million, other intangibles, net, of $519 million and other net liabilities of $328 million. The spin-off also resulted in a net decrease to *AOCL* of $449 million consisting of $421 million for the derecognition of net losses on foreign currency translation adjustments and $28 million associated with employee benefit plans. The distribution of the net liabilities and reduction to *AOCL* resulted in a net $4.6 billion increase to *Other paid-in capital*.

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

4. Acquisitions, Research Collaborations and License Agreements

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

2021 Transactions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2020 Transactions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2019 Transactions

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

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

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

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

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

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

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

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

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

5. Collaborative Arrangements

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

AstraZeneca

In 2017, Merck and AstraZeneca PLC (AstraZeneca) entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza (olaparib) for multiple cancer types. Independently, Merck and AstraZeneca will develop and commercialize Lynparza in combinations with their respective PD-1 and PD-L1 medicines, *Keytruda* and Imfinzi. The companies are also jointly developing and

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

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

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

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

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

Summarized financial information related to this collaboration is as follows:

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

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

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

[2] *Includes accrued milestone payments.*

Eisai

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

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

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

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

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

Summarized financial information related to this collaboration is as follows:

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

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

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

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

[3] *Includes accrued milestone payments.*

Bayer AG

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

In addition, the agreement provided for contingent payments from Merck to Bayer related to the successful achievement of sales-based milestones. Merck made a sales-based milestone payment to Bayer of $375 million in 2020. In 2021, following the approval of Verquvo noted above, Merck determined it was probable that sales of Adempas and Verquvo in the future would trigger the remaining $400 million sales-based milestone

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

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

Summarized financial information related to this collaboration is as follows:

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

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

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

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

Ridgeback Biotherapeutics LP

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

In December 2021, the FDA granted EUA for molnupiravir. Under a previously announced procurement agreement with the U.S. government, Merck agreed to supply 3.1 million courses of molnupiravir to the U.S. government upon EUA or approval from the FDA, of which approximately 888,000 courses were delivered in 2021. This procurement of molnupiravir is being supported in whole or in part with federal funds. Additionally, in December 2021, Japan's Ministry of Health, Labor and Welfare granted Special Approval for Emergency in Japan for molnupiravir. Under a supply agreement, the Japanese government will purchase 1.6 million courses of molnupiravir, of which approximately 200,000 courses were delivered in 2021. Also, in November 2021, the Medicines and Healthcare products Regulatory Agency in the United Kingdom (UK) granted conditional marketing authorization for molnupiravir. The UK government has committed to purchase a total of 2.23 million courses of molnupiravir, of which approximately 152,000 courses were delivered in 2021. Merck has entered into advance purchase and supply agreements for molnupiravir in more than 30 markets.

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

Summarized financial information related to this collaboration is as follows:

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

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

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

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

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

6. Restructuring

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

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

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

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

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

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

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

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

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

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

7. Financial Instruments

Derivative Instruments and Hedging Activities

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

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

Foreign Currency Risk Management

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

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

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

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

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

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

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

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

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

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

Interest Rate Risk Management

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

At December 31, 2021, the Company estimates $170 million of pretax net unrealized gains on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from *AOCL* to *Sales*. The amount ultimately reclassified to *Sales* may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.

Investments in Debt and Equity Securities

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

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

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

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

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

Fair Value Measurements

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

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

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

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

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

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

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

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

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

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

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

Contingent Consideration

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

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

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

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

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

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

Other Fair Value Measurements

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

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

Concentrations of Credit Risk

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

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

The Company's customers with the largest accounts receivable balances are: McKesson Corporation, AmerisourceBergen Corporation and Cardinal Health, Inc., which represented approximately 20%, 15% and 10%, respectively, of total accounts receivable at December 31, 2021. The Company monitors the creditworthiness of its customers to which it grants credit terms in the normal course of business. Bad debts have been minimal. The Company does not normally require collateral or other security to support credit sales.

The Company has accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable. The Company factored $2.8 billion and $2.1 billion of accounts receivable as of December 31, 2021 and 2020, respectively, under these factoring arrangements, which reduced outstanding accounts receivable. The cash received from the financial institutions is reported within operating activities in the Consolidated Statement of Cash Flows. In certain of these factoring arrangements, for ease of administration, the Company will collect customer payments related to the factored receivables, which it then remits to the financial institutions. At December 31, 2021 and 2020, the Company had collected $62 million and $102 million,

respectively, on behalf of the financial institutions, which is reflected as restricted cash in *Other current assets* and the related obligation to remit the cash within *Accrued and other current liabilities*. The Company remitted the cash to the financial institutions in January 2022 and 2021, respectively. The net cash flows relating to these collections are reported as financing activities in the Consolidated Statement of Cash Flows. The cost of factoring such accounts receivable was *de minimis*.

Derivative financial instruments are executed under International Swaps and Derivatives Association master agreements. The master agreements with several of the Company's financial institution counterparties also include credit support annexes. These annexes contain provisions that require collateral to be exchanged depending on the value of the derivative assets and liabilities, the Company's credit rating, and the credit rating of the counterparty. Cash collateral received by the Company from various counterparties was $164 million at December 31, 2021. The obligation to return such collateral is recorded in *Accrued and other current liabilities*. Cash collateral advanced by the Company to counterparties was $36 million at December 31, 2020.

8. Inventories

Inventories at December 31 consisted of:

	2021	2020
Finished goods	**$ 1,747**	$ 1,610
Raw materials and work in process	**6,220**	5,949
Supplies	**196**	146
Total (approximates current cost)	**8,163**	7,705
Decrease to LIFO cost	**(16)**	(81)
	$ 8,147	$ 7,624
Recognized as:		
Inventories	**$ 5,953**	$ 5,554
Other assets	**2,194**	2,070

Inventories valued under the LIFO method comprised approximately $3.3 billion and $2.8 billion at December 31, 2021 and 2020, respectively. Amounts recognized as *Other assets* are comprised almost entirely of raw materials and work in process inventories. At December 31, 2021 and 2020, these amounts included $1.9 billion and $1.8 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included $256 million and $279 million at December 31, 2021 and 2020, respectively, of inventories produced in preparation for product launches.

9. Goodwill and Other Intangibles

The following table summarizes goodwill activity by segment:

	Pharmaceutical	Animal Health	All Other	Total
Balance January 1, 2020	$ 14,825	$ 3,192	$ 52	$ 18,069
Acquisitions	742	105	—	847
Divestitures	—	—	(54)	(54)
Other [1]	47	(29)	2	20
Balance December 31, 2020 [2]	15,614	3,268	—	18,882
Acquisitions	**2,431**	**5**	**—**	**2,436**
Other [1]	**(48)**	**(6)**	**—**	**(54)**
Balance December 31, 2021 [2]	**$ 17,997**	**$ 3,267**	**$ —**	**$ 21,264**

[1] *Includes cumulative translation adjustments on goodwill balances.*

[2] *Accumulated goodwill impairment losses were $531 million at both December 31, 2021 and 2020.*

The additions to goodwill in the Pharmaceutical segment in 2021 were primarily related to the acquisition of Acceleron. The additions to goodwill in the Pharmaceutical segment in 2020 were primarily related to the acquisitions of ArQule and Themis. See Note 4 for more information on these acquisitions.

Other acquired intangibles at December 31 consisted of:

	2021			2020		
	Gross Carrying Amount	**Accumulated Amortization**	**Net**	Gross Carrying Amount	Accumulated Amortization	Net
Products and product rights	**$ 23,671**	**$ 15,776**	**$ 7,895**	$ 20,928	$ 16,138	$ 4,790
IPR&D	**9,281**	**—**	**9,281**	3,228	—	3,228
Trade names	**2,882**	**493**	**2,389**	2,882	352	2,530
Licenses and other	**6,604**	**3,236**	**3,368**	6,199	2,646	3,553
	$ 42,438	**$ 19,505**	**$ 22,933**	$ 33,237	$ 19,136	$ 14,101

Acquired intangibles include products and product rights, IPR&D, trade names and patents, licenses and other, which are initially recorded at fair value, assigned an estimated useful life, and amortized primarily on a straight-line basis over their estimated useful lives. Some of the more significant acquired intangibles, on a net basis, related to human health marketed products (included in products and product rights above) at December 31, 2021 include *Reblozyl*, $3.8 billion; *Zerbaxa*, $478 million; *Gardasil/Gardasil* 9, $191 million; *Bridion*, $145 million; *Dificid*, $145 million; *Sivextro*, $138 million; and *Simponi*, $101 million. Additionally, the Company had $5.0 billion of net acquired intangibles related to animal health marketed products at December 31, 2021, of which $2.3 billion relate primarily to trade names obtained through the 2019 acquisition of Antelliq (see Note 4). At December 31, 2021, IPR&D primarily relates to MK-7962 (sotatercept), $6.4 billion, obtained through the acquisition of Acceleron in 2021 (see Note 4); MK-1026 (nemtabrutinib), $2.0 billion, obtained through the acquisition of ArQule in 2020 (see below and Note 4); and MK-7264 (gefapixant) $832 million, obtained through the acquisition of Afferent Pharmaceuticals in 2016. Some of the more significant net intangible assets included in licenses and other above at December 31, 2021 include Lynparza, $1.1 billion, related to a collaboration with AstraZeneca; Lenvima, $1.0 billion, related to a collaboration with Eisai; Adempas, $806 million related to a collaboration with Bayer; and Verquvo, $68 million, also related to a collaboration with Bayer. See Note 5 for additional information related to the intangible assets associated with these collaborations.

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

In 2019, the Company recorded impairment charges related to marketed products and other intangibles of $705 million. Of this amount, $612 million related to *Sivextro* (tedizolid phosphate), a product for the treatment of acute bacterial skin and skin structure infections caused by designated susceptible Gram-positive organisms. As part of a reorganization and reprioritization of its internal sales force, the Company made the decision to cease promotion of *Sivextro* in the U.S. market by the end of 2019. This decision resulted in reduced cash flow projections for *Sivextro*, which indicated that the *Sivextro* intangible asset value was not fully recoverable on an undiscounted cash flows basis. The Company utilized market participant assumptions to determine its best estimate of the fair value of the intangible asset related to *Sivextro* that, when compared with its related carrying value, resulted in the impairment charge noted above.

IPR&D that the Company acquires through business combinations represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. Amounts capitalized as IPR&D are accounted for as indefinite-lived intangible assets, subject to impairment testing until

completion or abandonment of the projects. Upon successful completion of each IPR&D project, the Company will make a separate determination as to the then-useful life of the asset and begin amortization.

In 2021, the Company recorded a $275 million IPR&D impairment charge within *Research and development* expenses related to nemtabrutinib (MK-1026), a novel, oral BTK inhibitor currently being evaluated for the treatment of B-cell malignancies, obtained in connection with the acquisition of ArQule (see Note 4). As part of Merck's annual impairment assessment of IPR&D intangible assets, the Company estimated the current fair value of nemtabrutinib utilizing projected future cash flows. The market participant assumptions used to derive the forecasted cash flows were updated to reflect the current competitive landscape for nemtabrutinib, including increased expected development costs for additional clinical trial data needed to develop nemtabrutinib, as well as a delay in the anticipated launch date for nemtabrutinib, which collectively reduced the projected future cash flows and estimated fair value. Additionally, the discount rate utilized to determine the current fair value of the asset was reduced to 8.5% to reflect the current risk profile of the asset. The revised estimated fair value of nemtabrutinib when compared with its related carrying value resulted in the IPR&D impairment charge noted above. The remaining IPR&D intangible asset related to nemtabrutinib is $2.0 billion. If the assumptions used to estimate the fair value of nemtabrutinib prove to be incorrect and the development of nemtabrutinib does not progress as anticipated thereby adversely affecting projected future cash flows, the Company may record an additional impairment charge in the future and such charge could be material.

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

In 2019, the Company recorded $172 million of IPR&D impairment charges. Of this amount, $155 million relates to the write-off of the intangible asset balance for programs obtained in connection with the acquisition of IOmet Pharma Ltd following a review of clinical trial results conducted by Merck, along with external clinical trial results for similar compounds. The discontinuation of this clinical development program also resulted in a reversal of the related liability for contingent consideration of $11 million.

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

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

Aggregate amortization expense primarily recorded within *Cost of sales* was $1.6 billion in 2021, $1.8 billion in 2020 and $1.7 billion in 2019. The estimated aggregate amortization expense for each of the next five years is as follows: 2022, $1.7 billion; 2023, $1.6 billion; 2024, $1.6 billion; 2025, $1.4 billion; 2026, $1.4 billion.

10. Loans Payable, Long-Term Debt and Leases

Loans Payable

Loans payable at December 31, 2021 included $2.3 billion of notes due in 2022 and $149 million of long-dated notes that are subject to repayment at the option of the holders. Loans payable at December 31, 2020 included $2.3 billion of notes due in 2021, $4.0 billion of commercial paper borrowings and $73 million of long-dated notes that are subject to repayment at the option of the holders. The weighted-average interest rate of commercial paper borrowings was 0.08% and 0.79% for the years ended December 31, 2021 and 2020, respectively.

Long-Term Debt

Long-term debt at December 31 consisted of:

	2021	2020
2.75% notes due 2025	**$ 2,495**	$ 2,493
2.15% notes due 2031	**1,986**	—
2.75% notes due 2051	**1,979**	—
3.70% notes due 2045	**1,977**	1,976
2.80% notes due 2023	**1,749**	1,748
3.40% notes due 2029	**1,736**	1,734
1.70% notes due 2027	**1,493**	—
2.90% notes due 2061	**1,484**	—
4.00% notes due 2049	**1,470**	1,469
4.15% notes due 2043	**1,239**	1,238
1.45% notes due 2030	**1,235**	1,233
2.45% notes due 2050	**1,212**	1,211
1.875% euro-denominated notes due 2026	**1,123**	1,218
1.90% notes due 2028	**994**	—
0.75% notes due 2026	**993**	991
3.90% notes due 2039	**984**	983
2.35% notes due 2040	**983**	982
2.90% notes due 2024	**748**	746
6.50% notes due 2033	**715**	719
0.50% euro-denominated notes due 2024	**563**	611
1.375% euro-denominated notes due 2036	**559**	606
2.50% euro-denominated notes due 2034	**558**	605
3.60% notes due 2042	**491**	491
6.55% notes due 2037	**409**	411
5.75% notes due 2036	**338**	338
5.95% debentures due 2028	**306**	306
5.85% notes due 2039	**271**	271
6.40% debentures due 2028	**250**	250
6.30% debentures due 2026	**135**	135
2.35% notes due 2022	**—**	1,269
2.40% notes due 2022	**—**	1,032
Other	**215**	294
	$ 30,690	$ 25,360

Other (as presented in the table above) includes borrowings at variable rates that resulted in effective interest rates of zero and 0.45% for 2021 and 2020, respectively.

With the exception of the 6.30% debentures due 2026, the notes listed in the table above are redeemable in whole or in part, at Merck's option at any time, at varying redemption prices.

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

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

Certain of the Company's borrowings require that Merck comply with covenants and, at December 31, 2021, the Company was in compliance with these covenants.

The aggregate maturities of long-term debt for each of the next five years are as follows: 2022, $2.3 billion; 2023, $1.7 billion; 2024, $1.3 billion; 2025, $2.5 billion; 2026, $2.3 billion. Interest payments related to these debt obligations are as follows: 2022, $910 million; 2023, $875 million; 2024, $838 million; 2025, $771 million; 2026, $743 million.

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

Leases

The Company has operating leases primarily for manufacturing facilities, research and development facilities, corporate offices, employee housing, vehicles and certain equipment. The Company determines if an arrangement is a lease at inception. When evaluating contracts for embedded leases, the Company exercises judgment to determine if there is an explicit or implicit identified asset in the contract and if Merck controls the use of that asset. Embedded leases, primarily associated with contract manufacturing organizations, are immaterial. The lease term includes options to extend or terminate the lease when it is reasonably certain that Merck will exercise that option. Real estate leases for facilities have an average remaining lease term of seven years, which include options to extend the leases for up to four years where applicable. Vehicle leases are generally in effect for four years. The Company does not record short-term leases (leases with an initial term of 12 months or less) on the balance sheet; however, Merck currently has no short-term leases.

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

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

Operating lease cost was $343 million in 2021, $340 million in 2020 and $333 million in 2019. Cash paid for amounts included in the measurement of operating lease liabilities was $340 million in 2021, $334 million in 2020 and $275 million in 2019. Operating lease assets obtained in exchange for lease obligations were $117 million in 2021, $473 million in 2020 and $125 million in 2019.

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

December 31	**2021**	2020
Assets		
Other Assets [(1)]	**$ 1,586**	$ 1,688
Liabilities		
Accrued and other current liabilities	**304**	291
Other Noncurrent Liabilities	**1,225**	1,335
	$ 1,529	$ 1,626
Weighted-average remaining lease term (years)	**7.0**	8.0
Weighted-average discount rate	**2.6 %**	2.8 %

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

Maturities of operating leases liabilities are as follows:

2022	$ 336
2023	292
2024	242
2025	178
2026	146
Thereafter	511
Total lease payments	1,705
Less: Imputed interest	176
	$ 1,529

At December 31, 2021, the Company had entered into additional real estate operating leases that had not yet commenced; the obligations associated with these leases total $86 million.

11. Contingencies and Environmental Liabilities

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

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

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

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

Product Liability Litigation

Fosamax

As previously disclosed, Merck is a defendant in product liability lawsuits in the U.S. involving Fosamax (Fosamax Litigation). As of December 31, 2021, approximately 3,470 cases are pending against Merck in either a federal multidistrict litigation (Femur Fracture MDL) or state court. Plaintiffs in the vast majority of these cases generally allege that they sustained femur fractures and/or other bone injuries (Femur Fractures) in association with the use of Fosamax.

In March 2014, the Femur Fracture MDL court dismissed with prejudice approximately 650 cases on preemption grounds. Plaintiffs in approximately 515 of those cases appealed that decision to the U.S. Court of Appeals for the Third Circuit (Third Circuit). In March 2017, the Third Circuit issued a decision reversing the Femur Fracture MDL court's preemption ruling and remanding the appealed cases back to the Femur Fracture MDL court. In May 2019, the U.S. Supreme Court decided that the Third Circuit had incorrectly concluded that the issue of preemption should be resolved by a jury, and accordingly vacated the judgment of the Third Circuit and remanded the proceedings back to the Third Circuit to address the issue in a manner consistent with the Supreme Court's opinion. In November 2019, the Third Circuit remanded the cases back to the District Court in order to allow that court to determine in the first instance whether the plaintiffs' state law claims are preempted by federal law under the standards described by the Supreme Court in its opinion. Briefing on the issue is closed, and the parties await the decision of the District Court.

Discovery is presently stayed in the Femur Fracture MDL. As part of the spin-off of Organon, Organon is required to indemnify Merck for all liabilities relating to, arising from, or resulting from the Fosamax Litigation.

Januvia/Janumet

As previously disclosed, Merck is a defendant in product liability lawsuits in the U.S. involving *Januvia* and/or *Janumet*. As of December 31, 2021, Merck is aware of approximately 675 product users alleging that *Januvia* and/or *Janumet* caused the development of pancreatic cancer and other injuries.

Most claims have been filed in multidistrict litigation before the U.S. District Court for the Southern District of California (MDL). On March 9, 2021, the MDL Court issued an omnibus order granting defendants' summary judgment motions based on preemption and failure to establish general causation, as well as granting defendants' motions to exclude plaintiffs' expert witnesses. The plaintiffs appealed that order. Since that time, more than half of these claims have been dismissed with prejudice as to Merck, and on October 5, 2021, the U.S. Court of Appeals for the Ninth Circuit dismissed the appeal as to Merck and two of its codefendants.

Outside of the MDL, the majority of claims have been filed in coordinated proceedings before the Superior Court of California, County of Los Angeles (California State Court). On April 6, 2021, the court in California issued an omnibus order granting defendants' summary judgment motions and also granting defendants' motions to exclude plaintiffs' expert witnesses.

As of December 31, 2021, six product users have claims pending against Merck in state courts other than California, including Illinois. In June 2017, the Illinois trial court denied Merck's motion for summary judgment based on federal preemption. Merck appealed, and the Illinois appellate court affirmed in December 2018. Merck filed a petition for leave to appeal to the Illinois Supreme Court in February 2019. In April 2019, the Illinois Supreme Court stayed consideration of the pending petition to appeal until the U.S. Supreme Court issued its opinion in *Merck Sharp & Dohme Corp. v. Albrecht* (relating to the Fosamax matter discussed above). Merck filed the opinion in *Albrecht* with the Illinois Supreme Court in June 2019. The petition for leave to appeal was decided in September 2019, in which the Illinois Supreme Court directed the intermediate appellate court to reconsider its earlier ruling. The Illinois Appellate Court issued a favorable decision concluding, consistent with *Albrecht*, that preemption presents a legal question to be resolved by the court. In May 2020, the Illinois Appellate Court issued a mandate to the state trial court, which, as of December 31, 2021, had not scheduled a case management conference or otherwise taken action.

In addition to the claims noted above, the Company has agreed to toll the statute of limitations for approximately 50 additional claims. The Company intends to continue defending against any remaining lawsuits.

Governmental Proceedings

As previously disclosed, in the fall of 2018, the Company received a records subpoena from the U.S. Attorney's Office for the District of Vermont (VT USAO) pursuant to Section 248 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) relating to an investigation of potential health care offenses. The subpoena sought information relating to any actual or potential business relationship or arrangement Merck has had with Practice Fusion, Inc. (PFI), a cloud-based, electronic health records (EHR) company that was acquired by Allscripts in January 2018. The Company cooperated with the government and responded to that subpoena. Subsequently, in May 2019, Merck received a second records subpoena from the VT USAO that broadened the government's information request by seeking information relating to Merck's relationship with any EHR company. Shortly thereafter, the VT USAO served a Civil Investigation Demand (CID) upon Merck similarly seeking information on the Company's relationships with EHR vendors. The CID explains that the government is conducting a False Claims Act investigation concerning whether Merck and/or PFI submitted claims to federal health care programs that violate the Federal Anti-Kickback Statute. Merck is cooperating with the government's investigation.

As previously disclosed, in April 2019, Merck received a set of investigative interrogatories from the California Attorney General's Office pursuant to its investigation of conduct and agreements that allegedly affected or delayed competition to Lantus in the insulin market. The interrogatories seek information concerning Merck's development of an insulin glargine product, and its subsequent termination, as well as Merck's patent litigation against Sanofi S.A. concerning Lantus and the resolution of that litigation. Merck is cooperating with the California Attorney General's investigation.

As previously disclosed, in June 2020, Merck received a CID from the U.S. Department of Justice. The CID requests answers to interrogatories, as well as various documents, regarding temperature excursions at a third-party storage facility containing certain Merck products. Merck is cooperating with the government's investigation and intends to produce information and/or documents as necessary in response to the CID.

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

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

Commercial and Other Litigation

Zetia Antitrust Litigation

As previously disclosed, Merck, MSD, Schering Corporation, Schering-Plough Corporation, and MSP Singapore Company LLC (collectively, the Merck Defendants) are defendants in putative class action and opt-out lawsuits filed in 2018 on behalf of direct and indirect purchasers of Zetia alleging violations of federal and state antitrust laws, as well as other state statutory and common law causes of action. The cases have been consolidated for pretrial purposes in a federal multidistrict litigation before Judge Rebecca Beach Smith in the Eastern District of Virginia. In December 2018, the court denied the Merck Defendants' motions to dismiss or stay the direct purchaser putative class actions pending bilateral arbitration. In August 2019, the district court adopted in full the report and recommendation of the magistrate judge with respect to the Merck Defendants' motions to dismiss on non-arbitration issues, thereby granting in part and denying in part Merck Defendants' motions to dismiss. In addition, in June 2019, the representatives of the putative direct purchaser class filed an amended complaint, and in August 2019, retailer opt-out plaintiffs filed an amended complaint. In December 2019, the district court granted the Merck Defendants' motion to dismiss to the extent the motion sought dismissal of claims for overcharges paid by entities

that purchased generic ezetimibe from Par Pharmaceutical, Inc. (Par Pharmaceutical) and dismissed any claims for such overcharges.

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

In August 2020, the Merck Defendants filed a motion for summary judgment and other motions, and plaintiffs filed a motion for partial summary judgment, and other motions. Those motions are now fully briefed, and the court has heard argument on certain of the motions. The court may hold additional hearings on the other motions. Trial in this matter has been adjourned.

Also, in August 2020, the magistrate judge recommended that the court grant the motion for class certification filed by the putative indirect purchaser class. In August 2021, the district court granted certification of a class of indirect purchasers. In September 2021, the Merck Defendants petitioned to appeal the class certification decision to the Fourth Circuit. The Fourth Circuit denied that petition on September 30, 2021.

In September 2020, United Healthcare Services, Inc. filed a lawsuit in the U.S. District Court for the District of Minnesota against the Merck Defendants and others (the UHC Action). The UHC Action makes similar allegations as those made in the Zetia class action, as well as allegations about Vytorin. In September 2020, the U.S. Judicial Panel on Multidistrict Litigation transferred the case to the Eastern District of Virginia to proceed with the multidistrict Zetia litigation already in progress.

In December 2020, Humana Inc. filed a lawsuit in the Superior Court of the State of California, County of San Francisco, against Merck and others, alleging defendants violated state antitrust laws in multiple states. Also, in December 2020, Centene Corporation and others filed a lawsuit in the Superior Court of the State of California, County of San Francisco, against the same defendants as Humana. Both lawsuits allege similar anticompetitive acts to those alleged in the Zetia class action. In July 2021, the California Court ruled on defendants' Motion to Quash for lack of personal jurisdiction, granting the motion as to the out-of-state claims against defendants, and ordering limited jurisdictional discovery with regard to the California claims.

Also, on July 16, 2021, Humana and Centene filed actions against the Merck Defendants in New Jersey in the Bergen County Superior Court, re-asserting the claims that were dismissed in their California action. In September 2021, the parties reached an agreement that Humana and Centene would file their claims in New Jersey federal court, seek a transfer of those claims to the multidistrict Zetia litigation already in progress, and subsequently dismiss the actions previously filed in California and New Jersey state courts.

In June 2021, Kaiser Foundation Health Plan, Inc. similarly filed a lawsuit in the Superior Court of the State of California, County of San Francisco, against the same defendants as Humana and Centene. The Kaiser lawsuit alleges similar anticompetitive acts to those alleged in the Zetia class action. The Kaiser action was removed to the U.S. District Court for the Northern District of California on July 16, 2021. In September 2021, the U.S. Judicial Panel on Multidistrict Litigation transferred the case to the Eastern District of Virginia to proceed with the multidistrict Zetia litigation already in progress.

As of December 2021, all of the insurer plaintiffs (Kaiser, Humana, and Centene) are part of the multidistrict Zetia litigation, and are proceeding with discovery in that action. On February 9, 2022, United Healthcare, Kaiser, and Humana each filed an amended complaint.

Rotavirus Vaccines Antitrust Litigation

As previously disclosed, MSD is a defendant in putative class action lawsuits filed in 2018 on behalf of direct purchasers of *RotaTeq*, alleging violations of federal antitrust laws. The cases were consolidated in the Eastern District of Pennsylvania. In January 2019, the court denied MSD's motions to compel arbitration and to dismiss the consolidated complaint. In February 2019, MSD appealed the court's order on arbitration to the Third Circuit. In October 2019, the Third Circuit vacated the district court's order and remanded for limited discovery on the issue of

arbitrability. On July 6, 2020, MSD filed a renewed motion to compel arbitration, and plaintiffs filed a cross motion for summary judgment as to arbitrability. On November 20, 2020, the district court denied MSD's motion and granted plaintiffs' motion. On December 4, 2020, MSD filed a notice of appeal to the Third Circuit. MSD's appeal is fully briefed, and the Third Circuit heard argument on September 24, 2021.

Bravecto Litigation

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

Qui Tam Litigation

As previously disclosed, in June 2012, the U.S. District Court for the Eastern District of Pennsylvania unsealed a complaint that had been filed against the Company under the federal False Claims Act by two former employees alleging, among other things, that the Company defrauded the U.S. government by falsifying data in connection with a clinical study conducted on the mumps component of the Company's *M-M-R* II vaccine. The complaint alleges the fraud took place between 1999 and 2001. The U.S. government had the right to participate in and take over the prosecution of this lawsuit but notified the court that it declined to exercise that right. The two former employees are pursuing the lawsuit without the involvement of the U.S. government. In addition, as previously disclosed, two putative class action lawsuits on behalf of direct purchasers of the *M-M-R* II vaccine, which charge that the Company misrepresented the efficacy of the *M-M-R* II vaccine in violation of federal antitrust laws and various state consumer protection laws, are pending in the Eastern District of Pennsylvania. In September 2014, the court denied Merck's motion to dismiss the False Claims Act suit and granted in part and denied in part its motion to dismiss the then-pending antitrust suit. As a result, both the False Claims Act suit and the antitrust suits have proceeded into discovery, which is now complete, and the parties have filed and briefed cross-motions for summary judgment, which are currently pending before the court.

Merck KGaA Litigation

As previously disclosed, in January 2016, to protect its long-established brand rights in the U.S., the Company filed a lawsuit against Merck KGaA, Darmstadt, Germany (KGaA), historically operating as the EMD Group in the U.S., alleging it improperly uses the name "Merck" in the U.S. KGaA has filed suit against the Company in France, the UK, Germany, Switzerland, Mexico, India, Australia, Singapore, Hong Kong, SAR, PRC, and China alleging, among other things, unfair competition, trademark infringement and/or corporate name infringement. In the UK, Australia, Singapore, Hong Kong, SAR, PRC, and India, KGaA also alleges breach of the parties' coexistence agreement. The litigation is ongoing in the U.S. with no trial date set, and also ongoing in numerous jurisdictions outside of the U.S.

Patent Litigation

From time to time, generic manufacturers of pharmaceutical products file abbreviated New Drug Applications (NDAs) with the FDA seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned by the Company. To protect its patent rights, the Company may file patent infringement lawsuits against such generic companies. Similar lawsuits defending the Company's patent rights may exist in other countries. The Company intends to vigorously defend its patents, which it believes are valid, against infringement by companies attempting to market products prior to the expiration of such patents. As with any litigation, there can be no assurance of the outcomes, which, if adverse, could result in significantly shortened

periods of exclusivity for these products and, with respect to products acquired through acquisitions, potentially significant intangible asset impairment charges.

Bridion — As previously disclosed, between January and November 2020, the Company received multiple Paragraph IV Certification Letters under the Hatch-Waxman Act notifying the Company that generic drug companies have filed applications to the FDA seeking pre-patent expiry approval to sell generic versions of *Bridion* (sugammadex) Injection. In March, April and December 2020, the Company filed patent infringement lawsuits in the U.S. District Courts for the District of New Jersey and the Northern District of West Virginia against those generic companies. All actions in the District of New Jersey have been consolidated. These lawsuits, which assert one or more patents covering sugammadex and methods of using sugammadex, automatically stay FDA approval of the generic applications until June 2023 or until adverse court decisions, if any, whichever may occur earlier.

Mylan Pharmaceuticals Inc., Mylan API US LLC, and Mylan Inc. (Mylan) have filed motions to dismiss in the District of New Jersey for lack of venue and failure to state a claim against certain defendants, and in the Northern District of West Virginia for failure to state a claim against certain defendants. The New Jersey motion has not yet been decided, and the West Virginia action is stayed pending resolution of the New Jersey motion.

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

Januvia, Janumet, Janumet XR — As previously disclosed, the FDA has granted pediatric exclusivity with respect to *Januvia*, *Janumet*, and *Janumet XR*, which provides a further six months of exclusivity in the U.S. beyond the expiration of all patents listed in the FDA's Orange Book. Adding this exclusivity to the term of the key patent protection extends exclusivity on these products to January 2023. The Company currently anticipates that sales of *Januvia* and *Janumet* in the U.S. will decline significantly after this date. However, *Januvia*, *Janumet*, and *Janumet XR* contain sitagliptin phosphate monohydrate and the Company has another patent covering certain phosphate salt and polymorphic forms of sitagliptin (2027 salt/polymorph patent), which, if determined to be valid, would preclude generic manufacturers from making sitagliptin phosphate salt and polymorphic forms until 2027 with the expiration of that patent, plus pediatric exclusivity. In 2019, Par Pharmaceutical filed suit against the Company in the U.S. District Court for the District of New Jersey, seeking a declaratory judgment of invalidity of the 2027 salt/polymorph patent. In response, the Company filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Par Pharmaceutical and additional companies that also indicated an intent to market generic versions of *Januvia*, *Janumet*, and *Janumet XR* following expiration of key patent protection, but prior to the expiration of the 2027 salt/polymorph patent, and a later granted patent owned by the Company covering the *Janumet* formulation where its term plus the pediatric exclusivity, ends in 2029. The Company also filed a patent infringement lawsuit against Mylan in the Northern District of West Virginia. The Judicial Panel on Multidistrict Litigation entered an order transferring the Company's lawsuit against Mylan to the U.S. District Court for the District of Delaware for coordinated and consolidated pretrial proceedings with the other cases pending in that district.

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

In total, the Company has settled with 21 generic companies providing that these generic companies can bring their generic versions of *Januvia* and *Janumet* to the market in May 2026 or earlier under certain circumstances, and their generic versions of *Janumet XR* to the market in July 2026 or earlier under certain circumstances.

Additionally, in 2019, Mylan filed a petition for *Inter Partes* Review (IPR) at the U.S. Patent and Trademark Office (USPTO) seeking invalidity of some, but not all, of the claims of the 2027 salt/polymorph patent. The USPTO instituted IPR proceedings in May 2020, finding a reasonable likelihood that the challenged claims are not valid. A trial was held in February 2021 and a final decision was rendered in May 2021, holding that all of the challenged claims were not invalid. Mylan has appealed the USPTO's decision to the U.S. Court of Appeals for the Federal Circuit.

In March 2021, the Company filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Cadila Healthcare Ltd. (collectively, Zydus). In that lawsuit, the Company alleged infringement of the 2027 salt/polymorph patent based on the filing of Zydus's application seeking approval of its sitagliptin tablets. The U.S. District Court for the District of Delaware has set a three-day bench trial in this matter beginning on October 31, 2022.

In Germany, generic companies have sought the revocation of the Supplementary Protection Certificate (SPC) for *Janumet*. If the generic companies are successful, *Janumet* could lose market exclusivity in Germany at the same time as the expiry of *Januvia* pediatric market exclusivity in September 2022. A hearing was held in June 2021 and the court decided that the SPC for *Janumet* is invalid, which decision the Company has appealed. Challenges to the *Janumet* SPC have also occurred in the following European countries: Austria, Czech Republic, Finland, France, Hungary, Italy, Portugal, Romania, Slovakia, and Sweden.

Other Litigation

There are various other pending legal proceedings involving the Company, principally product liability and intellectual property lawsuits. While it is not feasible to predict the outcome of such proceedings, in the opinion of the Company, either the likelihood of loss is remote or any reasonably possible loss associated with the resolution of such proceedings is not expected to be material to the Company's financial condition, results of operations or cash flows either individually or in the aggregate.

Legal Defense Reserves

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of December 31, 2021 and 2020 of approximately $230 million and $235 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

Environmental Matters

The Company and its subsidiaries are parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund, and other federal and state equivalents. These proceedings seek to require the operators of hazardous waste disposal facilities, transporters of waste to the sites and generators of hazardous waste disposed of at the sites to clean up the sites or to reimburse the government for cleanup costs. The Company has been made a party to these proceedings as an alleged generator of waste disposed of at the sites. In each case, the government alleges that the defendants are jointly and severally liable for the cleanup costs. Although joint and several liability is alleged, these proceedings are frequently resolved so that the allocation of cleanup costs among the parties more nearly reflects the relative contributions of the parties to the site situation. The Company's potential liability varies greatly from site to site. For some sites the potential liability is *de minimis* and for others the final costs of cleanup have not yet been determined. While it is not feasible to predict the outcome of many of these proceedings brought by federal or state agencies or private litigants, in the opinion of the Company, such proceedings should not ultimately result in any liability which

would have a material adverse effect on the financial condition, results of operations or liquidity of the Company. The Company has taken an active role in identifying and accruing for these costs and such amounts do not include any reduction for anticipated recoveries of cleanup costs from former site owners or operators or other recalcitrant potentially responsible parties.

In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $40 million and $43 million at December 31, 2021 and 2020, respectively. These liabilities are undiscounted, do not consider potential recoveries from other parties and will be paid out over the periods of remediation for the applicable sites, which are expected to occur primarily over the next 15 years. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed approximately $40 million in the aggregate. Management also does not believe that these expenditures should result in a material adverse effect on the Company's financial condition, results of operations or liquidity for any year.

12. Equity

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

Capital Stock

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

	2021		2020		2019	
	Common Stock	**Treasury Stock**	Common Stock	Treasury Stock	Common Stock	Treasury Stock
Balance January 1	**3,577**	**1,047**	3,577	1,038	3,577	985
Purchases of treasury stock	**—**	**11**	—	16	—	66
Issuances [(1)]	**—**	**(9)**	—	(7)	—	(13)
Balance December 31	**3,577**	**1,049**	3,577	1,047	3,577	1,038

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

13. Share-Based Compensation Plans

The Company has share-based compensation plans under which the Company grants restricted stock units (RSUs) and performance share units (PSUs) to certain management level employees. In addition, employees and non-employee directors may be granted options to purchase shares of Company common stock at the fair market value at the time of grant. These plans were approved by the Company's shareholders.

At December 31, 2021, 93 million shares collectively were authorized for future grants under the Company's share-based compensation plans. These awards are settled with treasury shares.

Employee stock options are granted to purchase shares of Company stock at the fair market value at the time of grant. These awards generally vest one-third each year over a three-year period, with a contractual term of 7-10 years. RSUs are stock awards that are granted to employees and entitle the holder to shares of common stock as the awards vest. The fair value of the stock option and RSU awards is determined and fixed on the grant date based on the Company's stock price. PSUs are stock awards where the ultimate number of shares issued will be contingent on the Company's performance against a pre-set objective or set of objectives. The fair value of each PSU is determined on the date of grant based on the Company's stock price. For RSUs and PSUs, dividends declared during the vesting period are payable to the employees only upon vesting. Over the PSU performance period, the number of shares of stock that are expected to be issued will be adjusted based on the probability of achievement of a performance target and final compensation expense will be recognized based on the ultimate number of shares issued. RSU and PSU distributions will be in shares of Company stock after the end of the vesting or performance period, subject to the terms applicable to such awards. PSU awards generally vest after three years. RSU awards generally vest one-third each year over a three-year period.

Total pretax share-based compensation cost recorded in 2021, 2020 and 2019 was $498 million, $475 million and $417 million, respectively, including $479 million, $441 million and $388 million, respectively, related to continuing operations. Income tax benefits for share-based compensation expense recognized in 2021, 2020 and 2019 were $69 million, $65 million and $57 million, respectively.

The Company uses the Black-Scholes option pricing model for determining the fair value of option grants. In applying this model, the Company uses both historical data and current market data to estimate the fair value of its options. The Black-Scholes model requires several assumptions including expected dividend yield, risk-free interest rate, volatility, and term of the options. The expected dividend yield is based on historical patterns of dividend payments. The risk-free interest rate is based on the rate at grant date of zero-coupon U.S. Treasury Notes with a term equal to the expected term of the option. Expected volatility is estimated using a blend of historical and implied volatility. The historical component is based on historical monthly price changes. The implied volatility is obtained from market data on the Company's traded options. The expected life represents the amount of time that options granted are expected to be outstanding, based on historical and forecasted exercise behavior.

The weighted average exercise price of options granted in 2021, 2020 and 2019 was $75.99, $77.67 and $80.05 per option, respectively. The weighted average fair value of options granted in 2021, 2020 and 2019 was $9.80, $9.93 and $10.63 per option, respectively, and were determined using the following assumptions:

Years Ended December 31	**2021**	2020	2019
Expected dividend yield	**3.1 %**	3.1 %	3.2 %
Risk-free interest rate	**1.0 %**	0.4 %	2.4 %
Expected volatility	**20.9 %**	22.1 %	18.7 %
Expected life (years)	**5.9**	5.8	5.9

Summarized information relative to stock option plan activity (options in thousands) is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2021 [1]	19,446	$ 63.64		
Granted [1]	**4,781**	**75.99**		
Exercised [1]	**(3,728)**	**54.14**		
Forfeited [1]	**(626)**	**73.97**		
Awards transferred to Organon in the spin-off	**(1,947)**	**72.15**		
Adjustment to Merck awards related to the spin-off of Organon [2]	**646**	**—**		
Outstanding December 31, 2021	**18,572**	**$ 65.27**	**6.3**	**$ 213**
Vested and expected to vest December 31, 2021	**17,829**	**$ 64.90**	**6.2**	**$ 212**
Exercisable December 31, 2021	**12,136**	**$ 60.41**	**5.0**	**$ 198**

[1] *Activity prior to the Organon spin-off has not been restated.*

[2] *In connection with the spin-off of Organon, all outstanding Merck stock options (whether vested or unvested) were converted into adjusted Merck awards for current and former Merck employees or Organon awards for Organon employees. Such adjusted awards preserved the same intrinsic value and general terms and conditions (including vesting) as were in place immediately prior to the adjustments.*

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

Years Ended December 31	**2021**	2020	2019
Total intrinsic value of stock options exercised	**$ 106**	$ 51	$ 295
Fair value of stock options vested	**27**	25	27
Cash received from the exercise of stock options	**202**	89	361

A summary of nonvested RSU and PSU activity (shares in thousands) is as follows:

	RSUs		PSUs	
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested January 1, 2021 [1]	11,915	$ 74.17	2,100	$ 75.08
Granted [1]	**7,897**	**76.16**	**1,487**	**69.33**
Vested [1]	**(6,066)**	**70.25**	**(1,284)**	**57.14**
Forfeited [1]	**(1,015)**	**76.62**	**(149)**	**79.33**
Awards transferred to Organon in the spin-off	**(1,309)**	**76.99**	**(248)**	**77.39**
Adjustment to Merck awards related to the spin-off of Organon [2]	**368**	**—**	**60**	**—**
Nonvested December 31, 2021	**11,790**	**$ 74.88**	**1,966**	**$ 77.13**
Expected to vest December 31, 2021	**10,499**	**$ 74.93**	**1,832**	**$ 77.40**

[1] *Activity prior to the Organon spin-off has not been restated.*

[2] *In connection with the spin-off of Organon, all outstanding Merck RSUs and PSUs (whether vested or unvested) were converted into adjusted Merck awards for current and former Merck employees or Organon awards for Organon employees. Such adjusted awards preserved the same intrinsic value and general terms and conditions (including vesting) as were in place immediately prior to the adjustments.*

At December 31, 2021, there was $699 million of total pretax unrecognized compensation expense related to nonvested stock options, RSU and PSU awards which will be recognized over a weighted average period of 1.9 years. For segment reporting, share-based compensation costs are unallocated expenses.

14. Pension and Other Postretirement Benefit Plans

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

Net Periodic Benefit Cost

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

	Pension Benefits								
	U.S.			International			Other Postretirement Benefits		
Years Ended December 31	**2021**	2020	2019	**2021**	2020	2019	**2021**	2020	2019
Service cost	**$ 403**	$ 360	$ 293	**$ 328**	$ 297	$ 235	**$ 48**	$ 52	$ 48
Interest cost	**404**	431	458	**123**	136	176	**45**	57	69
Expected return on plan assets	**(755)**	(774)	(817)	**(416)**	(414)	(425)	**(79)**	(75)	(72)
Amortization of unrecognized prior service cost	**(38)**	(49)	(49)	**(16)**	(18)	(12)	**(63)**	(73)	(78)
Net loss (gain) amortization	**298**	303	151	**142**	127	64	**(42)**	(18)	(10)
Termination benefits	**56**	10	31	**5**	3	8	**37**	2	5
Curtailments	**16**	10	14	**(26)**	—	6	**(29)**	(4)	(11)
Settlements	**216**	13	—	**8**	15	1	**—**	—	—
Net periodic benefit cost (credit)	**$ 600**	$ 304	$ 81	**$ 148**	$ 146	$ 53	**$ (83)**	$ (59)	$ (49)

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

In connection with restructuring actions (see Note 6), termination charges were recorded in 2021, 2020 and 2019 on pension and other postretirement benefit plans related to expanded eligibility for certain employees exiting Merck. Also, in connection with these restructuring activities, curtailments and settlements were recorded on

certain pension plans. An increase in lump sum payments to U.S. pension plan participants also contributed to the settlements recorded during 2021.

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

Obligations and Funded Status

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

	Pension Benefits				Other Postretirement Benefits	
	U.S.		International			
	2021	2020	**2021**	2020	**2021**	2020
Fair value of plan assets January 1	**$ 12,672**	$ 11,361	**$ 12,009**	$ 10,135	**$ 1,221**	$ 1,102
Actual return on plan assets	**1,250**	1,908	**891**	1,026	**118**	175
Company contributions	**305**	199	**189**	383	**33**	19
Effects of exchange rate changes	**—**	—	**(671)**	743	**—**	—
Benefits paid	**(219)**	(751)	**(233)**	(214)	**(86)**	(93)
Settlements	**(941)**	(45)	**(55)**	(117)	**—**	—
Spin-off of Organon	**—**	—	**(55)**	—	**—**	—
Other	**—**	—	**120**	53	**6**	18
Fair value of plan assets December 31	**$ 13,067**	$ 12,672	**$ 12,195**	$ 12,009	**$ 1,292**	$ 1,221
Benefit obligation January 1	**$ 14,613**	$ 13,003	**$ 12,458**	$ 10,558	**$ 1,607**	$ 1,673
Service cost	**403**	360	**328**	297	**48**	52
Interest cost	**404**	431	**123**	136	**45**	57
Actuarial (gains) losses [(1)]	**(332)**	1,594	**(240)**	1,032	**(103)**	(98)
Benefits paid	**(219)**	(751)	**(233)**	(214)	**(86)**	(93)
Effects of exchange rate changes	**—**	—	**(678)**	788	**(1)**	(3)
Plan amendments	**—**	—	**4**	(64)	**—**	—
Curtailments	**15**	11	**(38)**	(8)	**(12)**	(1)
Termination benefits	**56**	10	**5**	3	**37**	2
Settlements	**(941)**	(45)	**(55)**	(117)	**—**	—
Spin-off of Organon	**—**	—	**(118)**	—	**—**	—
Other	**—**	—	**19**	47	**6**	18
Benefit obligation December 31	**$ 13,999**	$ 14,613	**$ 11,575**	$ 12,458	**$ 1,541**	$ 1,607
Funded status December 31	**$ (932)**	$ (1,941)	**$ 620**	$ (449)	**$ (249)**	$ (386)
Recognized as:						
Other Assets	**$ 9**	$ —	**$ 1,395**	$ 941	**$ —**	$ —
Accrued and other current liabilities	**(64)**	(82)	**(22)**	(13)	**(8)**	(9)
Other Noncurrent Liabilities	**(877)**	(1,859)	**(753)**	(1,377)	**(241)**	(377)

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

At December 31, 2021 and 2020, the accumulated benefit obligation was $24.9 billion and $26.3 billion, respectively, for all pension plans, of which $13.8 billion and $14.4 billion, respectively, related to U.S. pension plans.

Information related to the funded status of selected pension plans at December 31 is as follows:

	U.S.		International	
	2021	2020	**2021**	2020
Pension plans with a projected benefit obligation in excess of plan assets				
Projected benefit obligation	**$ 13,013**	$ 14,613	**$ 2,507**	$ 8,875
Fair value of plan assets	**12,072**	12,672	**1,731**	7,488
Pension plans with an accumulated benefit obligation in excess of plan assets				
Accumulated benefit obligation	**$ 12,916**	$ 13,489	**$ 2,462**	$ 4,234
Fair value of plan assets	**12,072**	11,685	**1,723**	2,995

Plan Assets

Entities are required to use a fair value hierarchy which maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest:

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

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

Level 3 — Unobservable inputs that are supported by little or no market activity. The Level 3 assets are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as instruments for which the determination of fair value requires significant judgment or estimation. At December 31, 2021 and 2020, $943 million and $942 million, respectively, or approximately 4% of the Company's pension investments were categorized as Level 3 assets.

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

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

	Fair Value Measurements Using					Fair Value Measurements Using				
	Level 1	Level 2	Level 3	NAV [1]	Total	Level 1	Level 2	Level 3	NAV [1]	Total
	2021					2020				
U.S. Pension Plans										
Cash and cash equivalents	$ 3	$ —	$ —	$ 289	$ 292	$ 5	$ —	$ —	$ 303	$ 308
Investment funds										
Developed markets equities	236	—	—	3,799	4,035	206	—	—	3,884	4,090
Emerging markets equities	—	—	—	919	919	169	—	—	927	1,096
Mortgage and asset-backed securities	—	—	—	—	—	—	89	—	—	89
Equity securities										
Developed markets	2,915	—	—	—	2,915	2,819	—	—	—	2,819
Fixed income securities										
Government and agency obligations	—	2,870	—	—	2,870	—	2,236	—	—	2,236
Corporate obligations	—	2,005	—	—	2,005	—	1,994	—	—	1,994
Mortgage and asset-backed securities	—	23	—	—	23	—	33	—	—	33
Other investments	2	—	6	—	8	—	—	7	—	7
Plan assets at fair value	$ 3,156	$ 4,898	$ 6	$ 5,007	$ 13,067	$ 3,199	$ 4,352	$ 7	$ 5,114	$ 12,672
International Pension Plans										
Cash and cash equivalents	$ 82	$ 10	$ —	$ 18	$ 110	$ 110	$ 1	$ —	$ 20	$ 131
Investment funds										
Developed markets equities	531	4,292	—	121	4,944	475	4,286	—	118	4,879
Government and agency obligations	240	4,025	—	171	4,436	1,516	2,614	—	172	4,302
Emerging markets equities	137	—	—	72	209	154	—	—	92	246
Corporate obligations	9	8	—	171	188	5	12	—	172	189
Other fixed income obligations	15	8	—	3	26	9	11	—	4	24
Real estate	—	1	—	16	17	—	1	—	15	16
Equity securities										
Developed markets	369	—	—	—	369	505	—	—	—	505
Fixed income securities										
Government and agency obligations	3	591	—	3	597	3	481	—	3	487
Corporate obligations	—	223	—	2	225	1	174	—	2	177
Mortgage and asset-backed securities	—	90	—	—	90	—	70	—	—	70
Other investments										
Insurance contracts [2]	—	44	937	1	982	—	42	935	1	978
Other	1	1	—	—	2	1	4	—	—	5
Plan assets at fair value	$ 1,387	$ 9,293	$ 937	$ 578	$ 12,195	$ 2,779	$ 7,696	$ 935	$ 599	$ 12,009

[1] *Certain investments that were measured at net asset value (NAV) per share or its equivalent have not been classified in the fair value hierarchy. The NAV amounts presented in this table are intended to permit reconciliation of the fair value hierarchy to the fair value of plan assets at December 31, 2021 and 2020.*

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

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

	2021				2020			
	Insurance Contracts	**Real Estate**	**Other**	**Total**	Insurance Contracts	Real Estate	Other	Total
U.S. Pension Plans								
Balance January 1	**$ —**	**$ —**	**$ 7**	**$ 7**	$ —	$ —	$ 9	$ 9
Actual return on plan assets:								
Relating to assets still held at December 31	**—**	**—**	**(5)**	**(5)**	—	—	(5)	(5)
Relating to assets sold during the year	**—**	**—**	**7**	**7**	—	—	5	5
Purchases and sales, net	**—**	**—**	**(3)**	**(3)**	—	—	(2)	(2)
Balance December 31	**$ —**	**$ —**	**$ 6**	**$ 6**	$ —	$ —	$ 7	$ 7
International Pension Plans								
Balance January 1	**$ 935**	**$ —**	**$ —**	**$ 935**	$ 851	$ —	$ —	$ 851
Actual return on plan assets:								
Relating to assets still held at December 31	**(34)**	**—**	**—**	**(34)**	103	—		103
Purchases and sales, net	**(42)**	**—**	**—**	**(42)**	(17)	—	—	(17)
Transfers in (out) of Level 3	**78**	**—**	**—**	**78**	(2)	—	—	(2)
Balance December 31	**$ 937**	**$ —**	**$ —**	**$ 937**	$ 935	$ —	$ —	$ 935

The fair values of the Company's other postretirement benefit plan assets at December 31 by asset category are as follows:

	Fair Value Measurements Using					Fair Value Measurements Using				
	Level 1	**Level 2**	**Level 3**	**NAV [1]**	**Total**	Level 1	Level 2	Level 3	NAV [1]	Total
	2021					2020				
Cash and cash equivalents	**$ 11**	**$ —**	**$ —**	**$ 28**	**$ 39**	$ 31	$ —	$ —	$ 28	$ 59
Investment funds										
Developed markets equities	**24**	**—**	**—**	**378**	**402**	19	—	—	355	374
Emerging markets equities	**—**	**—**	**—**	**92**	**92**	16	—	—	85	101
Government and agency obligations	**1**	**—**	**—**		**1**	1	—	—	—	1
Mortgage and asset-backed securities	**—**	**—**	**—**	**—**	**—**	—	8	—	—	8
Equity securities										—
Developed markets	**290**	**—**	**—**	**—**	**290**	258	—	—	—	258
Fixed income securities										
Government and agency obligations	**—**	**275**	**—**	**—**	**275**	—	221	—	—	221
Corporate obligations	**—**	**191**	**—**	**—**	**191**	—	196	—	—	196
Mortgage and asset-backed securities	**—**	**2**	**—**	**—**	**2**	—	3	—	—	3
Plan assets at fair value	**$ 326**	**$ 468**	**$ —**	**$ 498**	**$ 1,292**	$ 325	$ 428	$ —	$ 468	$ 1,221

[1] *Certain investments that were measured at net asset value (NAV) per share or its equivalent have not been classified in the fair value hierarchy. The NAV amounts presented in this table are intended to permit reconciliation of the fair value hierarchy to the fair value of plan assets at December 31, 2021 and 2020.*

The Company has established investment guidelines for its U.S. pension and other postretirement plans to create an asset allocation that is expected to deliver a rate of return sufficient to meet the long-term obligation of each plan, given an acceptable level of risk. The target investment portfolio of the Company's U.S. pension and other postretirement benefit plans is allocated 30% to 45% in U.S. equities, 15% to 30% in international equities, 35% to 45% in fixed-income investments, and up to 5% in cash and other investments. The portfolio's equity weighting is consistent with the long-term nature of the plans' benefit obligations. The expected annual standard deviation of returns of the target portfolio, which approximates 11%, reflects both the equity allocation and the diversification benefits among the asset classes in which the portfolio invests. For international pension plans, the

targeted investment portfolio varies based on the duration of pension liabilities and local government rules and regulations. Although a significant percentage of plan assets are invested in U.S. equities, concentration risk is mitigated through the use of strategies that are diversified within management guidelines.

Expected Contributions

Contributions during 2022 are expected to be approximately $280 million for U.S. pension plans, approximately $150 million for international pension plans and approximately $50 million for other postretirement benefit plans.

Expected Benefit Payments

Expected benefit payments are as follows:

	U.S. Pension Benefits	International Pension Benefits	Other Postretirement Benefits
2022	$ 724	$ 289	$ 84
2023	745	275	85
2024	731	278	87
2025	748	280	89
2026	770	308	90
2027 — 2031	4,230	1,715	469

Expected benefit payments are based on the same assumptions used to measure the benefit obligations and include estimated future employee service.

Amounts Recognized in Other Comprehensive Income

Net loss amounts reflect differences between expected and actual returns on plan assets as well as the effects of changes in actuarial assumptions. Net loss amounts in excess of certain thresholds are amortized into net periodic benefit cost over the average remaining service life of employees. The following amounts were reflected as components of *OCI*:

	Pension Plans						Other Postretirement Benefit Plans		
	U.S.			International					
Years Ended December 31	**2021**	2020	2019	**2021**	2020	2019	**2021**	2020	2019
Net gain (loss) arising during the period	**$ 1,048**	$ (448)	$ (816)	**$ 815**	$ (407)	$ (227)	**$ 144**	$ 198	$ 112
Prior service (cost) credit arising during the period	**(3)**	(1)	(4)	**(29)**	62	(1)	**(17)**	(3)	(11)
	$ 1,045	$ (449)	$ (820)	**$ 786**	$ (345)	$ (228)	**$ 127**	$ 195	$ 101
Net loss (gain) amortization included in benefit cost	**$ 298**	$ 303	$ 151	**$ 142**	$ 127	$ 64	**$ (42)**	$ (18)	$ (10)
Prior service credit amortization included in benefit cost	**(38)**	(49)	(49)	**(16)**	(18)	(12)	**(63)**	(73)	(78)
	$ 260	$ 254	$ 102	**$ 126**	$ 109	$ 52	**$ (105)**	$ (91)	$ (88)

Actuarial Assumptions

The Company reassesses its benefit plan assumptions on a regular basis. The weighted average assumptions used in determining U.S. pension and other postretirement benefit plan and international pension plan information are as follows:

	U.S. Pension and Other Postretirement Benefit Plans			International Pension Plans		
December 31	**2021**	2020	2019	**2021**	2020	2019
Net periodic benefit cost						
Discount rate	**2.70 %**	3.40 %	4.40 %	**1.10 %**	1.50 %	2.20 %
Expected rate of return on plan assets	**6.70 %**	7.30 %	8.10 %	**3.80 %**	4.40 %	4.90 %
Salary growth rate	**4.60 %**	4.20 %	4.30 %	**2.80 %**	2.80 %	2.80 %
Interest crediting rate	**4.70 %**	4.90 %	3.40 %	**3.00 %**	2.80 %	2.90 %
Benefit obligation						
Discount rate	**3.00 %**	2.70 %	3.40 %	**1.50 %**	1.10 %	1.50 %
Salary growth rate	**4.60 %**	4.60 %	4.20 %	**2.90 %**	2.80 %	2.80 %
Interest crediting rate	**5.00 %**	4.70 %	4.90 %	**3.00 %**	3.00 %	2.80 %

For both the pension and other postretirement benefit plans, the discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due. The expected rate of return for both the pension and other postretirement benefit plans represents the average rate of return to be earned on plan assets over the period the benefits included in the benefit obligation are to be paid and is determined on a plan basis. The expected rate of return for each plan is developed considering long-term historical returns data, current market conditions, and actual returns on the plan assets. Using this reference information, the long-term return expectations for each asset category and a weighted-average expected return for each plan's target portfolio is developed according to the allocation among those investment categories. The expected portfolio performance reflects the contribution of active management as appropriate. For 2022, the expected rate of return for the Company's U.S. pension and other postretirement benefit plans will be 6.70%, as compared to a range of 6.50% to 6.70% in 2021.

The health care cost trend rate assumptions for other postretirement benefit plans are as follows:

December 31	**2021**	2020
Health care cost trend rate assumed for next year	**6.4 %**	6.6 %
Rate to which the cost trend rate is assumed to decline	**4.5 %**	4.5 %
Year that the trend rate reaches the ultimate trend rate	**2032**	2032

Savings Plans

The Company also maintains defined contribution savings plans in the U.S. The Company matches a percentage of each employee's contributions consistent with the provisions of the plan for which the employee is eligible. Total employer contributions to these plans in 2021, 2020 and 2019 were $158 million, $158 million and $143 million, respectively.

15. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

Years Ended December 31	**2021**	2020	2019
Interest income	**$ (36)**	$ (59)	$ (274)
Interest expense	**806**	831	893
Exchange losses	**297**	145	187
Income from investments in equity securities, net [(1)]	**(1,940)**	(1,338)	(170)
Net periodic defined benefit plan (credit) cost other than service cost	**(212)**	(339)	(545)
Other, net	**(256)**	(130)	38
	$ (1,341)	$ (890)	$ 129

[(1)] *Includes net realized and unrealized gains and losses from investments in equity securities either owned directly or through ownership interests in investment funds. Unrealized gains and losses from investments that are directly owned are determined at the end of the reporting period, while gains and losses from ownership interests in investment funds are accounted for on a one quarter lag. The Company estimates losses of approximately $500 million will be recorded in the first quarter of 2022 from ownership interests in investment funds.*

Other, net (as presented in the table above) in 2019 includes $162 million of goodwill impairment charges related to certain businesses in the Healthcare Services segment, which were fully divested by the first quarter of 2020.

Interest paid was $779 million in 2021, $822 million in 2020 and $841 million in 2019.

16. Taxes on Income

A reconciliation between the effective tax rate for income from continuing operations and the U.S. statutory rate is as follows:

	2021		2020		2019	
	Amount	**Tax Rate**	Amount	Tax Rate	Amount	Tax Rate
U.S. statutory rate applied to income from continuing operations before taxes	**$ 2,915**	**21.0 %**	$ 1,231	21.0 %	$ 1,506	21.0 %
Differential arising from:						
Foreign earnings	**(1,446)**	**(10.4)**	(965)	(16.5)	(461)	(6.4)
GILTI and the foreign-derived intangible income deduction	**(75)**	**(0.5)**	349	6.0	323	4.5
Tax settlements	**(275)**	**(2.0)**	(13)	(0.2)	(139)	(1.9)
R&D tax credit	**(81)**	**(0.6)**	(108)	(1.8)	(116)	(1.6)
Acquisition of VelosBio	**(9)**	**(0.1)**	559	9.5	—	—
Acquisition of Pandion	**356**	**2.6**	—	—	—	—
Valuation allowances	**102**	**0.7**	37	0.6	115	1.6
Restructuring	**61**	**0.4**	105	1.8	39	0.5
Acquisition-related costs, including amortization	**8**	**0.1**	38	0.6	70	1.0
State taxes	**2**	**—**	57	1.0	(12)	(0.2)
Acquisition of OncoImmune	**—**	**—**	97	1.7	—	—
Acquisition of Peloton	**—**	**—**	—	—	209	2.9
Tax Cuts and Jobs Act of 2017	**—**	**—**	—	—	117	1.6
Other	**(37)**	**(0.2)**	(47)	(0.8)	(86)	(1.2)
	$ 1,521	**11.0 %**	$ 1,340	22.9 %	$ 1,565	21.8 %

The Tax Cuts and Jobs Act (TCJA) was enacted in December 2017 and the Company reflected the impact of the TCJA in its 2017 financial statements. However, since application of certain provisions of the TCJA

remained subject to further interpretation, in certain instances the Company made reasonable estimates of the effects of the TCJA, which were since finalized and resulted in additional income tax expense in 2018 and 2019. The Company's remaining transition tax liability under the TCJA, which has been reduced by payments and the utilization of foreign tax credits, was $2.6 billion at December 31, 2021, of which $390 million is included in *Income taxes payable* and the remainder of $2.2 billion is included in *Other Noncurrent Liabilities*. As a result of the transition tax under the TCJA, the Company is no longer indefinitely reinvested with respect to its undistributed earnings from foreign subsidiaries and has provided a deferred tax liability for foreign withholding taxes that would apply. The Company remains indefinitely reinvested with respect to its financial statement basis in excess of tax basis of its foreign subsidiaries. A determination of the deferred tax liability with respect to this basis difference is not practicable.

The foreign earnings tax rate differentials in the tax rate reconciliation above primarily reflect the impacts of operations in jurisdictions with different tax rates than the U.S., particularly Ireland and Switzerland, as well as Singapore and Puerto Rico which operate under tax incentive grants (which begin to expire in 2022), thereby yielding a favorable impact on the effective tax rate compared with the U.S. statutory rate of 21%. Beginning in 2021, the Company has an additional tax incentive in the form of a tax holiday in Switzerland for a newly active legal entity which is effective through 2030.

Income from continuing operations before taxes consisted of:

Years Ended December 31	**2021**	2020	2019
Domestic	**$ 1,854**	$ (3,814)	$ (66)
Foreign	**12,025**	9,677	7,237
	$ 13,879	$ 5,863	$ 7,171

Taxes on income from continuing operations consisted of:

Years Ended December 31	**2021**	2020	2019
Current provision			
Federal	**$ 74**	$ 893	$ 642
Foreign	**1,273**	969	1,523
State	**(13)**	44	(40)
	1,334	1,906	2,125
Deferred provision			
Federal	**240**	(605)	(328)
Foreign	**(77)**	64	(228)
State	**24**	(25)	(4)
	187	(566)	(560)
	$ 1,521	$ 1,340	$ 1,565

Deferred income taxes at December 31 consisted of:

	2021		2020	
	Assets	**Liabilities**	Assets	Liabilities
Product intangibles and licenses	**$ —**	**$ 2,933**	$ 109	$ 1,250
Inventory related	**119**	**370**	43	315
Accelerated depreciation	**—**	**589**	—	587
Equity investments	**—**	**335**	—	175
Pensions and other postretirement benefits	**487**	**338**	826	248
Compensation related	**301**	**—**	235	—
Unrecognized tax benefits	**75**	**—**	117	—
Net operating losses and other tax credit carryforwards	**867**	**—**	764	—
Other	**434**	**180**	743	81
Subtotal	**2,283**	**4,745**	2,837	2,656
Valuation allowance	**(287)**		(404)	
Total deferred taxes	**$ 1,996**	**$ 4,745**	$ 2,433	$ 2,656
Net deferred income taxes		**$ 2,749**		$ 223
Recognized as:				
Other Assets	**$ 692**		$ 782	
Deferred Income Taxes		**$ 3,441**		$ 1,005

The Company has net operating loss (NOL) carryforwards in several jurisdictions. As of December 31, 2021, $181 million of deferred tax assets on NOL carryforwards relate to foreign jurisdictions. Valuation allowances of $164 million have been established on these foreign NOL carryforwards and other foreign deferred tax assets. In addition, the Company has $686 million of deferred tax assets relating to various U.S. tax credit carryforwards and NOL carryforwards. Valuation allowances of $123 million have been established on these U.S. tax credit carryforwards and NOL carryforwards.

Income taxes paid in 2021, 2020 and 2019 (including amounts attributable to discontinued operations) were $2.4 billion, $2.7 billion and $4.5 billion, respectively. Tax benefits relating to stock option exercises were $21 million in 2021, $12 million in 2020 and $65 million in 2019.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	2021	2020	2019
Balance January 1	**$ 1,537**	$ 1,225	$ 1,893
Additions related to current year positions	**306**	298	199
Additions related to prior year positions	**63**	110	46
Reductions for tax positions of prior years [(1)]	**(230)**	(4)	(454)
Settlements [(1)]	**(46)**	(70)	(356)
Lapse of statute of limitations [(2)]	**(58)**	(22)	(103)
Spin-off of Organon	**(43)**	—	—
Balance December 31	**$ 1,529**	$ 1,537	$ 1,225

[(1)] *Amounts in 2021 and 2019 reflect settlements with the IRS discussed below.*

[(2)] *Amount in 2019 includes $78 million related to the divestiture of Merck's Consumer Care business in 2014.*

If the Company were to recognize the unrecognized tax benefits of $1.5 billion at December 31, 2021, the income tax provision would reflect a favorable net impact of $1.5 billion.

The Company is under examination by numerous tax authorities in various jurisdictions globally. The Company believes that it is reasonably possible that the total amount of unrecognized tax benefits as of December 31, 2021 could decrease by up to approximately $11 million in the next 12 months as a result of various audit closures, settlements or the expiration of the statute of limitations. The ultimate finalization of the Company's

examinations with relevant taxing authorities can include formal administrative and legal proceedings, which could have a significant impact on the timing of the reversal of unrecognized tax benefits. The Company believes that its reserves for uncertain tax positions are adequate to cover existing risks or exposures.

Interest and penalties associated with uncertain tax positions amounted to a (benefit) expense of $(37) million in 2021, $16 million in 2020 and $(53) million in 2019. These amounts reflect the beneficial impacts of various tax settlements, including the settlements discussed below. Liabilities for accrued interest and penalties were $192 million and $205 million as of December 31, 2021 and 2020, respectively.

In 2021, the Internal Revenue Service (IRS) concluded its examinations of Merck's 2015-2016 U.S. federal income tax returns. As a result, the Company was required to make a payment of $190 million (of which $172 million related to continuing operations and $18 million related to discontinued operations). The Company's reserves for unrecognized tax benefits for the years under examination exceeded the adjustments relating to this examination period and therefore the Company recorded a $236 million net tax benefit in 2021 (of which $207 million related to continuing operations and $29 million related to discontinued operations). This net benefit reflects reductions in reserves for unrecognized tax benefits and other related liabilities for tax positions relating to the years that were under examination.

In 2019, the IRS concluded its examinations of Merck's 2012-2014 U.S. federal income tax returns. As a result, the Company was required to make a payment of $107 million (of which $142 million related to discontinued operations with an offsetting credit of $35 million related to continuing operations). The Company's reserves for unrecognized tax benefits for the years under examination exceeded the adjustments relating to this examination period and therefore the Company recorded a $364 million net tax benefit in 2019 (of which $106 million related to continuing operations and $258 million related to discontinued operations). This net benefit reflects reductions in reserves for unrecognized tax benefits for tax positions relating to the years that were under examination, partially offset by additional reserves for tax positions not previously reserved for.

The IRS is currently conducting examinations of the Company's tax returns for the years 2017 and 2018. In addition, various state and foreign tax examinations are in progress and for these jurisdictions, the Company's income tax returns are open for examination for the period 2003 through 2021.

17. Earnings per Share

The calculations of earnings per share (shares in millions) are as follows:

Years Ended December 31	**2021**	2020	2019
Net Income from Continuing Operations Attributable to Merck & Co., Inc.	**$ 12,345**	$ 4,519	$ 5,690
Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests	**704**	2,548	4,153
Net income attributable to Merck & Co., Inc.	**$ 13,049**	$ 7,067	$ 9,843
Average common shares outstanding	**2,530**	2,530	2,565
Common shares issuable [(1)]	**8**	11	15
Average common shares outstanding assuming dilution	**2,538**	2,541	2,580
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders:			
Income from Continuing Operations	**$ 4.88**	$ 1.79	$ 2.22
Income from Discontinued Operations	**0.28**	1.01	1.62
Net Income	**$ 5.16**	$ 2.79	$ 3.84
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders:			
Income from Continuing Operations	**$ 4.86**	$ 1.78	$ 2.21
Income from Discontinued Operations	**0.28**	1.00	1.61
Net Income	**$ 5.14**	$ 2.78	$ 3.81

[(1)] *Issuable primarily under share-based compensation plans.*

In 2021, 2020 and 2019, 9 million, 5 million and 2 million, respectively, of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

18. Other Comprehensive Income (Loss)

Changes in each component of other comprehensive income (loss) are as follows:

	Derivatives	Investments	Employee Benefit Plans	Foreign Currency Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance January 1, 2019, net of taxes	$ 166	$ (78)	$ (3,556)	$ (2,077)	$ (5,545)
Other comprehensive income (loss) before reclassification adjustments, pretax	86	140	(948)	112	(610)
Tax	(15)	—	192	(16)	161
Other comprehensive income (loss) before reclassification adjustments, net of taxes	71	140	(756)	96	(449)
Reclassification adjustments, pretax	(261) [1]	(44) [2]	66 [3]	—	(239)
Tax	55	—	(15)	—	40
Reclassification adjustments, net of taxes	(206)	(44)	51	—	(199)
Other comprehensive income (loss), net of taxes	(135)	96	(705)	96	(648)
Balance at December 31, 2019, net of taxes	31	18	(4,261)	(1,981)	(6,193)
Other comprehensive income (loss) before reclassification adjustments, pretax	(383)	3	(599)	64	(915)
Tax	84	—	111	89	284
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(299)	3	(488)	153	(631)
Reclassification adjustments, pretax	2 [1]	(21) [2]	272 [3]	—	253
Tax	—	—	(63)	—	(63)
Reclassification adjustments, net of taxes	2	(21)	209	—	190
Other comprehensive income (loss), net of taxes	(297)	(18)	(279)	153	(441)
Balance at December 31, 2020, net of taxes	(266)	—	(4,540) [4]	(1,828)	(6,634)
Other comprehensive income (loss) before reclassification adjustments, pretax	**333**	**—**	**1,922**	**(304)**	**1,951**
Tax	**(75)**	**—**	**(374)**	**(119)**	**(568)**
Other comprehensive income (loss) before reclassification adjustments, net of taxes	**258**	**—**	**1,548**	**(423)**	**1,383**
Reclassification adjustments, pretax	**192** [1]	**—**	**281** [3]	**—**	**473**
Tax	**(40)**	**—**	**(60)**	**—**	**(100)**
Reclassification adjustments, net of taxes	**152**	**—**	**221**	**—**	**373**
Other comprehensive income (loss), net of taxes	**410**	**—**	**1,769**	**(423)**	**1,756**
Spin-off of Organon (see Note 3)	**—**	**—**	**28**	**421**	**449**
Balance at December 31, 2021, net of taxes	**$ 144**	**$ —**	**$ (2,743)** [4]	**$ (1,830)**	**$ (4,429)**

[1] *Primarily relates to foreign currency cash flow hedges that were reclassified from* AOCL *to* Sales.

[2] *Represents net realized gains on the sales of available-for-sale debt securities that were reclassified from* AOCL *to* Other (income) expense, net.

[3] *Includes net amortization of prior service cost and actuarial gains and losses included in net periodic benefit cost (see Note 14).*

[4] *Includes pension plan net loss of $3.6 billion and $5.4 billion at December 31, 2021 and 2020, respectively, and other postretirement benefit plan net gain of $473 million and $391 million at December 31, 2021 and 2020, respectively, as well as pension plan prior service credit of $190 million and $255 million at December 31, 2021 and 2020, respectively, and other postretirement benefit plan prior service credit of $181 million and $244 million at December 31, 2021 and 2020, respectively.*

19. Segment Reporting

The Company's operations are principally managed on a products basis and include two operating segments, which are the Pharmaceutical and Animal Health segments, both of which are reportable segments.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. A large component of pediatric and adolescent vaccine sales are made to the U.S. Centers for Disease Control and Prevention Vaccines for Children program, which is funded by the U.S. government. Additionally, the Company sells vaccines to the Federal government for placement into vaccine stockpiles.

The Animal Health segment discovers, develops, manufactures and markets a wide range of veterinary pharmaceutical and vaccine products, as well as health management solutions and services, for the prevention, treatment and control of disease in all major livestock and companion animal species. The Company also offers an extensive suite of digitally connected identification, traceability and monitoring products. The Company sells its products to veterinarians, distributors and animal producers.

Beginning in 2021, the amortization of intangible assets previously included as part of the calculation of segment profits is now included in unallocated non-segment corporate expenses. Prior period Pharmaceutical and Animal Health segment profits have been recast to reflect this change on a comparable basis.

The Company previously had a Healthcare Services segment that provided services and solutions focused on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company divested the remaining businesses in this segment during the first quarter of 2020.

Sales of the Company's products were as follows:

Years Ended December 31	**2021**			2020			2019		
	U.S.	**Int'l**	**Total**	U.S.	Int'l	Total	U.S.	Int'l	Total
Pharmaceutical:									
Oncology									
Keytruda	**$ 9,765**	**$ 7,421**	**$17,186**	$ 8,352	$ 6,028	$14,380	$ 6,305	$ 4,779	$ 11,084
Alliance revenue - Lynparza [(1)]	**515**	**473**	**989**	417	308	725	269	176	444
Alliance revenue - Lenvima [(1)]	**417**	**287**	**704**	359	220	580	239	165	404
Vaccines									
Gardasil/Gardasil 9	**1,881**	**3,792**	**5,673**	1,755	2,184	3,938	1,831	1,905	3,737
ProQuad/M-M-R II/Varivax	**1,629**	**506**	**2,135**	1,378	500	1,878	1,683	592	2,275
Pneumovax 23	**547**	**346**	**893**	727	359	1,087	679	247	926
RotaTeq	**473**	**334**	**807**	486	311	797	506	284	791
Vaqta	**100**	**79**	**179**	103	67	170	130	108	238
Hospital Acute Care									
Bridion	**762**	**770**	**1,532**	583	615	1,198	533	598	1,131
Prevymis	**153**	**218**	**370**	119	162	281	84	81	165
Primaxin	**2**	**258**	**259**	2	248	251	2	271	273
Noxafil	**60**	**199**	**259**	42	287	329	282	380	662
Cancidas	**4**	**208**	**212**	7	207	213	6	242	249
Invanz	**(5)**	**207**	**202**	9	202	211	30	233	263
Zerbaxa	**4**	**(5)**	**(1)**	74	56	130	63	58	121
Immunology									
Simponi	**—**	**825**	**825**	—	838	838	—	830	830
Remicade	**—**	**299**	**299**	—	330	330	—	411	411
Neuroscience									
Belsomra	**78**	**241**	**318**	81	247	327	92	214	306
Virology									
Molnupiravir	**632**	**320**	**952**	—	—	—	—	—	—
Isentress/Isentress HD	**294**	**474**	**769**	326	531	857	398	576	975
Cardiovascular									
Alliance revenue - Adempas/Verquvo [(2)]	**312**	**30**	**342**	259	22	281	194	10	204
Adempas	**—**	**252**	**252**	—	220	220	—	215	215
Diabetes									
Januvia	**1,404**	**1,920**	**3,324**	1,470	1,836	3,306	1,724	1,758	3,482
Janumet	**367**	**1,597**	**1,964**	477	1,494	1,971	589	1,452	2,041
Other pharmaceutical [(3)]	**1,007**	**1,302**	**2,310**	984	1,328	2,312	1,215	1,661	2,873
Total Pharmaceutical segment sales	**20,401**	**22,353**	**42,754**	18,010	18,600	36,610	16,854	17,246	34,100
Animal Health:									
Livestock	**667**	**2,628**	**3,295**	612	2,327	2,939	582	2,201	2,784
Companion Animals	**1,091**	**1,182**	**2,273**	872	892	1,764	724	885	1,609
Total Animal Health segment sales	**1,758**	**3,810**	**5,568**	1,484	3,219	4,703	1,306	3,086	4,393
Other segment sales [(4)]	**—**	**—**	**—**	23	—	23	174	1	175
Total segment sales	**22,159**	**26,163**	**48,322**	19,517	21,819	41,336	18,334	20,333	38,668
Other [(5)]	**266**	**116**	**382**	71	111	182	86	368	453
	$22,425	**$26,279**	**$48,704**	$19,588	$21,930	$41,518	$18,420	$20,701	$ 39,121

U.S. plus international may not equal total due to rounding.

(1) Alliance revenue represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs (see Note 5).

(2) Alliance revenue represents Merck's share of profits from sales in Bayer's marketing territories, which are product sales net of cost of sales and commercialization costs (see Note 5).

(3) Other pharmaceutical primarily reflects sales of other human health pharmaceutical products, including products within the franchises not listed separately.

(4) Represents sales for the Healthcare Services segment. All the businesses in the Healthcare Services segment were fully divested by the first quarter of 2020.

(5) Other is primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, as well as third-party manufacturing sales (including sales to Organon). Other for 2021 also includes $185 million related to the achievement of milestones for an out-licensed product that triggered contingent payments to Merck.

Consolidated sales by geographic area where derived are as follows:

Years Ended December 31	**2021**	2020	2019
United States	**$ 22,425**	$ 19,588	$ 18,420
Europe, Middle East and Africa	**13,341**	11,547	10,496
China	**4,378**	2,751	2,180
Japan	**2,726**	2,602	2,609
Asia Pacific (other than China and Japan)	**2,407**	2,113	2,126
Latin America	**2,206**	1,890	2,015
Other	**1,221**	1,027	1,275
	$ 48,704	$ 41,518	$ 39,121

A reconciliation of segment profits to *Income from Continuing Operations Before Taxes* is as follows:

Years Ended December 31	**2021**	2020	2019
Segment profits:			
Pharmaceutical segment	**$ 30,977**	$ 26,106	$ 23,448
Animal Health segment	**1,950**	1,669	1,612
Other segments	**—**	1	(7)
Total segment profits	**32,927**	27,776	25,053
Other profits	**156**	75	295
Unallocated:			
Interest income	**36**	59	274
Interest expense	**(806)**	(831)	(893)
Amortization	**(1,636)**	(1,817)	(1,695)
Depreciation	**(1,414)**	(1,519)	(1,491)
Research and development	**(11,692)**	(12,911)	(9,351)
Restructuring costs	**(661)**	(575)	(626)
Other unallocated, net	**(3,031)**	(4,394)	(4,395)
	$ 13,879	$ 5,863	$ 7,171

Pharmaceutical segment profits are comprised of segment sales less standard costs, as well as selling, general and administrative expenses directly incurred by the segment. Animal Health segment profits are comprised of segment sales, less all cost of sales, as well as selling, general and administrative expenses and research and development costs directly incurred by the segment. For internal management reporting presented to the chief operating decision maker, Merck does not allocate the remaining cost of sales not included in segment profits as described above, research and development expenses incurred in Merck Research Laboratories, the Company's research and development division that focuses on human health-related activities, or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. In addition, costs related to restructuring activities, as well as the amortization of intangible assets and purchase accounting adjustments are not allocated to segments.

Other profits are primarily comprised of miscellaneous corporate profits, as well as operating profits related to third-party manufacturing sales.

Other unallocated, net, includes expenses from corporate and manufacturing cost centers, goodwill and other intangible asset impairment charges, gains or losses on sales of businesses, expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration, and other miscellaneous income or expense items.

Equity loss from affiliates and depreciation included in segment profits is as follows:

	Pharmaceutical	Animal Health	All Other	Total
Year Ended December 31, 2021				
Included in segment profits:				
Equity loss from affiliates	**$ 11**	**$ —**	**$ —**	**$ 11**
Depreciation	**6**	**158**	**—**	**164**
Year Ended December 31, 2020				
Included in segment profits:				
Equity loss from affiliates	$ 6	$ —	$ —	$ 6
Depreciation	6	143	1	150
Year Ended December 31, 2019				
Included in segment profits:				
Equity loss from affiliates	$ —	$ —	$ —	$ —
Depreciation	9	105	10	124

Property, plant and equipment, net, by geographic area where located is as follows:

December 31	**2021**	2020	2019
United States	**$ 11,759**	$ 10,394	$ 8,963
Europe, Middle East and Africa	**6,081**	5,314	4,129
Asia Pacific (other than China and Japan)	**857**	737	692
China	**220**	216	174
Latin America	**199**	169	180
Japan	**159**	166	152
Other	**4**	4	7
	$ 19,279	$ 17,000	$ 14,297

The Company does not disaggregate assets on a products and services basis for internal management reporting and, therefore, such information is not presented.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Merck & Co., Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheet of Merck & Co., Inc. and its subsidiaries (the "Company") as of December 31, 2021 and 2020, and the related consolidated statements of income, of comprehensive income, of equity and of cash flows for each of the three years in the period ended December 31, 2021, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

U.S. Rebate Accruals - Medicaid, Managed Care and Medicare Part D

As described in Note 2 to the consolidated financial statements, the Company records certain variable consideration including discounts, which are estimated at the time of sale generally using the expected value method. Amounts accrued for aggregate customer discounts are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal and state agencies, and other customers to the amounts accrued. Certain of these discounts representing a portion of the accrual take the form of rebates, which are amounts owed based upon definitive contractual agreements or legal requirements with private sector (Managed Care) and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product to a benefit plan participant. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. Management uses historical customer segment utilization mix, sales forecasts, changes to product mix and price, inventory levels in the distribution channel, government pricing calculations and prior payment history in order to estimate the expected provision. The accrued balance relative to the provision for rebates included in accrued and other current liabilities was $2.6 billion as of December 31, 2021, of which the majority relates to U.S. rebate accruals – Medicaid, Managed Care and Medicare Part D.

The principal considerations for our determination that performing procedures relating to U.S. rebate accruals - Medicaid, Managed Care, and Medicare Part D is a critical audit matter are the significant judgment by management due to the significant measurement uncertainty involved in developing the rebate accruals, as the accruals are based on assumptions developed using pricing information and historical customer segment utilization mix, and a high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating evidence related to these assumptions.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to U.S. rebate accruals - Medicaid, Managed Care, and Medicare Part D, including management's controls over the assumptions used to estimate the corresponding rebate accruals. These procedures also included, among others (i) developing an independent estimate of the rebate accruals by utilizing third party data on historical customer segment utilization mix in the U.S., pricing information, the terms of the specific rebate programs, and the historical trend of actual rebate claims paid, (ii) comparing the independent estimate to the rebate accruals recorded by management, and (iii) testing rebate claims paid, including evaluating those claims for consistency with the contractual terms of the Company's rebate agreements.



PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 25, 2022

We have served as the Company's auditor since 2002.

(b) Supplementary Data

Selected Quarterly Financial Data (Unaudited)

($ in millions except per share amounts)	4th Q [1]	3rd Q [2]	2nd Q [3]	1st Q
2021 [4]				
Sales	**$ 13,521**	**$ 13,154**	**$ 11,402**	**$ 10,627**
Gross Profit	**9,648**	**9,704**	**8,298**	**7,428**
Net Income from Continuing Operations Attributable to Merck & Co., Inc.	**3,820**	**4,567**	**1,213**	**2,745**
(Loss) Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests	**(62)**	**—**	**332**	**434**
Net Income Attributable to Merck & Co., Inc.	**3,758**	**4,567**	**1,545**	**3,179**
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders				
Income from Continuing Operations	**$ 1.51**	**$ 1.81**	**$ 0.48**	**$ 1.08**
(Loss) Income from Discontinued Operations	**(0.02)**	**—**	**0.13**	**0.17**
Net Income	**$ 1.49**	**$ 1.81**	**$ 0.61**	**$ 1.26**
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders				
Income from Continuing Operations	**$ 1.51**	**$ 1.80**	**$ 0.48**	**$ 1.08**
(Loss) Income from Discontinued Operations	**(0.02)**	**—**	**0.13**	**0.17**
Net Income	**$ 1.48**	**$ 1.80**	**$ 0.61**	**$ 1.25**
2020 [4]				
Sales	$ 10,948	$ 10,929	$ 9,353	$ 10,288
Gross Profit	5,919	7,916	6,606	7,459
Net (Loss) Income from Continuing Operations Attributable to Merck & Co., Inc.	(2,617)	2,324	2,341	2,471
Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests	523	617	661	748
Net (Loss) Income Attributable to Merck & Co., Inc.	(2,094)	2,941	3,002	3,219
Basic (Loss) Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders				
(Loss) Income from Continuing Operations	$ (1.03)	$ 0.92	$ 0.93	$ 0.98
Income from Discontinued Operations	0.21	0.24	0.26	0.30
Net (Loss) Income	$ (0.83)	$ 1.16	$ 1.19	$ 1.27
(Loss) Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders				
(Loss) Income from Continuing Operations	$ (1.03)	$ 0.92	$ 0.92	$ 0.97
Income from Discontinued Operations	0.21	0.24	0.26	0.29
Net (Loss) Income	$ (0.83)	$ 1.16	$ 1.18	$ 1.26

[1] *Amounts in the fourth quarter of 2020 include charges related to the acquisitions of VelosBio Inc. and OncoImmune (see Note 4) and an intangible asset impairment charge related to* Zerbaxa *(see Note 9).*

[2] *Amounts in the third quarter of 2020 include charges related to transactions with Seagen Inc (see Note 4).*

[3] *Amounts in the second quarter of 2021 include a charge related to the acquisition of Pandion Therapeutics, Inc. (see Note 4).*

[4] *Reflects the results of the businesses that were spun-off to Organon on June 2, 2021 as discontinued operations for all periods presented (see Note 3).*

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures. Based on their evaluation, as of the end of the period covered by this Form 10-K, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Act)) are effective. For the fourth quarter of 2021, there have been no changes in internal control over financial reporting that materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Act. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control — Integrated Framework* issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2021. PricewaterhouseCoopers LLP, an independent registered public accounting firm, has performed its own assessment of the effectiveness of the Company's internal control over financial reporting and its attestation report is included in this Form 10-K filing.

Management's Report

Management's Responsibility for Financial Statements

Responsibility for the integrity and objectivity of the Company's financial statements rests with management. The financial statements report on management's stewardship of Company assets. These statements are prepared in conformity with generally accepted accounting principles and, accordingly, include amounts that are based on management's best estimates and judgments. Nonfinancial information included in the Annual Report on Form 10-K has also been prepared by management and is consistent with the financial statements.

To assure that financial information is reliable and assets are safeguarded, management maintains an effective system of internal controls and procedures, important elements of which include: careful selection, training and development of operating and financial managers; an organization that provides appropriate division of responsibility; and communications aimed at assuring that Company policies and procedures are understood throughout the organization. A staff of internal auditors regularly monitors the adequacy and application of internal controls on a worldwide basis.

To ensure that personnel continue to understand the system of internal controls and procedures, and policies concerning good and prudent business practices, annually all employees of the Company are required to complete Code of Conduct training. This training reinforces the importance and understanding of internal controls by reviewing key corporate policies, procedures and systems. In addition, the Company has compliance programs, including an ethical business practices program to reinforce the Company's long-standing commitment to high ethical standards in the conduct of its business.

The financial statements and other financial information included in the Annual Report on Form 10-K fairly present, in all material respects, the Company's financial condition, results of operations and cash flows. Our formal certification to the Securities and Exchange Commission is included in this Form 10-K filing.

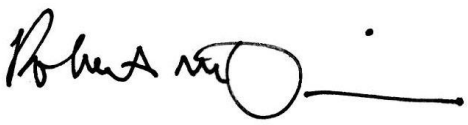
Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control — Integrated*

Framework issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2021.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2021, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.





Robert M. Davis
Chief Executive Officer and President

Caroline Litchfield
Executive Vice President and Chief Financial Officer

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The required information on directors and nominees is incorporated by reference from the discussion under Proposal 1. Election of Directors of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2022. Information on executive officers is set forth in Part I of this document on page 44.

The required information on compliance with Section 16(a) of the Securities Exchange Act of 1934, if applicable, is incorporated by reference from the discussion under the heading "Stock Ownership Information" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2022.

The Company has a Code of Conduct — *Our Values and Standards* applicable to all employees, including the principal executive officer, principal financial officer, principal accounting officer and Controller. The Code of Conduct is available on the Company's website at merck.com/company-overview/culture-and-values/code-of-conduct/values-and-standards. The Company intends to disclose future amendments to certain provisions of the Code of Conduct, and waivers of the Code of Conduct granted to executive officers and directors, if any, on the website within four business days following the date of any amendment or waiver. Every Merck employee is responsible for adhering to business practices that are in accordance with the law and with ethical principles that reflect the highest standards of corporate and individual behavior.

The required information on the identification of the audit committee and the audit committee financial expert is incorporated by reference from the discussion under the heading "Board Meetings and Committees" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2022.

Item 11. Executive Compensation.

The information required on executive compensation is incorporated by reference from the discussion under the headings "Compensation Discussion and Analysis," "Summary Compensation Table," "All Other Compensation" table, "Grants of Plan-Based Awards" table, "Outstanding Equity Awards" table, "Option Exercises and Stock Vested" table, "Pension Benefits" table, "Nonqualified Deferred Compensation" table, and "Potential Payments Upon Termination or a Change in Control", including the discussion under the subheadings "Separation" and "Change in Control," as well as all footnote information to the various tables, of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2022.

The required information on director compensation is incorporated by reference from the discussion under the heading "Director Compensation" and related "2021 Schedule of Director Fees" table and "2021 Director Compensation" table of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2022.

The required information under the headings "Compensation and Management Development Committee Interlocks and Insider Participation" and "Compensation and Management Development Committee Report" is incorporated by reference from the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2022.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information with respect to security ownership of certain beneficial owners and management is incorporated by reference from the discussion under the heading "Stock Ownership Information" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2022.

Equity Compensation Plan Information

The following table summarizes information about the options, warrants and rights and other equity compensation under the Company's equity compensation plans as of the close of business on December 31, 2021. The table does not include information about tax qualified plans such as the Merck U.S. Savings Plan.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders[(1)]	18,572,010[(2)]	$ 65.27	92,994,903
Equity compensation plans not approved by security holders	—	—	—
Total	18,572,010	$ 65.27	92,994,903

(1) *Includes options to purchase shares of Company Common Stock and other rights under the following shareholder-approved plans: the Merck & Co., Inc. 2010 and 2019 Incentive Stock Plans, and the Merck & Co., Inc. 2010 Non-Employee Directors Stock Option Plan.*

(2) *Excludes approximately 11,790,206 shares of restricted stock units and 1,965,983 performance share units (assuming maximum payouts) under the Merck Sharp & Dohme 2010 and 2019 Incentive Stock Plans. Also excludes 193,107 shares of phantom stock deferred under the MSD Employee Deferral Program and 468,633 shares of phantom stock deferred under the Merck & Co., Inc. Plan for Deferred Payment of Directors' Compensation.*

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The required information on transactions with related persons is incorporated by reference from the discussion under the heading "Related Person Transactions" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2022.

The required information on director independence is incorporated by reference from the discussion under the heading "Independence of Directors" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2022.

Item 14. Principal Accountant Fees and Services.

The information required for this item is incorporated by reference from the discussion under Proposal 3. Ratification of Appointment of Independent Registered Public Accounting Firm for 2022 beginning with the caption "Pre-Approval Policy for Services of Independent Registered Public Accounting Firm" through "Fees for Services Provided by the Independent Registered Public Accounting Firm" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2022.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this Form 10-K

1. Financial Statements

Consolidated statement of income for the years ended December 31, 2021, 2020 and 2019

Consolidated statement of comprehensive income for the years ended December 31, 2021, 2020 and 2019

Consolidated balance sheet as of December 31, 2021 and 2020

Consolidated statement of equity for the years ended December 31, 2021, 2020 and 2019

Consolidated statement of cash flows for the years ended December 31, 2021, 2020 and 2019

Notes to consolidated financial statements

Report of PricewaterhouseCoopers LLP, independent registered public accounting firm (PCAOB ID 238)

2. Financial Statement Schedules

Schedules are omitted because they are either not required or not applicable.

Financial statements of affiliates carried on the equity basis have been omitted because, considered individually or in the aggregate, such affiliates do not constitute a significant subsidiary.

3. Exhibits

Exhibit Number		Description
3.1	—	Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) — Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
3.2	—	By-Laws of Merck & Co., Inc. (effective July 22, 2015) — Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed July 28, 2015 (No. 1-6571)
4.1	—	Indenture, dated as of April 1, 1991, between Merck Sharp & Dohme Corp. (f/k/a Schering Corporation) and U.S. Bank Trust National Association (as successor to Morgan Guaranty Trust Company of New York), as Trustee (the 1991 Indenture) — Incorporated by reference to Exhibit 4 to MSD's Registration Statement on Form S-3 (No. 33-39349)
4.2	—	First Supplemental Indenture to the 1991 Indenture, dated as of October 1, 1997 — Incorporated by reference to Exhibit 4(b) to MSD's Registration Statement on Form S-3 filed September 25, 1997 (No. 333-36383)
4.3	—	Second Supplemental Indenture to the 1991 Indenture, dated November 3, 2009 — Incorporated by reference to Exhibit 4.3 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No.1-6571)
4.4	—	Third Supplemental Indenture to the 1991 Indenture, dated May 1, 2012 — Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the period ended March 31, 2012 (No. 1-6571)
4.5	—	Indenture, dated November 26, 2003, between Merck & Co., Inc. (f/k/a Schering-Plough Corporation) and The Bank of New York as Trustee (the 2003 Indenture) — Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed November 28, 2003 (No. 1-6571)
4.6	—	Second Supplemental Indenture to the 2003 Indenture (including Form of Note), dated November 26, 2003 — Incorporated by reference to Exhibit 4.3 to Schering-Plough's Current Report on Form 8-K filed November 28, 2003 (No. 1-6571)
4.7	—	Third Supplemental Indenture to the 2003 Indenture (including Form of Note), dated September 17, 2007 — Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed September 17, 2007 (No. 1-6571)
4.8	—	Fifth Supplemental Indenture to the 2003 Indenture, dated November 3, 2009 — Incorporated by reference to Exhibit 4.4 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
4.9	—	Indenture, dated as of January 6, 2010, between Merck & Co., Inc. and U.S. Bank Trust National Association, as Trustee — Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed December 10, 2010 (No. 1-6571)
4.10	—	Description of the Registrant's Common Stock - Incorporated by reference to Exhibit 4.10 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2020 filed February 25, 2021 (No. 1-6571)
4.11	—	Description of the Registrant's 1.125% Notes due 2021, 1.875% Notes due 2026, and 2.500% Notes due 2034 - Incorporated by reference to Exhibit 4.11 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2020 filed February 25, 2021 (No. 1-6571)
4.12	—	Description of the Registrant's 0.500% Notes due 2024 and 1.375% Notes due 2036 - Incorporated by reference to Exhibit 4.12 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2020 filed February 25, 2021 (No. 1-6571)

Exhibit Number		Description
*10.1	—	Merck & Co., Inc. Executive Incentive Plan (as amended and restated effective June 1, 2015) — Incorporated by reference to Merck & Co., Inc.'s Schedule 14A filed April 13, 2015 (No. 1-6571)
*10.2	—	Merck & Co., Inc. Deferral Program Including the Base Salary Deferral Plan (Amended and Restated effective December 1, 2019) - Incorporated by reference to Exhibit 10.2 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2019 filed February 26, 2020 (No. 1-6571)
*10.3	—	Merck & Co., Inc. 2010 Incentive Stock Plan (as amended and restated June 1, 2015) — Incorporated by reference to Merck & Co., Inc.'s Schedule 14A filed April 13, 2015 (No. 1-6571)
*10.4	—	Form of stock option terms for 2011 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.2 to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the period ended March 31, 2011 filed May 9, 2011 (No. 1-6571)
*10.5	—	Form of stock option terms for 2012 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.20 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2011 filed February 28, 2012 (No. 1-6571)
*10.6	—	Form of stock option terms for 2013 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.19 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2012 filed February 28, 2013 (No. 1-6571)
*10.7	—	Form of stock option terms for 2014 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.18 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2014 filed February 27, 2015 (No. 1-6571)
*10.8	—	Form of stock option terms for 2015 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.20 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2015 filed February 26, 2016 (No. 1-6571)
*10.9	—	Form of stock option terms for 2018 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by referent to Exhibit 10.12 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2017 filed February 27, 2018 (No. 1-6571)
*10.10	—	Form of stock option terms for 2016 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.19 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2016 filed February 28, 2017 (No. 1-6571)
*10.11	—	Form of restricted stock unit terms for 2018 quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.17 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2017 filed on February 28, 2018 (No. 1-6571)
*10.12	—	2018 Performance Share Unit Award Terms under the Merck & Co., Inc. 2010 Stock Incentive Plan — Incorporated by reference to Exhibit 10 to Merck & Co., Inc.'s Current Report on Form 10-Q Quarterly Report for the period ended March 31, 2018 filed May 8, 2018 (No. 1-6571)

Exhibit Number		Description
*10.13	—	Merck & Co., Inc. 2019 Incentive Stock Plan - Incorporated by reference to Appendix C to Merck & Co., Inc.'s Schedule 14A filed April 8, 2019 (No. 1-6571)
*10.14	—	Merck & Co., Inc. Change in Control Separation Benefits Plan (effective as amended and restated, as of January 1, 2013) — Incorporated by reference to Exhibit 10.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 29, 2012 (No. 1-6571)
*10.15	—	Merck & Co., Inc. U.S. Separation Benefits Plan (amended and restated as of January 1, 2019) - Incorporated by reference to Exhibit 10.19 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2018 filed February 27, 2019 (No. 1-6571)
*10.16	—	Retirement Plan for the Directors of Merck & Co., Inc. (amended and restated June 21, 1996) — Incorporated by reference to Exhibit 10.C to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1996 filed August 13, 1996 (No. 1-3305)
*10.17	—	Merck & Co., Inc. Plan for Deferred Payment of Directors' Compensation (Amended and Restated effective as of January 1, 2022)
10.18	—	Distribution agreement between Schering-Plough and Centocor, Inc., dated April 3, 1998 — Incorporated by reference to Exhibit 10(u) to Schering-Plough's Amended 10-K for the year ended December 31, 2003 filed May 3, 2004 (No. 1-6571)†
10.19	—	Amendment Agreement to the Distribution Agreement between Centocor, Inc., CAN Development, LLC, and Schering-Plough (Ireland) Company — Incorporated by reference to Exhibit 10.1 to Schering-Plough's Current Report on Form 8-K filed December 21, 2007 (No. 1-6571)†
10.20	—	Severance Agreement and General Release between Merck & Co., Inc. and Adam H. Schechter, dated December 1, 2018 - Incorporated by reference to Exhibit 10.27 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2018 filed February 27, 2019 (No. 1-6571)
10.21	—	Offer Letter between Merck & Co., Inc. and Jennifer Zachary, dated March 16, 2018 - Incorporated by reference to Exhibit 10.28 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2018 filed February 27, 2019 (No. 1-6571)
*10.22	—	Form of stock option terms for 2021 annual non-qualified option grants under the Merck & Co., Inc. 2019 Incentive Stock Plan - Incorporated by reference to Exhibit 10.23 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2020 filed February 25, 2021 (No. 1-6571)
*10.23	—	Form of restricted stock unit terms for 2021 annual grants under the Merck & Co., Inc. 2019 Incentive Stock Plan - Incorporated by reference to Exhibit 10.24 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2020 filed February 25, 2021 (No. 1-6571)
*10.24	—	Form of stock option terms for 2022 annual non-qualified option grants under the Merck & Co., Inc. 2019 Incentive Stock Plan
*10.25	—	Form of restricted stock unit terms for 2022 annual grants under the Merck & Co., Inc. 2019 Incentive Stock Plan
21	—	Subsidiaries of Merck & Co., Inc.
23	—	Consent of Independent Registered Public Accounting Firm
24.1	—	Power of Attorney
24.2	—	Certified Resolution of Board of Directors

31.1	—	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
31.2	—	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer
32.1	—	Section 1350 Certification of Chief Executive Officer
32.2	—	Section 1350 Certification of Chief Financial Officer

Exhibit Number		Description
101.INS	—	XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	—	XBRL Taxonomy Extension Schema Document.
101.CAL	—	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	—	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	—	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	—	XBRL Taxonomy Extension Presentation Linkbase Document.
104	—	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

---

* *Management contract or compensatory plan or arrangement.*

† *Certain portions of the exhibit have been omitted pursuant to a request for confidential treatment. The non-public information has been filed separately with the Securities and Exchange Commission pursuant to rule 24b-2 under the Securities Exchange Act of 1934, as amended.*

Long-term debt instruments under which the total amount of securities authorized does not exceed 10% of Merck & Co., Inc.'s total consolidated assets are not filed as exhibits to this report. Merck & Co., Inc. will furnish a copy of these agreements to the Securities and Exchange Commission on request.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: February 25, 2022

MERCK & CO., INC.

By: ROBERT M. DAVIS
(Chief Executive Officer and 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	Chief Executive Officer and President; Principal Executive Officer; Director	February 25, 2022
CAROLINE LITCHFIELD	Executive Vice President and Chief Financial Officer; Principal Financial Officer	February 25, 2022
RITA A. KARACHUN	Senior Vice President Finance-Global Controller; Principal Accounting Officer	February 25, 2022
KENNETH C. FRAZIER	Executive Chairman and Director	February 25, 2022
MARY ELLEN COE	Director	February 25, 2022
PAMELA J. CRAIG	Director	February 25, 2022
THOMAS H. GLOCER	Director	February 25, 2022
RISA J. LAVIZZO-MOUREY	Director	February 25, 2022
STEPHEN L. MAYO	Director	February 25, 2022
PAUL B. ROTHMAN	Director	February 25, 2022
PATRICIA F. RUSSO	Director	February 25, 2022
CHRISTINE E. SEIDMAN	Director	February 25, 2022
INGE G. THULIN	Director	February 25, 2022
KATHY J. WARDEN	Director	February 25, 2022
PETER C. WENDELL	Director	February 25, 2022

Jennifer Zachary, by signing her name hereto, does hereby sign this document pursuant to powers of attorney duly executed by the persons named, filed with the Securities and Exchange Commission as an exhibit to this document, on behalf of such persons, all in the capacities and on the date stated, such persons including a majority of the directors of the Company.

By: /S/ JENNIFER ZACHARY
Jennifer Zachary
(Attorney-in-Fact)