As filed with the Securities and Exchange Commission on February 26, 2020

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

FORM 10-K

(MARK ONE)

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

For the Fiscal Year Ended December 31, 2019

OR

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

For the transition period from _____ to _____

Commission File No. 1-6571

Merck & Co., Inc.

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

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

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

Title of Each Class	*Trading Symbol(s)*	*Name of Each Exchange on which Registered*
Common Stock ($0.50 par value)	MRK	New York Stock Exchange
1.125% Notes due 2021	MRK/21	New York Stock Exchange
0.500% Notes due 2024	MRK 24	New York Stock Exchange
1.875% Notes due 2026	MRK/26	New York Stock Exchange
2.500% Notes due 2034	MRK/34	New York Stock Exchange
1.375% Notes due 2036	MRK 36A	New York Stock Exchange

Number of shares of Common Stock ($0.50 par value) outstanding as of January 31, 2020: 2,536,268,760.

Aggregate market value of Common Stock ($0.50 par value) held by non-affiliates on June 30, 2019 based on closing price on June 30, 2019: $215,106,000,000.

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

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

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

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

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

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

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

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

Documents Incorporated by Reference:

Document	*Part of Form 10-K*
Proxy Statement for the Annual Meeting of Shareholders to be held May 26, 2020, to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this report	Part III

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PART I

Item 1. Business.

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

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

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

The Healthcare Services segment provides services and solutions that focus on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company has recently sold certain businesses in the Healthcare Services segment and is in the process of divesting the remaining businesses. While the Company continues to look for investment opportunities in this area of health care, the approach to these investments has shifted toward venture capital investments in third parties as opposed to wholly-owned businesses.

The Alliances segment primarily includes activity from the Company's relationship with AstraZeneca LP related to sales of Nexium and Prilosec, which concluded in 2018.

The Company was incorporated in New Jersey in 1970.

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

Planned Spin-Off of Women's Health, Legacy Brands and Biosimilars into a New Company

In February 2020, Merck announced its intention to spin-off (the Spin-Off) products from its women's health, trusted legacy brands and biosimilars businesses into a new, yet-to-be-named, independent, publicly traded company (NewCo) through a distribution of NewCo's publicly traded stock to Company shareholders. The distribution is expected to qualify as tax-free to the Company and its shareholders for U.S. federal income tax purposes. The legacy brands included in the transaction consist of dermatology, pain, respiratory, and select cardiovascular products including *Zetia* and *Vytorin*, as well as the rest of Merck's diversified brands franchise. Merck's existing research pipeline programs will continue to be owned and developed within Merck as planned. NewCo will have development capabilities initially focused on late-stage development and life-cycle management, and is expected over time to develop research capabilities in selected therapeutic areas. The Spin-Off is expected to be completed in the first half of 2021, subject to market and certain other conditions. See "Risk Factors - Risks Related to the Proposed Spin-Off of NewCo."

Product Sales

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

($ in millions)	**2019**	**2018**	2017
Total Sales	**$ 46,840**	**$ 42,294**	$ 40,122
Pharmaceutical	**41,751**	**37,689**	35,390
Keytruda	**11,084**	**7,171**	3,809
Januvia/Janumet	**5,524**	**5,914**	5,896
Gardasil/Gardasil 9	**3,737**	**3,151**	2,308
ProQuad/M-M-R II/*Varivax*	**2,275**	**1,798**	1,676
Bridion	**1,131**	**917**	704
Isentress/Isentress HD	**975**	**1,140**	1,204
Pneumovax 23	**926**	**907**	821
NuvaRing	**879**	**902**	761
Zetia/Vytorin	**874**	**1,355**	2,095
Simponi	**830**	**893**	819
Animal Health	**4,393**	**4,212**	3,875
Livestock	**2,784**	**2,630**	2,484
Companion Animals	**1,609**	**1,582**	1,391
Other Revenues[(1)]	**696**	**393**	857

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

Pharmaceutical

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

Oncology

Keytruda (pembrolizumab), the Company's anti-PD-1 (programmed death receptor-1) therapy, as monotherapy for the treatment of certain patients with melanoma, non-small-cell lung cancer (NSCLC), small-cell lung cancer (SCLC), head and neck squamous cell carcinoma (HNSCC), classical Hodgkin Lymphoma (cHL), primary mediastinal large B-cell lymphoma (PMBCL), urothelial carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient cancer, gastric or gastroesophageal junction adenocarcinoma, esophageal cancer, cervical cancer, hepatocellular carcinoma, and merkel cell carcinoma. *Keytruda* is also used for the treatment of certain patients in combination with chemotherapy for metastatic squamous and non-squamous NSCLC, in combination with chemotherapy for HNSCC, in combination with axitinib for renal cell carcinoma, and in combination with lenvatinib for endometrial carcinoma; and *Emend* (aprepitant) for the prevention of chemotherapy-induced and post-operative nausea and vomiting. In addition, the Company recognizes alliance revenue related to sales of Lynparza (olaparib), an oral poly (ADP-ribose) polymerase (PARP) inhibitor, for certain types of advanced ovarian, breast and pancreatic cancers; and Lenvima (lenvatinib) for certain types of thyroid cancer, hepatocellular carcinoma, in combination with everolimus for certain patients with renal cell carcinoma, and in combination with *Keytruda* for certain patients with endometrial carcinoma.

Vaccines

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

Hospital Acute Care

Bridion (sugammadex) Injection, a medication for the reversal of two types of neuromuscular blocking agents used during surgery; *Noxafil* (posaconazole) for the prevention of invasive fungal infections; *Primaxin* (imipenem and cilastatin sodium) an anti-bacterial product; *Invanz* (ertapenem sodium) for the treatment of certain infections; *Cubicin* (daptomycin for injection), an I.V. antibiotic for complicated skin and skin structure infections or bacteremia, when caused by designated susceptible organisms; *Cancidas* (caspofungin acetate), an anti-fungal product; and *Prevymis* (letermovir) for the prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant.

Immunology

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

Neuroscience

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

Virology

Isentress/Isentress HD (raltegravir), an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection; and *Zepatier* (elbasvir and grazoprevir) for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype (GT) 1 or GT4 infection, with ribavirin in certain patient populations.

Cardiovascular

Zetia (ezetimibe) (marketed as *Ezetrol* in most countries outside the United States); *Vytorin* (ezetimibe/simvastatin) (marketed as *Inegy* outside the United States); *Atozet* (ezetimibe and atorvastatin) (marketed outside of the United States) and *Rosuzet* (ezetimibe and rosuvastatin) (marketed outside of the United States), cholesterol modifying medicines; and Adempas (riociguat), a cardiovascular drug for the treatment of pulmonary arterial hypertension.

Diabetes

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

Women's Health

NuvaRing (etonogestrel/ethinyl estradiol vaginal ring), a vaginal contraceptive product; and *Implanon* (etonogestrel implant), a single-rod subdermal contraceptive implant/*Nexplanon* (etonogestrel implant), a single, radiopaque, rod-shaped subdermal contraceptive implant.

Animal Health

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

Livestock Products

Nuflor (Florfenicol) antibiotic range for use in cattle and swine; *Bovilis*/*Vista* vaccine lines for infectious diseases in cattle; *Banamine* (Flunixin meglumine) bovine and swine anti-inflammatory; *Estrumate* (cloprostenol sodium) for the treatment of fertility disorders in cattle; *Matrix* (altrenogest) fertility management for swine; *Resflor* (florfenicol and flunixin meglumine), a combination broad-spectrum antibiotic and non-steroidal anti-inflammatory drug for bovine respiratory disease; *Zuprevo* (Tildipirosin) for bovine respiratory disease; *Zilmax* (zilpaterol hydrochloride) and *Revalor* (trenbolone acetate and estradiol) to improve production efficiencies in beef cattle; *Safe-Guard* (fenbendazole) de-wormer for cattle; *M+Pac* (Mycoplasma Hyopneumoniae Bacterin) swine pneumonia vaccine; *Porcilis* (Lawsonia intracellularis baterin) and *Circumvent* (Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector) vaccine lines for infectious diseases in swine; *Nobilis*/*Innovax* (Live Marek's Disease Vector), vaccine lines for poultry; *Paracox* and *Coccivac* coccidiosis vaccines; *Exzolt*, a systemic treatment for poultry red mite infestations; *Slice* (Emamectin benzoate) parasiticide for sea lice in salmon; *Aquavac* (Avirulent Live Culture)/*Norvax* vaccines against bacterial and viral disease in fish; *Compact PD* vaccine for salmon; *Aquaflor* (Florfenicol) antibiotic for farm-raised fish; and *Allflex Livestock Intelligence* solutions for animal identification, monitoring and traceability.

Companion Animal Products

Bravecto (fluralaner), a line of oral and topical parasitic control products for dogs and cats that last up to 12 weeks; *Nobivac* vaccine lines for flexible dog and cat vaccination; *Otomax* (Gentamicin sulfate, USP; Betamethasone valerate USP; and Clotrimazole USP ointment)/*Mometamax* (Gentamicin sulfate, USP, Mometasone Furoate Monohydrate and Clotrimazole, USP, Otic Suspension)/*Posatex* (Orbifloxacin, Mometasone Furoate Monohydrate and Posaconazole, Suspension) ear ointments for acute and chronic otitis; *Caninsulin*/*Vetsulin* (porcine insulin zinc suspension) diabetes mellitus treatment for dogs and cats; *Panacur* (fenbendazole)/*Safeguard* (fenbendazole) broad-spectrum anthelmintic (de-wormer) for use in many animals; *Regumate* (altrenogest) fertility management for horses; *Prestige* vaccine line for horses; and *Scalibor* (Deltamethrin)*/Exspot* for protecting against bites from fleas, ticks, mosquitoes and sandflies.

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

2019 Product Approvals

Set forth below is a summary of significant product approvals received by the Company in 2019.

Product	Date	Approval
Ervebo	December 2019	The U.S. Food and Drug Administration (FDA) approved *Ervebo* for the prevention of disease caused by *Zaire ebolavirus* in individuals 18 years of age and older.
	November 2019	The European Commission (EC) granted a conditional marketing authorization for *Ervebo* for active immunization of individuals 18 years of age or older to protect against Ebola Virus Disease caused by Zaire Ebola virus.
Keytruda	December 2019	The Japanese Ministry of Health, Labour and Welfare (MHLW) approved *Keytruda* for three new first-line indications across advanced renal cell carcinoma (RCC) and recurrent or distant metastatic head and neck cancer.
	November 2019	EC approved two new regimens of *Keytruda* as first-line treatment for metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC).
	November 2019	The China National Medical Products Administration (NMPA) approved *Keytruda* for first-line treatment of metastatic squamous non-small cell lung cancer (NSCLC) in combination with chemotherapy.
	October 2019	NMPA approved *Keytruda* as monotherapy for first-line treatment of certain patients with advanced NSCLC whose tumors express PD-L1.
	September 2019	FDA approved *Keytruda* plus Lenvima combination treatment for patients with certain types of endometrial carcinoma.
	September 2019	EC approved *Keytruda* in combination with axitinib as first-line treatment for patients with advanced RCC.
	July 2019	FDA approved *Keytruda* for recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus in patients whose tumors express PD-L1 combined positive score [CPS] (CPS ≥10) with disease progression after one of more prior lines of systemic therapy.

Keytruda	June 2019	FDA approved *Keytruda* as monotherapy for patients with metastatic small-cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy.
	June 2019	FDA approved two indications for *Keytruda* for first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC as monotherapy for patients whose tumors express PD-L1 CPS ≥1 or in combination with platinum and fluorouracil regardless of PD-L1 expression.
	April 2019	FDA approved *Keytruda* in combination with axitinib for first-line treatment of patients with advanced RCC.
	April 2019	FDA approved an expanded label for *Keytruda* as monotherapy for the first-line treatment of patients with stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC, and whose tumors express PD-L1 (tumor proportion score [TPS] ≥1%) as determined by an FDA-approved test, with no epidermal growth factor receptor□ (EGFR) or anaplastic lymphoma kinase positive (ALK) genomic tumor aberrations.
	April 2019	EC approved new extended dosing schedule for *Keytruda* for all approved monotherapy indications.
	April 2019	NMPA approved *Keytruda* for first-line treatment of metastatic nonsquamous NSCLC in combination with chemotherapy.
	March 2019	EC approved *Keytruda* in combination with chemotherapy for first-line treatment of adults with metastatic squamous NSCLC.
	February 2019	FDA approved *Keytruda* for the adjuvant treatment of patients with melanoma with involvement of lymph node(s) following complete resection.
	January 2019	MHLW approved *Keytruda* for five indications, including three expanded uses in advanced NSCLC, one in melanoma, as well as a new indication in advanced microsatellite instability-high tumors.
Lynparza[(1)]	December 2019	FDA approved Lynparza for first-line maintenance therapy for patients with germline *BRCA*-mutated (g*BRCA*-m) metastatic pancreatic cancer whose disease has not progressed for at least 16 weeks of a first-line, platinum-based chemotherapy regimen.
	December 2019	NMPA approved Lynparza as a first-line maintenance therapy in *BRCA*-m advanced ovarian cancer.
	July 2019	EC approved Lynparza as monotherapy for the maintenance treatment of adult patients with advanced *BRCA*-m, high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer.
	June 2019	MHLW approved Lynparza as first-line maintenance therapy in patients with *BRCA*-m advanced ovarian cancer.
	June 2019	EC approved Lynparza for use as first-line maintenance therapy in patients with *BRCA*-m advanced ovarian cancer.
	April 2019	EC approved Lynparza for the treatment of g*BRCA*-m HER2-negative advanced breast cancer.
Pifeltro and *Delstrigo*	September 2019	FDA approved supplemental New Drug Applications (sNDAs) for *Pifeltro* (doravirine) in combination with other antiretroviral agents, and *Delstrigo* (doravirine, lamivudine, and tenofovir disoproxil fumarate) as a complete regimen, for use in appropriate adults with HIV-1 infection who are virologically suppressed on a stable antiretroviral regimen.

Recarbrio	July 2019	FDA approved *Recarbrio* (imipenem, cilastatin, and relebactam) for the treatment of adults with complicated urinary tract and complicated intra-abdominal bacterial infections where limited or no alternative treatment options are available.
Zerbaxa	August 2019	EC approved *Zerbaxa* for the treatment of adults with hospital-acquired pneumonia, including ventilator-associated pneumonia (to be used in combination with an antibacterial agent active against Gram-positive pathogens when these are known or suspected to be contributing to the infectious process.)
	June 2019	FDA approved *Zerbaxa* 3g dose for the treatment of patients 18 years and older with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP).
Bravecto	November 2019	FDA approved *Bravecto Plus* topical solution for cats indicated for both external and internal parasite infestations.

[(1)] *In July 2017, Merck and AstraZeneca entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza.*

Competition and the Health Care Environment

Competition

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

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

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

Health Care Environment and Government Regulation

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access. In the United States, federal and state governments for many years also have pursued methods to reduce the cost of drugs and vaccines for which they pay. For example, federal laws require the Company to pay specified rebates for medicines reimbursed by Medicaid and to provide discounts for outpatient medicines purchased by certain Public Health Service entities and hospitals serving a disproportionate share of low income or uninsured patients.

Against this backdrop, the United States enacted major health care reform legislation in 2010 (the Patient Protection and Affordable Care Act (ACA)). Various insurance market reforms have since advanced and state and federal insurance exchanges were launched in 2014. With respect to the effect of the law on the pharmaceutical industry, the law increased the mandated Medicaid rebate from 15.1% to 23.1%, expanded the rebate to Medicaid managed care utilization, and increased the types of entities eligible for the federal 340B drug discount program. The law also required pharmaceutical manufacturers to pay a 50% point of service discount to Medicare Part D beneficiaries when they are in the Medicare Part D coverage gap (i.e., the so-called "donut hole"). As a result of the Balanced Budget Act of 2018 and effective at the beginning of 2019, the 50% point of service discount increased to a 70% point of service discount in the coverage gap. In addition, this point of service discount was extended to biosimilar products. Merck recorded a reduction to revenue of approximately $615 million, $365 million and $385 million in 2019, 2018 and 2017, respectively, related to the donut hole provision. Also, pharmaceutical manufacturers are required to pay an annual non-tax deductible health care reform fee. The total annual industry fee was $4.1 billion in 2018 and decreased to $2.8 billion in 2019 and is expected to remain at that amount for 2020. The fee is assessed on each company in proportion to its share of prior year branded pharmaceutical sales to certain government programs, such as Medicare and Medicaid. The Company recorded $112 million, $124 million and $210 million of costs within *Selling, general and administrative* expenses in 2019, 2018 and 2017, respectively, for the annual health care reform fee. In February 2016, the Centers for Medicare & Medicaid Services (CMS) issued the Medicaid rebate final rule that implements provisions of the ACA effective April 1, 2016. The rule provides comprehensive guidance on the calculation of Average Manufacturer Price and Best Price; two metrics utilized to determine the rebates drug manufacturers are required to pay to state Medicaid programs. The impact of changes resulting from the issuance of the rule is not material to Merck at this time. However, the Company is still awaiting guidance from CMS on two aspects of the rule that were deferred for later implementation. These include a definition of what constitutes a product 'line extension' and a delay in the participation of the U.S. Territories in the Medicaid Drug Rebate Program until April 1, 2022. The Company will evaluate the financial impact of these two elements when they become effective.

There is significant uncertainty about the future of the ACA in particular and health care laws in general in the United States. The Company is participating in the debate, and monitoring how any proposed changes could affect its business. The Company is unable to predict the likelihood of changes to the ACA. Depending on the nature of any repeal and replacement of the ACA, such actions could have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects.

A number of states have passed pharmaceutical price and cost transparency laws. These laws typically require manufacturers to report certain product price information or other financial data to the state. Some laws also require manufacturers to provide advance notification of price increases. The Company expects that states will continue their focus on pharmaceutical price transparency and that this focus will continue to exert pressure on product pricing.

The Company also faces increasing pricing pressure globally from managed care organizations, government agencies and programs that could negatively affect the Company's sales and profit margins. In the United States, these include (i) practices of managed care organizations, federal and state exchanges, and institutional and governmental purchasers, and (ii) U.S. federal laws and regulations related to Medicare and Medicaid, including the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and the ACA.

Changes to the health care system enacted as part of health care reform in the United States, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, could result in further pricing pressures. As an example, health care reform is contributing to an increase in the number of patients in the Medicaid program under which sales of pharmaceutical products are subject to substantial rebates.

The pharmaceutical industry could be considered a potential source of savings via legislative proposals that have been debated but not enacted. These types of revenue generating or cost saving proposals include additional direct price controls. In addition, Congress and/or the administration may again consider proposals to allow international reference pricing or, under certain conditions, the importation of medicines from other countries.

The administration has recently proposed a draft rule that would allow importation of certain lower-cost prescription drugs from Canada. If the rule is finalized as proposed, states or certain other non-federal governmental entities would be able to submit importation program proposals to the FDA for review and authorization of two-year programs (with the opportunity to extend for two more years). There will be a public comment period on the proposed rule which will expire on March 9, 2020. Following the comment period, the FDA will have to review and finalize its

proposal before any states or other parties can submit their plans to comply with the federal rule. If the proposed rule is adopted, it likely will be some time before states or other parties can actually implement importation plans.

In October 2018, the administration also issued an advance notice of proposed rulemaking to implement an "International Pricing Index" (IPI) model in the United States for products covered under Medicare Part B. The proposal would: (1) reduce Medicare Part B payments for drugs based on a market basket of international prices; (2) allow private sector vendors to negotiate prices for drugs, take title to drugs, and compete for physician and hospital business; and (3) change the physician reimbursement under Medicare Part B from the current model to eliminate the buy and bill system and instead pay physicians based on a flat fee that approximates the revenue they currently receive from drugs. Public comments on the IPI proposal were accepted through late 2018 and it is unclear when the agency may issue a proposed rule on the IPI model. Adoption of one or both of the proposed rules could have a material adverse effect on the Company's business, results of operations and financial condition.

It remains uncertain as to what proposals, if any, may be included as part of future federal legislative proposals that would directly or indirectly affect the Company.

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

In order to provide information about the Company's pricing practices, the Company annually posts on its website its Pricing Transparency Report for the United States. The report provides the Company's average annual list price, net price increases, and average discounts across the Company's U.S. portfolio dating back to 2010. In 2019, the Company's gross U.S. sales were reduced by approximately 44% as a result of rebates, discounts and returns.

Efforts toward health care cost containment also remain intense in European countries. The Company faces competitive pricing pressure resulting from generic and biosimilar drugs. In addition, a majority of countries in Europe attempt to contain drug costs by engaging in reference pricing in which authorities examine pre-determined markets for published prices of drugs by brand. The authorities then use price data from those markets to set new local prices for brand-name drugs, including the Company's drugs. Guidelines for examining reference pricing are usually set in local markets and can be changed pursuant to local regulations.

In addition, in Japan, the pharmaceutical industry is subject to government-mandated biennial price reductions of pharmaceutical products and certain vaccines, which occurred in 2018 and will occur again in 2020. Furthermore, the government can order re-pricings for specific products if it determines that use of such product will exceed certain thresholds defined under applicable re-pricing rules. Pursuant to those rules, the Japanese government reduced the price of *Keytruda* by 17.5% effective February 2020. Additionally, *Keytruda* will be subject to another significant price reduction in April 2020 under a provision of the Japanese pricing rules.

The Company's business in China has grown rapidly in the past few years, and the importance of China to the Company's overall pharmaceutical and vaccines business has increased accordingly. Continued growth of the Company's business in China is dependent upon ongoing development of a favorable environment for innovative pharmaceutical products and vaccines, sustained access for the Company's current in-line products, and the absence of trade impediments or adverse pricing controls. In recent years, the Chinese government has introduced and implemented a number of structural reforms to accelerate the shift to innovative products and reduce costs. Since 2017, there have been multiple new policies introduced by the government to improve access to new innovation, reduce the

complexity of regulatory filings, and accelerate the review and approval process. This has led to a significant increase in the number of new products being approved each year. Additionally, in 2017, the Chinese government updated the National Reimbursement Drug List for the first time in eight years. While the mechanism for drugs being added to the list evolves, inclusion may require a price negotiation which could impact the outlook in the market for selected brands. In 2019, drugs were added through two pathways, direct inclusion and price negotiations. For price negotiations, price reductions of approximately 60% on average were required for inclusion. While pricing pressure has always existed in China, health care reform has increased this pressure in part due to the acceleration of generic substitution through volume based procurement (VBP). In 2019, the government implemented the VBP program through a tendering process for mature products which have generic substitutes with a Generic Quality Consistency Evaluation approval. Mature products that have entered into the first two rounds of VBP have had, on average, a price reduction of 50%. The expansion of the VBP program remains to be seen.

The Company's focus on emerging markets, in addition to China, has continued. Governments in many emerging markets are also focused on constraining health care costs and have enacted price controls and related measures, such as compulsory licenses, that aim to put pressure on the price of pharmaceuticals and constrain market access. The Company anticipates that pricing pressures and market access challenges will continue in 2020 to varying degrees in the emerging markets, including China.

Certain markets outside of the United States have also implemented other cost management strategies, such as health technology assessments (HTA). Examples include the UK, France, Germany, Ireland, Italy and Sweden. The HTA process is the procedure according to which the assessment of the public health impact, therapeutic impact, and the economic and social impact of use of a given medicinal product in the national health care system of the individual country is conducted. HTAs generally focus on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual medicinal products as well as their potential implications for the health care system. Those elements of medicinal products are compared with other treatment options available on the market. The outcome of HTAs will often influence the pricing and reimbursement status granted to medicinal products by the regulatory authorities of individual European Union (EU) Member States. A negative HTA of one of the Company's products by a leading and recognized HTA body could undermine the Company's ability to obtain reimbursement for such product in the EU Member State in which such negative assessment was issued, and also in other EU Member States. HTA procedures require additional data, reviews and administrative processes, all of which increase the complexity, timing and costs of obtaining product reimbursement and exert downward pressure on available reimbursement. In the United States, HTAs are also being used by government and private payers.

Beyond pricing and market access challenges, other conditions in emerging market countries can affect the Company's efforts to continue to grow in these markets, including potential political instability, changes in trade sanctions and embargoes, significant currency fluctuation and controls, financial crises, limited or changing availability of funding for health care, and other developments that may adversely impact the business environment for the Company. Further, the Company may engage third-party agents to assist in operating in emerging market countries, which may affect its ability to realize continued growth and may also increase the Company's risk exposure.

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

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

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

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

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

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

Access to Medicines

As a global health care company, Merck's primary role is to discover and develop innovative medicines and vaccines. The Company also recognizes that it has an important role to play in helping to improve access to its medicines, vaccines, and to quality health care around the world. The Company's efforts in this regard are wide-ranging and include a set of principles that the Company strives to embed into its operations and business strategies to guide the Company's worldwide approach to expanding access to health care. In addition, through innovative social investments, including philanthropic programs and impact investing, Merck is also helping to strengthen health systems and build capacity, particularly in under-resourced communities. The Merck Patient Assistance Program provides medicines and adult vaccines for free to people in the United States who do not have prescription drug or health insurance coverage and who, without the Company's assistance, cannot afford their Merck medicines and vaccines. In 2011, Merck launched "Merck for Mothers," a long-term effort with global health partners to end preventable deaths from complications of pregnancy and childbirth. Merck has also provided funds to the Merck Foundation, an independent grantmaking organization, which has partnered with a variety of organizations dedicated to improving global health.

Privacy and Data Protection

The Company is subject to a significant number of privacy and data protection laws and regulations globally, many of which place restrictions on the Company's ability to transfer, access and use personal data across its business. The legislative and regulatory landscape for privacy and data protection continues to evolve. There has been increased attention to privacy and data protection issues in both developed and emerging markets with the potential to affect directly the Company's business, including both the EU General Data Protection Regulation, which went into effect on May 25, 2018 and imposes penalties of up to 4% of global revenue, and the California Consumer Privacy Act, which became effective January 1, 2020. Additional laws and regulations enacted in the United States, Europe, Asia and Latin America, increased enforcement and litigation activity in the United States and other developed markets, and increased regulatory cooperation among privacy authorities globally. The Company has adopted a comprehensive global privacy program to manage these evolving risks which has been certified as compliant with and approved by the Asia Pacific Economic Cooperation Cross-Border Privacy Rules System, the EU-U.S. and Swiss-U.S. Privacy Shield Programs, and the Binding Corporate Rules in the EU.

Distribution

The Company sells its human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers, such as health maintenance organizations, pharmacy

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

Raw Materials

Raw materials and supplies, which are generally available from multiple sources, are purchased worldwide and are normally available in quantities adequate to meet the needs of the Company's business.

Patents, Trademarks and Licenses

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

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

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

Product	Year of Expiration (U.S.)	Year of Expiration (EU)[1]	Year of Expiration (Japan)[2]	Year of Expiration (China)
Emend for Injection	Expired	2020[3]	2020	N/A
Januvia	2022[3]	2022[3]	2025-2026	2022
Janumet	2022[3]	2023	N/A	2022
Janumet XR	2022[3]	N/A	N/A	2022
Isentress	2024	2023[3]	2022-2026	2022
Simponi	N/A[4]	2024[5]	N/A[4]	N/A[4]
Lenvima[6]	2025[3] (with pending PTE)	2021 (patents), 2026[3] (SPCs)	2026	2021
Adempas[7]	2026[3]	2028[3]	2027-2028	2023
Bridion	2026[3] (with pending PTE)	2023	2024	2020
Nexplanon	2027 (device)	2025 (device)	Not Marketed	2025
Bravecto	2027 (with pending PTE)	2025 (patents), 2029 (SPCs)	2029	2033
Gardasil	2028	2021[3]	Expired	N/A
Gardasil 9	2028	2025 (patents), 2030[3] (SPCs)	N/A	2025
Keytruda	2028	2028 (patents), 2030[3] (SPCs)	2032-2033	2028
Lynparza[8]	2028[3] (with pending PTE)	2024 (patents), 2029[3] (SPCs)	2028-2029	2024
Zerbaxa	2028[3]	2023 (patents), 2028[3] (SPCs)	2028 (with pending PTE)	N/A
Belsomra	2029[3]	N/A	2031	N/A
Prevymis	2029[3] (with pending PTE)	2024 (patents), 2029[3] (SPCs)	2029	N/A
Steglatro[9]	2031[3] (with pending PTE)	2029 (patents), 2034[3] (SPCs)	N/A	2029
Steglujan[9]	2031 (with pending PTE)	2029 (patents), 2034 (SPCs)	N/A	2029
Segluromet[9]	2031 (with pending PTE)	2029 (patents), 2034 (SPCs)	N/A	2029
Delstrigo	2032 (with pending PTE)	2031 (patents), 2033 (SPCs)	N/A	N/A
Pifeltro	2032 (with pending PTE)	2031 (patents), 2033 (SPCs)	N/A	N/A
Recarbrio	2033[3] (with pending PTE)	N/A	N/A	N/A

Note: Compound patent unless otherwise noted. Certain of the products listed may be the subject of patent litigation. See Item 8. "Financial Statements and Supplementary Data," Note 10. "Contingencies and Environmental Liabilities" below.

N/A: Currently no marketing approval.

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

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

(3) *Eligible for 6 months Pediatric Exclusivity.*

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

(5) *Expiration of the distribution agreement with Janssen Pharmaceuticals, Inc.*

(6) *Part of a global strategic oncology collaboration with Eisai.*

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

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

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

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

Phase 3 Drug Candidate	Currently Anticipated Year of Expiration (in the U.S.)
MK-7264 (gefapixant)	2027
MK-1242 (vericiguat)[(1)]	2031
V114 (pneumoconjugate vaccine)	2031
MK-8591A (islatravir/doravirine)	2032

[(1)] *Being developed in a worldwide collaboration with Bayer AG.*

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

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

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

For further information with respect to the Company's patents, see Item 1A. "Risk Factors" and Item 8. "Financial Statements and Supplementary Data," Note 10. "Contingencies and Environmental Liabilities" below.

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

Royalty income in 2019 on patent and know-how licenses and other rights amounted to $135 million. Merck also incurred royalty expenses amounting to $1.7 billion in 2019 under patent and know-how licenses it holds.

Research and Development

The Company's business is characterized by the introduction of new products or new uses for existing products through a strong research and development program. At December 31, 2019, approximately 15,600 people were employed in the Company's research activities. The Company prioritizes its research and development efforts and focuses on candidates that it believes represent breakthrough science that will make a difference for patients and payers.

The Company maintains a number of long-term exploratory and fundamental research programs in biology and chemistry as well as research programs directed toward product development. The Company's research and development model is designed to increase productivity and improve the probability of success by prioritizing the

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

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

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

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

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

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

in order to support approval. Resubmissions are subject to review period targets, which vary depending on the underlying submission type and the content of the resubmission.

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

In addition, under the Generating Antibiotic Incentives Now Act, the FDA may grant Qualified Infectious Disease Product (QIDP) status to antibacterial or antifungal drugs intended to treat serious or life threatening infections including those caused by antibiotic or antifungal resistant pathogens, novel or emerging infectious pathogens, or other qualifying pathogens. QIDP designation offers certain incentives for development of qualifying drugs, including Priority Review of the NDA when filed, eligibility for Fast Track designation, and a five-year extension of applicable exclusivity provisions under the Food, Drug and Cosmetic Act.

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

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

Research and Development Update

The Company currently has several candidates under regulatory review in the United States and internationally.

Keytruda is an anti-PD-1 therapy approved for the treatment of many cancers that is in clinical development for expanded indications. These approvals were the result of a broad clinical development program that currently consists of more than 1,000 clinical trials, including more than 600 trials that combine *Keytruda* with other cancer treatments. These studies encompass more than 30 cancer types including: biliary tract, cervical, colorectal, cutaneous squamous cell, endometrial, gastric, head and neck, hepatocellular, Hodgkin lymphoma, non-Hodgkin lymphoma, melanoma, mesothelioma, nasopharyngeal, non-small-cell lung, ovarian, PMBCL, prostate, renal, small-cell lung, triple-negative breast, and urothelial, many of which are currently in Phase 3 clinical development. Further trials are being planned for other cancers.

Keytruda is under review in the EU as monotherapy for the first-line treatment of patients with stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC, and whose tumors express PD-L1 (TPS ≥1%) with no EGFR or ALK genomic tumor aberrations based on results from the Phase 3 KEYNOTE-042 trial.

Keytruda is under review in Japan as monotherapy and in combination with chemotherapy for the first-line treatment of advanced gastric or gastroesophageal junction adenocarcinoma based on results from the pivotal Phase 3 KEYNOTE-062 trial.

Keytruda is also under review in Japan as monotherapy for the second-line treatment of advanced or metastatic esophageal or esophagogastric junction carcinoma based on the results of the Phase 3 KEYNOTE-181 trial. Merck has made the decision to withdraw its Type II variation application for *Keytruda* for this indication in the EU.

In October 2019, the FDA accepted a supplemental BLA seeking use of *Keytruda* for the treatment of patients with recurrent and/or metastatic cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation based on the results of the KEYNOTE-629 trial. The FDA set a PDUFA date of June 29, 2020.

In February 2020, Merck announced the FDA issued a Complete Response Letter (CRL) regarding Merck's supplemental BLAs seeking to update the dosing frequency for *Keytruda* to include a 400 mg dose infused over 30 minutes every-six-weeks (Q6W) option in multiple indications. The submitted applications are based on pharmacokinetic modeling and simulation data presented at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting. These data supported the EC approval of 400 mg Q6W dosing for *Keytruda* monotherapy indications in March 2019. Merck is reviewing the letter and will discuss next steps with the FDA.

Additionally, *Keytruda* has received Breakthrough Therapy designation from the FDA in combination with neoadjuvant chemotherapy for the treatment of high-risk early-stage triple-negative breast cancer (TNBC) and in combination with enfortumab vedotin, in the first-line setting for the treatment of patients with unresectable locally advanced or metastatic urothelial cancer who are not eligible for cisplatin-containing chemotherapy. The FDA's Breakthrough Therapy designation is intended to expedite the development and review of a candidate that is planned for use, alone or in combination, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

In September 2019, Merck announced results from the pivotal neoadjuvant/adjuvant Phase 3 KEYNOTE-522 trial in patients with early-stage TNBC. The trial investigated a regimen of neoadjuvant *Keytruda* plus chemotherapy, followed by adjuvant *Keytruda* as monotherapy (the *Keytruda* regimen) compared with a regimen of neoadjuvant chemotherapy followed by adjuvant placebo (the chemotherapy-placebo regimen). Interim findings were presented at the European Society for Medical Oncology (ESMO) 2019 Congress. In the neoadjuvant phase, *Keytruda* plus chemotherapy resulted in a statistically significant increase in pathological complete response (pCR) versus chemotherapy in patients with early-stage TNBC. The improvement seen when adding *Keytruda* to neoadjuvant chemotherapy was observed regardless of PD-L1 expression. In the other dual primary endpoint of event-free-survival (EFS), with a median follow-up of 15.5 months, the *Keytruda* regimen reduced the risk of progression in the neoadjuvant phase and recurrence in the adjuvant phase compared with the chemotherapy-placebo regimen. Merck continues to discuss interim analysis data from KEYNOTE-522 with regulatory authorities. The *Keytruda* breast cancer clinical development program encompasses several internal and external collaborative studies.

In February 2020, Merck announced that the pivotal Phase 3 KEYNOTE-355 trial investigating *Keytruda* in combination with chemotherapy met one of its dual primary endpoints of progression-free survival (PFS) in patients with metastatic triple-negative breast cancer (mTNBC) whose tumors expressed PD-L1 (CPS ≥10). Based on an interim analysis conducted by an independent Data Monitoring Committee (DMC), first-line treatment with *Keytruda* in combination with chemotherapy (nab-paclitaxel, paclitaxel or gemcitabine/carboplatin) demonstrated a statistically significant and clinically meaningful improvement in PFS compared to chemotherapy alone in these patients. Based on the recommendation of the DMC, the trial will continue without changes to evaluate the other dual primary endpoint of overall survival (OS).

In May 2019, Merck announced that the Phase 3 KEYNOTE-119 trial evaluating *Keytruda* as monotherapy for the second- or third-line treatment of patients with metastatic TNBC did not meet its pre-specified primary endpoint of superior OS compared to chemotherapy. Other endpoints were not formally tested per the study protocol because the primary endpoint of OS was not met.

In June 2019, Merck announced full results from the pivotal Phase 3 KEYNOTE-062 trial evaluating *Keytruda* as monotherapy and in combination with chemotherapy for the first-line treatment of advanced gastric or gastroesophageal junction adenocarcinoma. In the monotherapy arm of the study, *Keytruda* met a primary endpoint by demonstrating noninferiority to chemotherapy, the current standard of care, for OS in patients whose tumors expressed PD-L1 (CPS ≥1). In the combination arm of KEYNOTE-062, *Keytruda* plus chemotherapy was not found to be statistically superior for OS (CPS ≥1 or CPS ≥10) or PFS (CPS ≥1) compared with chemotherapy alone. Results were presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting. In September 2017, the FDA

approved *Keytruda* as a third-line treatment for previously treated patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction cancer whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test. KEYNOTE-062 was a potential confirmatory trial for this accelerated, third-line approval. In addition to KEYNOTE-062, additional first-line, Phase 3 studies in Merck's gastric clinical program include KEYNOTE-811 and KEYNOTE-859, as well as KEYNOTE-585 in the neoadjuvant and adjuvant treatment setting.

In January 2020, Merck announced that the Phase 3 KEYNOTE-604 trial investigating *Keytruda* in combination with chemotherapy met one of its dual primary endpoints of PFS in the first-line treatment of patients with extensive stage SCLC. At the final analysis of the study, there was also an improvement in OS for patients treated with *Keytruda* in combination with chemotherapy compared to chemotherapy alone; however, these OS results did not meet statistical significance per the pre-specified statistical plan. Results will be presented at an upcoming medical meeting and discussed with regulatory authorities.

Lynparza, is an oral PARP inhibitor currently approved for certain types of advanced ovarian, breast and pancreatic cancers being co-developed for multiple cancer types as part of a collaboration with AstraZeneca.

Lynparza is under review in the EU as a first-line maintenance monotherapy for patients with g*BRCA*m metastatic pancreatic cancer whose disease has not progressed following first-line platinum-based chemotherapy. Lynparza was approved for this indication by the FDA in December 2019 based on results from the Phase 3 POLO trial. A decision from the EMA is expected in the second half of 2020.

In January 2020, the FDA accepted a supplemental NDA for Lynparza in combination with bevacizumab for the maintenance treatment of women with advanced ovarian cancer whose disease showed a complete or partial response to first-line treatment with platinum-based chemotherapy and bevacizumab based on the results from the pivotal Phase 3 PAOLA-1 trial. A PDUFA date is set for the second quarter of 2020. This indication is also under review in the EU.

In January 2020, the FDA accepted for Priority Review a supplemental NDA for Lynparza for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) and deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutations, who have progressed following prior treatment with a new hormonal agent based on positive results from the Phase 3 PROfound trial. A PDUFA date is set for the second quarter of 2020. This indication is also under review in the EU.

In June 2019, Merck and AstraZeneca presented full results from the Phase 3 SOLO-3 trial which evaluated Lynparza, compared to chemotherapy, for the treatment of platinum-sensitive relapsed patients with g*BRCA*m advanced ovarian cancer, who have received two or more prior lines of chemotherapy. The results from the trial showed a statistically-significant and clinically-meaningful improvement in objective response rate (ORR) in the Lynparza arm compared to the chemotherapy arm. The key secondary endpoint of PFS was also significantly increased in the Lynparza arm compared to the chemotherapy arm. The results were presented at the 2019 ASCO Annual Meeting.

MK-5618, selumetinib, is a MEK 1/2 inhibitor being co-developed as part of a strategic collaboration with AstraZeneca. Selumetinib is under Priority Review with the FDA as a potential new medicine for pediatric patients aged three years and older with neurofibromatosis type 1 (NF1) and symptomatic, inoperable plexiform neurofibromas. This regulatory submission was based on positive results from the National Cancer Institute Cancer Therapy Evaluation Program-sponsored SPRINT Phase 2 Stratum 1 trial. A PDUFA date is set for the second quarter of 2020.

V503 is under review in Japan for an initial indication in females for the prevention of certain HPV-related diseases and precursors.

In February 2020, the FDA accepted for Priority Review a supplemental BLA for *Gardasil* 9 for the prevention of certain head and neck cancers caused by vaccine-type HPV in females and males 9 through 45 years of age. The FDA set a PDUFA date of June 2020.

In addition to the candidates under regulatory review, the Company has several drug candidates in Phase 3 clinical development in addition to the *Keytruda* programs discussed above.

Lynparza, in addition to the indications under review discussed above, is in Phase 3 development in combination with *Keytruda* for the treatment of NSCLC.

Lenvima is an orally available tyrosine kinase inhibitor currently approved for certain types of thyroid cancer, HCC, and in combination for certain patients with RCC being co-developed as part of a strategic collaboration with Eisai. Pursuant to the agreement, the companies will jointly initiate clinical studies evaluating the *Keytruda*/ Lenvima combination in six types of cancer (endometrial cancer, NSCLC, HCC, HNSCC, bladder cancer and melanoma), as well as a basket trial targeting multiple cancer types. The FDA granted Breakthrough Therapy designation

for *Keytruda* in combination with Lenvima both for the potential treatment of patients with advanced and/or metastatic RCC and for the potential treatment of patients with unresectable HCC not amenable to locoregional treatment.

MK-7264, gefapixant, is a selective, non-narcotic, orally-administered P2X3-receptor antagonist being investigated in Phase 3 trials for the treatment of refractory, chronic cough and in a Phase 2 trial for the treatment of women with endometriosis-related pain.

MK-1242, vericiguat, is a sGC stimulator for the potential treatment of patients with worsening chronic heart failure being developed as part of a worldwide strategic collaboration between Merck and Bayer. Vericiguat is being studied in patients suffering from chronic heart failure with reduced ejection fraction (Phase 3 clinical trial) and from chronic heart failure with preserved ejection fraction (Phase 2 clinical trial). In November 2019, Merck announced that the Phase 3 VICTORIA study evaluating the efficacy and safety of vericiguat met the primary efficacy endpoint. Vericiguat reduced the risk of the composite endpoint of heart failure hospitalization or cardiovascular death in patients with worsening chronic heart failure with reduced ejection fraction compared to placebo when given in combination with available heart failure therapies. The results of the VICTORIA study will be presented at an upcoming medical meeting in 2020.

V114 is an investigational polyvalent conjugate vaccine for the prevention of pneumococcal disease. In June 2018, Merck initiated the first Phase 3 study in the adult population for the prevention of invasive pneumococcal disease. Currently six Phase 3 adult studies are ongoing, including studies in healthy adults 50 years of age or older, adults with risk factors for pneumococcal disease, those infected with HIV, and those who are recipients of allogeneic hematopoietic stem cell transplant. In October 2018, Merck began the first Phase 3 study in the pediatric population. Currently, eight studies are ongoing, including studies in healthy infants and in children afflicted with sickle cell disease. V114 has received Breakthrough Therapy designation from the FDA for the prevention of invasive pneumococcal disease caused by the vaccine serotypes in pediatric patients (6 weeks to 18 years of age) and in adults.

The chart below reflects the Company's research pipeline as of February 21, 2020. Candidates shown in Phase 3 include specific products and the date such candidate entered into Phase 3 development. Candidates shown in Phase 2 include the most advanced compound with a specific mechanism or, if listed compounds have the same mechanism, they are each currently intended for commercialization in a given therapeutic area. Small molecules and biologics are given MK-number designations and vaccine candidates are given V-number designations. Except as otherwise noted, candidates in Phase 1, additional indications in the same therapeutic area (other than with respect to cancer) and additional claims, line extensions or formulations for in-line products are not shown.

Phase 2	Phase 3 (Phase 3 Entry Date)	Under Review
Cancer	**Cancer**	**New Molecular Entities/Vaccines**
MK-3475 *Keytruda*	MK-3475 *Keytruda*	**Pediatric Neurofibromatosis Type-1**
Advanced Solid Tumors	Biliary Tract (September 2019)	MK-5618 (selumetinib)[1] (U.S.)
MK-6482	Breast (October 2015)	**HPV Vaccine**
Renal Cell Carcinoma	Cervical (October 2018) (EU)	V503 Human Papillomavirus 9-valent Vaccine, Recombinant (JPN)
MK-7123[2]	Colorectal (November 2015)	**Certain Supplemental Filings**
Solid Tumors	Cutaneous Squamous Cell Carcinoma (August 2019) (EU)	**Cancer**
MK-7339 Lynparza[1]	Endometrial (August 2019) (EU)	MK-3475 *Keytruda*
Advanced Solid Tumors	Esophageal (December 2015) (EU)	• First-Line Metastatic Non-Small-Cell Lung Cancer (KEYNOTE-042) (EU)
MK-7690 (vicriviroc)[2]	Gastric (May 2015) (EU)	• First-Line Metastatic Gastric Cancer (KEYNOTE-062) (JPN)
Colorectal	Hepatocellular (May 2016) (EU)	• Recurrent Locally Advanced or Metastatic Esophageal Cancer (KEYNOTE-180/181) (JPN)
MK-7902 Lenvima[1]	Mesothelioma (May 2018)	• Recurrent and/or Metastatic Cutaneous Squamous Cell Carcinoma (KEYNOTE-629) (U.S.)
Biliary Tract	Nasopharyngeal (April 2016)	• Alternative Dosing Regimen[3] (Q6W) (U.S.)
V937	Ovarian (December 2018)	MK-7339 Lynparza[1]
Melanoma	Prostate (May 2019)	• First-Line g*BRCA*m Pancreatic Cancer (POLO) (EU)
MK-7684[2]	Small-Cell Lung (May 2017) (EU)	• First-Line Maintenance Newly Diagnosed Advanced Ovarian Cancer (PAOLA) (U.S.) (EU)
Non-Small-Cell Lung	MK-7339 Lynparza[1,2]	• Metastatic Prostate Cancer (PROfound) (U.S.) (EU)
MK-1026	Non-Small-Cell Lung (June 2019)	
Hematological Malignancies	MK-7902 Lenvima[1,2]	
MK-4280[2]	Bladder (May 2019)	
Hematological Malignancies	Endometrial (June 2018) (EU)	
Non-Small-Cell Lung	Head and Neck Squamous Cell Carcinoma (February 2020)	
MK-1308[2]	Melanoma (March 2019)	
Non-Small-Cell Lung	Non-Small-Cell Lung (March 2019)	
MK-5890[2]	**Cough**	
Non-Small-Cell Lung	MK-7264 (gefapixant) (March 2018)	
Cytomegalovirus	**Heart Failure**	
V160	MK-1242 (vericiguat) (September 2016)[1]	
HIV-1 Infection	**HIV-1 Infection**	
MK-8591 (islatravir)	MK-8591A (islatravir/doravirine) (February 2020)	
Overgrowth Syndrome	**Pneumoconjugate Vaccine**	
MK-7075	V114 (June 2018)	
Pediatric Neurofibromatosis Type-1		
MK-5618 (selumetinib)[1] (EU)		
Respiratory Syncytial Virus		
MK-1654		
Schizophrenia		
MK-8189		

Footnotes:

[1] Being developed in a collaboration.

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

[3] The Company received a CRL in February 2020. Merck is reviewing the letter and will discuss next steps with the FDA.

Employees

As of December 31, 2019, the Company had approximately 71,000 employees worldwide, with approximately 26,000 employed in the United States, including Puerto Rico. Approximately 30% of worldwide employees of the Company are represented by various collective bargaining groups.

Restructuring Activities

In early 2019, Merck approved a new global restructuring program (Restructuring Program) as part of a worldwide initiative focused on further optimizing the Company's manufacturing and supply network, as well as reducing its global real estate footprint. This program is a continuation of the Company's plant rationalization, builds on prior restructuring programs and does not include any actions associated with the planned spin-off of NewCo. As the Company continues to evaluate its global footprint and overall operating model, it has subsequently identified additional actions under the Restructuring Program, and could identify further actions over time. The actions currently contemplated under the Restructuring Program are expected to be substantially completed by the end of 2023. Actions under previous global restructuring programs have been substantially completed.

Environmental Matters

The Company believes that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on the Company. The Company is also remediating environmental contamination resulting from past industrial activity at certain of its sites. Expenditures for remediation and environmental liabilities were $19 million in 2019 and are estimated at $47 million in the aggregate for the years 2020 through 2024. These amounts do not consider potential recoveries from other parties. The Company has taken an active role in identifying and accruing for these costs and, in management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $67 million and $71 million at December 31, 2019 and 2018, respectively. Although it is not possible to predict with certainty the outcome

of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed $58 million in the aggregate. Management also does not believe that these expenditures should have a material adverse effect on the Company's financial condition, results of operations, liquidity or capital resources for any year.

Merck believes that climate change could present risks to its business. Some of the potential impacts of climate change to its business include increased operating costs due to additional regulatory requirements, physical risks to the Company's facilities, water limitations and disruptions to its supply chain. These potential risks are integrated into the Company's business planning including investment in reducing energy, water use and greenhouse gas emissions. The Company does not believe these risks are material to its business at this time.

Geographic Area Information

The Company's operations outside the United States are conducted primarily through subsidiaries. Sales worldwide by subsidiaries outside the United States as a percentage of total Company sales were 57% of sales in each of 2019, 2018 and 2017.

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

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

Available Information

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

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

Item 1A. Risk Factors.

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

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

Patent protection is considered, in the aggregate, to be of material importance to the Company's marketing of human health and animal health products in the United States and in most major foreign markets. Patents covering products that it has introduced normally provide market exclusivity, which is important for the successful marketing

and sale of its products. The Company seeks patents covering each of its products in each of the markets where it intends to sell the products and where meaningful patent protection is available.

Even if the Company succeeds in obtaining patents covering its products, third parties or government authorities may challenge or seek to invalidate or circumvent its patents and patent applications. It is important for the Company's business to defend successfully the patent rights that provide market exclusivity for its products. The Company is often involved in patent disputes relating to challenges to its patents or claims by third parties of infringement against the Company. The Company defends its patents both within and outside the United States, including by filing claims of infringement against other parties. See Item 8. "Financial Statements and Supplementary Data," Note 10. "Contingencies and Environmental Liabilities" below. In particular, manufacturers of generic pharmaceutical products from time to time file abbreviated NDAs with the FDA seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned or licensed by the Company. The Company normally responds by defending its patent, including by filing lawsuits alleging patent infringement. Patent litigation and other challenges to the Company's patents are costly and unpredictable and may deprive the Company of market exclusivity for a patented product or, in some cases, third-party patents may prevent the Company from marketing and selling a product in a particular geographic area.

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

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

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

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

The Company depends upon patents to provide it with exclusive marketing rights for its products for some period of time. Loss of patent protection for one of the Company's products typically leads to a significant and rapid loss of sales for that product as lower priced generic versions of that drug become available. In the case of products that contribute significantly to the Company's sales, the loss of market exclusivity can have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects. For example, the patents that provided U.S. and EU market exclusivity for certain forms of *Noxafil* expired in July 2019 and December 2019, respectively, and the Company anticipates a significant decline in U.S. and EU *Noxafil* sales. Also, the patent that provided U.S. market exclusivity for *NuvaRing* expired in April 2018 and generic competition began in December 2019. The Company anticipates a rapid and substantial decline in U.S. *NuvaRing* sales in 2020 as a result of this generic competition. In addition, the patents that provide market exclusivity for *Januvia* and *Janumet* in the U.S. expire in July 2022 (although six-month pediatric exclusivity may extend this date). The patent that provides market exclusivity for *Januvia* in the EU expires in July 2022 (although pediatric exclusivity may extend this date to September 2022). Finally, the SPC that provides market exclusivity for *Janumet* in the EU expires in April 2023. The Company anticipates sales of *Januvia* and *Janumet* in these markets will decline substantially after these patent expiries.

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

The Company's ability to generate profits and operating cash flow depends largely upon the continued profitability of the Company's key products, such as *Keytruda, Gardasil/Gardasil* 9, *Januvia*, *Janumet*, and *Bridion*. In particular, in 2019, the Company's oncology portfolio, led by *Keytruda,* represented the majority of the Company's revenue and earnings growth. As a result of the Company's dependence on key products, any event that adversely affects any of these products or the markets for any of these products could have a significant adverse impact on results of operations and cash flows. These events could include loss of patent protection, increased costs associated with manufacturing, generic or over-the-counter availability of the Company's product or a competitive product, the discovery of previously unknown side effects, results of post-approval trials, increased competition from the introduction of new, more effective treatments and discontinuation or removal from the market of the product for any reason. Such events could have a material adverse effect on the sales of any such products.

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

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

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

The Company cannot state with certainty when or whether any of its products now under development will be approved or launched; whether it will be able to develop, license or otherwise acquire compounds, product candidates or products; or whether any products, once launched, will be commercially successful. The Company must maintain a continuous flow of successful new products and successful new indications or brand extensions for existing products sufficient both to cover its substantial research and development costs and to replace sales that are lost as profitable products lose market exclusivity or are displaced by competing products or therapies. Failure to do so in the short term or long term would have a material adverse effect on the Company's business, results of operations, cash flow, financial condition and prospects.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The Company faces intense competition from lower cost generic products.

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

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

The Company faces intense competition from competitors' products.

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

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

The Company faces continued pricing pressure globally and, particularly in mature markets, from managed care organizations, government agencies and programs that could negatively affect the Company's sales and profit margins. In the United States, these include (i) practices of managed care groups and institutional and governmental purchasers, (ii) U.S. federal laws and regulations related to Medicare and Medicaid, including the Medicare Prescription Drug Improvement and Modernization Act of 2003 and the ACA, and (iii) state activities aimed at increasing price transparency, including new laws as noted above in Item 1. "Competition and the Health Care Environment — Health

Care Environment and Government Regulations." Changes to the health care system enacted as part of health care reform in the United States, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, could result in further pricing pressures. In addition, in the United States, larger customers have received higher rebates on drugs in certain highly competitive categories. The Company must also compete to be placed on formularies of managed care organizations. Exclusion of a product from a formulary can lead to reduced usage in the managed care organization.

In order to provide information about the Company's pricing practices, the Company annually posts on its website its Pricing Transparency Report for the United States. The report provides the Company's average annual list price and net price increases across the Company's U.S. portfolio dating back to 2010. In 2019, the Company's gross U.S. sales were reduced by approximately 44% as a result of rebates, discounts and returns.

Outside the United States, numerous major markets, including the EU, Japan and China have pervasive government involvement in funding health care and, in that regard, fix the pricing and reimbursement of pharmaceutical and vaccine products. Consequently, in those markets, the Company is subject to government decision making and budgetary actions with respect to its products. In Japan, the pharmaceutical industry is subject to government-mandated biennial price reductions of pharmaceutical products and certain vaccines, which will occur again in 2020. Furthermore, the government can order re-pricing for specific products if it determines that use of such product will exceed certain thresholds defined under applicable re-pricing rules. For example, pursuant to a re-pricing rule, the Japanese government reduced the price of *Keytruda* by 17.5%, effective February 2020. Additionally, *Keytruda* will be subject to another significant price reduction in April 2020 under a provision of the Japanese pricing rules.

The Company expects pricing pressures to continue in the future.

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

The Company believes that the health care industry will continue to be subject to increasing regulation as well as political and legal action, as future proposals to reform the health care system are considered by the Executive branch, Congress and state legislatures.

In 2010, the United States enacted major health care reform legislation in the form of the ACA. Various insurance market reforms have advanced and state and federal insurance exchanges were launched in 2014. The ACA increased the mandated Medicaid rebate from 15.1% to 23.1%, expanded the rebate to Medicaid managed care utilization, and increased the types of entities eligible for the federal 340B drug discount program.

The ACA also requires pharmaceutical manufacturers to pay a point of service discount to Medicare Part D beneficiaries when they are in the Medicare Part D coverage gap (i.e., the so-called "donut hole") which increased to 70% in 2019 and was extended to biosimilar products. In 2019, the Company's revenue was reduced by approximately $615 million due to this requirement. Also, pharmaceutical manufacturers are required to pay an annual non-tax deductible health care reform fee. In 2019, the Company recorded $112 million of costs for this annual fee.

In 2016, the Centers for Medicare & Medicaid Services (CMS) issued the Medicaid rebate final rule that implements provisions of the ACA effective April 1, 2016. The rule provides comprehensive guidance on the calculation of Average Manufacturer Price and Best Price; two metrics utilized to determine the rebates drug manufacturers are required to pay to state Medicaid programs. The impact of changes resulting from the issuance of the rule is not material to Merck at this time. However, the Company is still awaiting guidance from CMS on two aspects of the rule that were deferred for later implementation. These include a definition of what constitutes a product 'line extension' and a delay in the participation of the U.S. Territories in the Medicaid Drug Rebate Program until April 1, 2022. The Company will evaluate the financial impact of these two elements when they become effective.

In addition, as discussed above in "Competition and the Health Care Environment," the administration has recently proposed a draft rule that would allow importation of certain lower-cost prescription drugs from Canada. If the rule is finalized as proposed, states or certain other non-federal governmental entities would be able to submit importation program proposals to the FDA for review and authorization of two-year programs (with the opportunity to extend for two more years). There will be a public comment period on the proposed rule which will expire on March 9, 2020. Following the comment period, the FDA will have to review and finalize its proposal before any states or other

parties can submit their plans to comply with the federal rule. If the proposed rule is adopted, it likely will be some time before states or other parties can actually implement importation plans.

Also, in October 2018, the administration issued an advance notice of proposed rulemaking to implement an "International Pricing Index" (IPI) model in the United States for products covered under Medicare Part B. The proposal would: (1) reduce Medicare Part B payments for drugs based on a market basket of international prices; (2) allow private sector vendors to negotiate prices for drugs, take title to drugs, and compete for physician and hospital business; and (3) change the physician reimbursement under Medicare Part B from the current model to eliminate the buy and bill system and instead pay physicians based on a flat fee that approximates the revenue they currently receive from drugs. Public comments on the IPI proposal were accepted through late 2018 and it is unclear when the agency may issue a proposed rule on the IPI model. Adoption of one or both of the proposed rules could have a material adverse effect on the Company's business, results of operations and financial condition.

The Company cannot predict the likelihood of additional future changes in the health care industry in general, or the pharmaceutical industry in particular, or what impact they may have on the Company's business, cash flow, results of operations, financial condition and prospects.

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

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

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

The Company has insurance coverage insuring against losses resulting from cyber-attacks and has received proceeds in connection with the 2017 cyber-attack. However, there are disputes with certain of the insurers about the availability of some of the insurance coverage for claims related to the 2017 cyber-attack.

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

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

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

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

The uncertainty in global economic conditions together with cost-reduction measures being taken by certain governments could negatively affect the Company's operating results.

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

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. Changes to the U.S. health care system as part of health care reform, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, have contributed to pricing pressure. In several international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. In addition, the Company's revenue performance in 2019 was negatively affected by other cost-reduction measures taken by governments and other third-parties to lower health care costs. The Company anticipates all of these actions, and additional actions in the future, will continue to negatively affect revenue performance.

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

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

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

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

In addition, there may be changes to the Company's business and political position if there is instability, disruption or destruction in a significant geographic region, regardless of cause, including war, terrorism, riot, civil insurrection or social unrest; and natural or man-made disasters, including famine, flood, fire, earthquake, storm or disease.

In 2016, the United Kingdom (UK) held a referendum in which voters approved an exit from the EU, commonly referred to as "Brexit." As a result of that referendum and subsequent negotiations, the UK left the EU on January 31, 2020. A transitional period will apply from January 31, 2020 until December 31, 2020, and during this period the EU will treat the UK as if it were an EU Member State, and the UK will continue to participate in the EU Customs Union allowing for the freedom of movement for people and goods. During the transitional period the EU and the UK will continue to negotiate a trade agreement to formalize the terms of the UK's future relationship with the EU. The Company has taken actions and made certain contingency plans for scenarios in which the UK and the EU do not reach a mutually satisfactory understanding as to a future trade agreement. It is not possible at this time to predict whether there will be any such understanding before the end of 2020, or if such an understanding is reached, whether its terms will vary in ways that result in greater restrictions on imports and exports between the UK and EU countries, increased regulatory complexities, and/or cross border labor issues that could materially adversely impact the Company's business operations in the UK.

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

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

In the past, the Company has experienced difficulties and delays in manufacturing certain of its products, including vaccines.

Merck has, in the past, experienced difficulties in manufacturing certain of its products, including vaccines. In addition, the network cyber-attack experienced by the Company in June 2017 led to a disruption of the Company's operations, including its manufacturing operations. The Company may, in the future, experience difficulties and delays inherent in manufacturing its products, such as (i) failure of the Company or any of its vendors or suppliers to comply with Current Good Manufacturing Practices and other applicable regulations and quality assurance guidelines that could lead to manufacturing shutdowns, product shortages and delays in product manufacturing; (ii) delays related to the construction of new facilities or the expansion of existing facilities, including those intended to support future demand for the Company's products; and (iii) other manufacturing or distribution problems including changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, changes in types of products produced, or physical limitations that could impact continuous supply. In addition, the Company could experience difficulties or delays in manufacturing its products caused by natural disasters, such as hurricanes. For example, in 2017, the Company's lone manufacturing plant in Puerto Rico was negatively affected by Hurricane Maria. Manufacturing difficulties can result in product shortages, leading to lost sales and reputational harm to the Company.

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

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

The Company's business in China has grown rapidly in the past few years, and the importance of China to the Company's overall pharmaceutical and vaccines business outside the United States has increased accordingly. Continued growth of the Company's business in China is dependent upon ongoing development of a favorable environment for innovative pharmaceutical products and vaccines, sustained access for the Company's currently marketed products, and the absence of trade impediments or adverse pricing controls. As noted above in "*Health Care Environment and Government Regulation*," pricing pressure in China has increased as the Chinese government has been taking steps to reduce costs, including implementing healthcare reform that has led to the acceleration of generic

substitution, where available. While pricing pressure has always existed in China, health care reform has increased this pressure in part due to the acceleration of generic substitution through the government's VBP program. In 2019, the government implemented the VBP program through a tendering process for mature products which have generic substitutes with a Generic Quality Consistency Evaluation approval. Mature products that have entered into the first two rounds of VBP had, on average, a price reduction of 50%. The expansion of the VBP program remains to be seen. In addition, the Company anticipates that the reported inquiries made by various governmental authorities involving multinational pharmaceutical companies in China may continue.

Also, in December 2019, a new Coronavirus, now known as COVID-19, which has proved to be highly contagious, emerged in Wuhan, China. The outbreak of the virus has caused material disruptions to the Chinese economy, including its health care system, which will have a negative effect on the Company's first quarter 2020 results which, at this time, is not expected to be material. Since the future course and duration of the COVID-19 outbreak are unknown, the Company is currently unable to determine whether the outbreak will have a further negative effect on the Company's results in 2020. The outbreak of COVID-19 currently has also had a limited effect on the Company's supply chain of drugs into and raw materials out of China. The outbreak has also negatively affected certain of the Company's clinical trials.

For all these reasons, sales within emerging markets carry significant risks. However, a failure to maintain the Company's presence in emerging markets could have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects.

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

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

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

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

Certain of the Company's interest rate derivatives and investments are based on the London Interbank Offered Rate (LIBOR), and a portion of Merck's indebtedness bears interest at variable interest rates, primarily based on LIBOR. LIBOR is the subject of recent national, international and other regulatory guidance and proposals for reform, which may cause LIBOR to cease to exist entirely after 2021. While the Company expects that reasonable alternatives to LIBOR will be implemented prior to the 2021 target date, the Company cannot predict the consequences and timing of these developments, which could include an increase in interest expense and may also require the amendment of contracts that reference LIBOR.

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

The Company is subject to evolving and complex tax laws in the jurisdictions in which it operates. Significant judgment is required for determining the Company's tax liabilities, and the Company's tax returns are periodically examined by various tax authorities. The Company believes that its accrual for tax contingencies is adequate for all open years based on past experience, interpretations of tax law, and judgments about potential actions by tax authorities; however, due to the complexity of tax contingencies, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued. In addition, the Company may be negatively affected by changes in tax laws, or new tax laws, affecting, for example, tax rates, and/or revised tax law interpretations in domestic or foreign jurisdictions.

Pharmaceutical products can develop unexpected safety or efficacy concerns.

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

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

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

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

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

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

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

- There may be limited access to, and supply of, normal and diseased tissue samples, cell lines, pathogens, bacteria, viral strains and other biological materials. In addition, government regulations in multiple jurisdictions, such as the United States and the EU, could result in restricted access to, or transport or use of, such materials. If the Company loses access to sufficient sources of such materials, or if tighter restrictions are imposed on the use of such materials, the Company may not be able to conduct research activities as planned and may incur additional development costs.
- The development, manufacturing and marketing of biologics and vaccines are subject to regulation by the FDA, the EMA and other regulatory bodies. These regulations are often more complex and extensive than the regulations applicable to other pharmaceutical products. For example, in the United States, a BLA, including both pre-clinical and clinical trial data and extensive data regarding the manufacturing procedures, is required for human vaccine candidates, and FDA approval is generally required for the release of each manufactured commercial lot.
- Manufacturing biologics and vaccines, especially in large quantities, is often complex and may require the use of innovative technologies to handle living micro-organisms. Each lot of an approved biologic and vaccine must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to

the manufacturing process, the Company may be required to provide pre-clinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes.

- Biologics and vaccines are frequently costly to manufacture because production ingredients are derived from living animal or plant material, and most biologics and vaccines cannot be made synthetically. In particular, keeping up with the demand for vaccines may be difficult due to the complexity of producing vaccines.
- The use of biologically derived ingredients can lead to variability in the manufacturing process and could lead to allegations of harm, including infections or allergic reactions, which allegations would be reviewed through a standard investigation process that could lead to closure of product facilities due to possible contamination. Any of these events could result in substantial costs.

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

As a result of a number of factors, product liability insurance has become less available while the cost of such insurance has increased significantly. The Company is subject to a substantial number of product liability claims. See Item 8. "Financial Statements and Supplementary Data," Note 10. "Contingencies and Environmental Liabilities" below for more information on the Company's current product liability litigation. With respect to product liability, the Company self-insures substantially all of its risk, as the availability of commercial insurance has become more restrictive. The Company has evaluated its risks and has determined that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and, as such, has no insurance for most product liabilities. The Company will continually assess the most efficient means to address its risk; however, there can be no guarantee that insurance coverage will be obtained or, if obtained, will be sufficient to fully cover product liabilities that may arise.

Social media platforms present risks and challenges.

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

Risks Related to the Proposed Spin-Off of NewCo.

The proposed Spin-Off of NewCo may not be completed on the terms or timeline currently contemplated, if at all, and may not achieve the expected results.

In February 2020, the Company announced its intention to Spin-Off products from its women's health, trusted legacy brands and biosimilars businesses into a new, yet-to-be-named, independent, publicly traded company (NewCo) through a distribution of NewCo's publicly traded stock to Company shareholders. The distribution is expected to qualify as tax-free to the Company and its shareholders for U.S. federal income tax purposes. The transaction is expected to be completed in the first half of 2021. Completion of the Spin-Off will be subject to a number of factors and conditions, and there can be no assurances that the Company will be able to complete the Spin-Off on the terms or on the timeline that was announced, if at all. Unanticipated developments could delay, prevent or otherwise adversely affect the proposed Spin-Off, including but not limited to disruptions in general or financial market conditions or potential problems or delays in obtaining various regulatory and tax approvals or clearances. In addition, consummation of the proposed Spin-Off will require final approval from the Company's Board of Directors.

The costs to complete the proposed Spin-Off will be significant. In addition, the Company may be unable to achieve some or all of the strategic and financial benefits that it expects to achieve from the Spin-Off of NewCo.

The Company will incur significant expenses in connection with the Spin-Off. In addition, the Company may not be able to achieve the full strategic and financial benefits that are expected to result from the Spin-Off. The anticipated benefits of the Spin-Off are based on a number of assumptions, some of which may prove incorrect.

Following the Spin-Off, the price of shares of the Company's common stock may fluctuate significantly.

The Company cannot predict the effect of the Spin-Off on the trading price of shares of its common stock, and the market value of shares of its common stock may be less than, equal to or greater than the market value of shares of its common stock prior to the Spin-Off. In addition, the price of Merck's common stock may be more volatile around the time of the Spin-Off.

There could be significant income tax liability if the Spin-Off or certain related transactions are determined to be taxable for U.S. federal income tax purposes.

The Company expects that prior to completion of the Spin-Off it will receive an opinion from its U.S. tax counsel that concludes, among other things, that the Spin-Off of all of the outstanding NewCo shares to Merck shareholders and certain related transactions will qualify as tax-free to Merck and its shareholders under Sections 355, 361 and 368 of the U.S. Internal Revenue Code, except to the extent of any cash received in lieu of fractional shares of NewCo common stock. Any such opinion is not binding on the Internal Revenue Service (IRS). Accordingly, while the Company believes the risk is low, the IRS may reach conclusions with respect to the Spin-Off that are different from the conclusions reached in the opinion. The opinion will rely on certain facts, assumptions, representations and undertakings from Merck and NewCo regarding the past and future conduct of the companies' respective businesses and other matters, which, if incomplete, incorrect or not satisfied, could alter the conclusions of the party giving such opinion.

If the proposed Spin-Off ultimately is determined to be taxable, which the Company believes is unlikely, the Spin-Off could be treated as a taxable dividend to Merck's shareholders for U.S. federal income tax purposes, and Merck's shareholders could incur significant U.S. federal income tax liabilities. In addition, Merck would recognize a taxable gain to the extent that the fair market value of NewCo common stock exceeds Merck's tax basis in such stock on the date of the Spin-Off.

Cautionary Factors that May Affect Future Results

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

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

- Competition from generic and/or biosimilar products as the Company's products lose patent protection.
- Increased "brand" competition in therapeutic areas important to the Company's long-term business performance.

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

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

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

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

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

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

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

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

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

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

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

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

- The proposed Spin-Off might be delayed or the costs to complete the Spin-Off might be more significant than expected.

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

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

The Company's corporate headquarters is located in Kenilworth, New Jersey. The Company also maintains operational or divisional headquarters in Kenilworth, New Jersey, Madison, New Jersey and Upper Gwynedd, Pennsylvania. Principal U.S. research facilities are located in Rahway and Kenilworth, New Jersey, West Point, Pennsylvania, Palo Alto, California, Boston, Massachusetts, South San Francisco, California and Elkhorn, Nebraska (Animal Health). Principal research facilities outside the United States are located in the United Kingdom, Switzerland

and China. Merck's manufacturing operations are headquartered in Whitehouse Station, New Jersey. The Company also has production facilities for human health products at nine locations in the United States and Puerto Rico. Outside the United States, through subsidiaries, the Company owns or has an interest in manufacturing plants or other properties in Japan, Singapore, South Africa, and other countries in Western Europe, Central and South America, and Asia.

Capital expenditures were $3.5 billion in 2019, $2.6 billion in 2018 and $1.9 billion in 2017. In the United States, these amounted to $1.9 billion in 2019, $1.5 billion in 2018 and $1.2 billion in 2017. Abroad, such expenditures amounted to $1.6 billion in 2019, $1.1 billion in 2018 and $728 million in 2017.

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

Item 3. Legal Proceedings.

The information called for by this Item is incorporated herein by reference to Item 8. "Financial Statements and Supplementary Data," Note 10. "Contingencies and Environmental Liabilities".

Item 4. Mine Safety Disclosures.

Not Applicable.

Executive Officers of the Registrant (ages as of February 1, 2020)

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

Name	Age	Offices and Business Experience
Kenneth C. Frazier	65	Chairman, President and Chief Executive Officer (since December 2011)
Sanat Chattopadhyay	60	Executive Vice President and President, Merck Manufacturing Division (since March 2016); Senior Vice President, Operations, Merck Manufacturing Division (November 2009-March 2016)
Frank Clyburn	55	Executive Vice President, Chief Commercial Officer (since January 2019); President, Global Oncology Business Unit (October 2013-December 2018)
Robert M. Davis	53	Executive Vice President, Global Services, and Chief Financial Officer (since April 2016); Executive Vice President and Chief Financial Officer (April 2014-April 2016)
Richard R. DeLuca, Jr.	57	Executive Vice President and President, Merck Animal Health (since September 2011)
Michael W. Fleming	61	Senior Vice President, Chief Ethics and Compliance Officer (since March 2019); Senior Vice President, International Legal and Compliance (January 2017-March 2019); Vice President, International Legal and Compliance (July 2008-January 2017)
Julie L. Gerberding	64	Executive Vice President and Chief Patient Officer, Strategic Communications, Global Public Policy and Population Health (since July 2016); Executive Vice President for Strategic Communications, Global Public Policy and Population Health (January 2015-July 2016)
Rita A. Karachun	56	Senior Vice President Finance - Global Controller (since March 2014)
Steven C. Mizell	59	Executive Vice President, Chief Human Resources Officer (since October 2018); Executive Vice President, Chief Human Resources Officer (December 2016-October 2018) and Executive Vice President, Human Resources, Monsanto Company (August 2011-December 2016)
Michael T. Nally	44	Executive Vice President, Chief Marketing Officer (since January 2019); President, Global Vaccines, Global Human Health (September 2016-January 2019); Managing Director, United Kingdom and Ireland, Global Human Health (January 2014-September 2016)
Roger M. Perlmutter, M.D., Ph.D.	67	Executive Vice President and President, Merck Research Laboratories (since April 2013)
Jennifer Zachary	42	Executive Vice President, General Counsel and Corporate Secretary (since January 2020); Executive Vice President and General Counsel (April 2018-January 2020); Partner, Covington & Burling LLP (January 2013-March 2018)

PART II

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

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

As of January 31, 2020, there were approximately 109,500 shareholders of record of the Company's Common Stock.

Issuer purchases of equity securities for the three months ended December 31, 2019 were as follows:

Issuer Purchases of Equity Securities

Period	Total Number of Shares Purchased[1]	Average Price Paid Per Share	($ in millions) Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs[1]
October 1 — October 31	5,064,526	$83.63	$7,796
November 1 — November 30	4,182,277	$84.72	$7,441
December 1 — December 31	3,053,800	$89.16	$7,169
Total	12,300,603	$85.37	$7,169

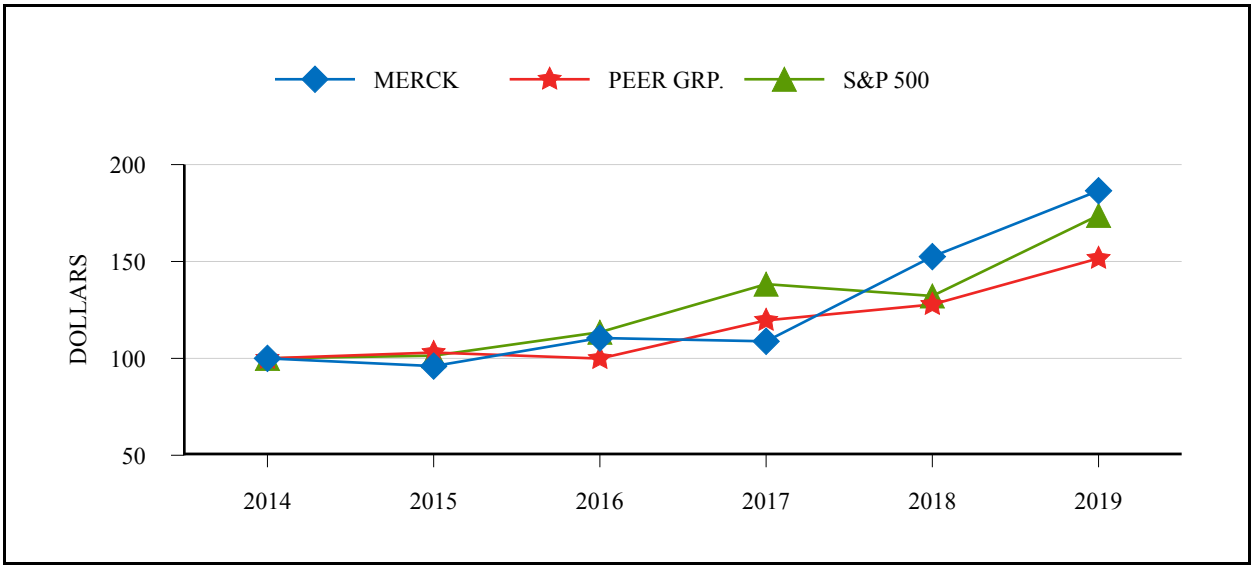
[1] *All shares purchased during the period were made as part of a plan approved by the Board of Directors in October 2018 to purchase up to $10 billion in Merck shares for its treasury.*

Performance Graph

The following graph assumes a $100 investment on December 31, 2014, and reinvestment of all dividends, in each of the Company's Common Shares, the S&P 500 Index, and a composite peer group of major U.S. and European-based pharmaceutical companies, which are: AbbVie Inc., Amgen Inc., AstraZeneca plc, Bristol-Myers Squibb Company, Johnson & Johnson, Eli Lilly and Company, GlaxoSmithKline plc, Novartis AG, Pfizer Inc., Roche Holding AG, and Sanofi SA.

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

	End of Period Value	2019/2014 CAGR*
MERCK	$187	13%
PEER GRP.**	152	9%
S&P 500	174	12%



	2014	2015	2016	2017	2018	2019
MERCK	100.0	96.0	110.5	108.8	152.5	186.5
PEER GRP.	100.0	103.0	99.9	119.6	127.8	151.6
S&P 500	100.0	101.4	113.5	138.3	132.2	173.8

* *Compound Annual Growth Rate*
** *Peer group average was calculated on a market cap weighted basis.*

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

Item 6. Selected Financial Data.

The following selected financial data should be read in conjunction with Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and consolidated financial statements and notes thereto contained in Item 8. "Financial Statements and Supplementary Data" of this report.

Merck & Co., Inc. and Subsidiaries
($ in millions except per share amounts)

	2019 [1]	2018 [2]	2017 [3]	2016 [4]	2015 [5]
Results for Year:					
Sales	**$ 46,840**	$ 42,294	$ 40,122	$ 39,807	$ 39,498
Cost of sales	**14,112**	13,509	12,912	14,030	15,043
Selling, general and administrative	**10,615**	10,102	10,074	10,017	10,508
Research and development	**9,872**	9,752	10,339	10,261	6,796
Restructuring costs	**638**	632	776	651	619
Other (income) expense, net	**139**	(402)	(500)	189	1,131
Income before taxes	**11,464**	8,701	6,521	4,659	5,401
Taxes on income	**1,687**	2,508	4,103	718	942
Net income	**9,777**	6,193	2,418	3,941	4,459
Less: Net (loss) income attributable to noncontrolling interests	**(66)**	(27)	24	21	17
Net income attributable to Merck & Co., Inc.	**9,843**	6,220	2,394	3,920	4,442
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	**$ 3.84**	$ 2.34	$ 0.88	$ 1.42	$ 1.58
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	**$ 3.81**	$ 2.32	$ 0.87	$ 1.41	$ 1.56
Cash dividends declared	**5,820**	5,313	5,177	5,135	5,115
Cash dividends declared per common share	**$ 2.26**	$ 1.99	$ 1.89	$ 1.85	$ 1.81
Capital expenditures	**3,473**	2,615	1,888	1,614	1,283
Depreciation	**1,679**	1,416	1,455	1,611	1,593
Average common shares outstanding (millions)	**2,565**	2,664	2,730	2,766	2,816
Average common shares outstanding assuming dilution (millions)	**2,580**	2,679	2,748	2,787	2,841
Year-End Position:					
Working capital	**$ 5,263**	$ 3,669	$ 6,152	$ 13,410	$ 10,550
Property, plant and equipment, net	**15,053**	13,291	12,439	12,026	12,507
Total assets	**84,397**	82,637	87,872	95,377	101,677
Long-term debt	**22,736**	19,806	21,353	24,274	23,829
Total equity	**26,001**	26,882	34,569	40,308	44,767
Year-End Statistics:					
Number of stockholders of record	**110,023**	115,800	121,700	129,500	135,500
Number of employees	**71,000**	69,000	69,000	68,000	68,000

[1] *Amounts for 2019 include a charge for the acquisition of Peloton Therapeutics, Inc.*

[2] *Amounts for 2018 include a charge related to the formation of a collaboration with Eisai Co., Ltd.*

[3] *Amounts for 2017 include a provisional net tax charge related to the enactment of U.S. tax legislation and a charge related to the formation of a collaboration with AstraZeneca PLC.*

[4] *Amounts for 2016 include a charge related to the settlement of worldwide patent litigation related to* Keytruda.

[5] *Amounts for 2015 include a net charge related to the settlement of* Vioxx *shareholder class action litigation, foreign exchange losses related to Venezuela, gains on the dispositions of businesses and other assets, and the favorable benefit of certain tax items.*

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

The following section of this Form 10-K generally discusses 2019 and 2018 results and year-to-year comparisons between 2019 and 2018. Discussion of 2017 results and year-to-year comparisons between 2018 and 2017 that are not included in this Form 10-K can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 filed on February 27, 2019.

Description of Merck's Business

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

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

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

The Healthcare Services segment provides services and solutions that focus on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company has recently sold certain businesses in the Healthcare Services segment and is in the process of divesting the remaining businesses. While the Company continues to look for investment opportunities in this area of health care, the approach to these investments has shifted toward venture capital investments in third parties as opposed to wholly-owned businesses.

The Alliances segment primarily includes activity from the Company's relationship with AstraZeneca LP related to sales of Nexium and Prilosec, which concluded in 2018.

Planned Spin-Off of Women's Health, Legacy Brands and Biosimilars into New Company

In February 2020, Merck announced its intention to spin-off products from its women's health, trusted legacy brands and biosimilars businesses into a new, yet-to-be-named, independent, publicly traded company (NewCo) through a distribution of NewCo's publicly traded stock to Company shareholders. The distribution is expected to qualify as tax-free to the Company and its shareholders for U.S. federal income tax purposes. The legacy brands included in the transaction consist of dermatology, pain, respiratory, and select cardiovascular products including *Zetia* and *Vytorin*, as well as the rest of Merck's diversified brands franchise. Merck's existing research pipeline programs will continue to be owned and developed within Merck as planned. NewCo will have development capabilities initially focused on late-stage development and life-cycle management, and is expected over time to develop research capabilities in selected therapeutic areas. The spin-off is expected to be completed in the first half of 2021, subject to market and certain other conditions.

Overview

Merck's performance during 2019 demonstrates execution in both commercial and research operations driven by a focus on key growth drivers and innovative pipeline investment reinforcing the Company's science-led strategy. In 2019, Merck enhanced its portfolio and pipeline with external innovation, increased investment in new capital projects focused primarily on expanding manufacturing capacity across Merck's key businesses, and returned capital to shareholders.

Worldwide sales were $46.8 billion in 2019, an increase of 11% compared with 2018, including a 2% unfavorable effect from foreign exchange. The sales increase was driven primarily by Merck's growth pillars of oncology, human health vaccines, certain hospital acute care products, and animal health. Growth in these areas was partially offset by the ongoing effects of generic competition, particularly in the diversified brands and cardiovascular franchises, as well as by competitive pressure, particularly in the diabetes and virology franchises.

Merck continued to prioritize business development aimed at enhancing its portfolio and strengthening its pipeline by executing several business development transactions in 2019. To expand its oncology presence, Merck completed the acquisitions of Peloton Therapeutics, Inc. (Peloton), a clinical-stage biopharmaceutical company focused on the development of novel small molecule therapeutic candidates for the treatment of cancer and other diseases, and Immune Design, a late-stage immunotherapy company employing next-generation *in vivo* approaches to enable the body's immune system to fight disease. Merck also announced an agreement to acquire ArQule, Inc. (ArQule), a biopharmaceutical company focused on kinase inhibitor discovery and development for the treatment of cancer and other diseases; the acquisition closed in January 2020. To augment Merck's animal health business, the Company acquired Antelliq Group (Antelliq), a leader in digital animal identification, traceability and monitoring solutions.

During 2019, the Company received numerous regulatory approvals and progressed many important pipeline candidates through clinical development. Within oncology, *Keytruda* received multiple additional approvals in the United States, European Union (EU), China and Japan as monotherapy in the therapeutic areas of non-small-cell lung cancer (NSCLC), small-cell lung cancer (SCLC), esophageal cancer and in combination with axitinib for the treatment of renal cell carcinoma (RCC), in combination with chemotherapy for head and neck squamous cell carcinoma (HNSCC), and in combination with Lenvima for endometrial carcinoma. Lynparza, which is being developed in collaboration with AstraZeneca PLC (AstraZeneca), received U.S. Food and Drug Administration (FDA) approval for the treatment of appropriate patients with germline *BRCA*-mutated (g*BRCA*m) pancreatic cancer and European Commission (EC) approval for use in certain patients with advanced ovarian cancer and advanced or metastatic breast cancer.

In addition to oncology, the Company received regulatory approvals in the hospital acute care and vaccines therapeutic areas. The FDA approved *Recarbrio* (imipenem, cilastatin, and relebactam) for injection, a new combination antibacterial for the treatment of certain patients with complicated urinary tract infections caused by certain Gram-negative microorganisms. *Recarbrio* was approved by the EC in February 2020. The FDA and EC also approved expanded indications for *Zerbaxa* for the treatment of patients with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by certain susceptible Gram-negative microorganisms. Additionally, *Ervebo* (Ebola Zaire Vaccine, Live), a vaccine for the prevention of disease caused by *Zaire ebolavirus* in adults, was approved in the United States and received conditional approval in the EU.

In addition to the recent regulatory approvals discussed above, the Company advanced its late-stage pipeline, particularly in oncology, with several regulatory submissions for *Keytruda*, Lynparza and Lenvima in the United States and internationally. The Company's Phase 3 oncology programs include *Keytruda* in the therapeutic areas of biliary tract, breast, cervical, colorectal, cutaneous squamous cell, endometrial, esophageal, gastric, hepatocellular, mesothelioma, nasopharyngeal, ovarian, prostate and small-cell lung cancers; Lynparza in combination with *Keytruda* for non-small cell lung cancer; and Lenvima in combination with *Keytruda* for bladder, endometrial, head and neck, melanoma and non-small-cell lung cancers. Additionally, the Company has candidates in Phase 3 clinical development in several other therapeutic areas, including V114, an investigational polyvalent conjugate vaccine for the prevention of pneumococcal disease that received Breakthrough Therapy designation from the FDA for the prevention of invasive pneumococcal disease caused by the vaccine serotypes in pediatric patients (6 weeks to 18 years of age) and in adults; MK-7264, gefapixant, a selective, non-narcotic, orally-administered P2X3-receptor antagonist being developed for the treatment of refractory, chronic cough; MK-8591A, islatravir, an investigational nucleoside reverse transcriptase translocation inhibitor (NRTTI) in combination with doravirine for the treatment of HIV-1 infection; and MK-1242, vericiguat, an investigational treatment for heart failure being developed in a collaboration (see "Research and Development" below).

The Company is allocating resources to effectively support its commercial opportunities in the near term while making the necessary investments to support long-term growth. Research and development expenses in 2019 reflect higher clinical development spending and increased investment in discovery research and early drug development.

In November 2019, Merck's Board of Directors approved an increase to the Company's quarterly dividend, raising it to $0.61 per share from $0.55 per share on the Company's outstanding common stock. During 2019, the Company returned $10.5 billion to shareholders through dividends and share repurchases.

Earnings per common share assuming dilution attributable to common shareholders (EPS) for 2019 were $3.81 compared with $2.32 in 2018. EPS in both years reflects the impact of acquisition and divestiture-related costs, as well as restructuring costs and certain other items. Certain other items in 2019 include a charge related to the acquisition of Peloton and in 2018 include a charge related to the formation of a collaboration with Eisai Co., Ltd. (Eisai). Non-GAAP EPS, which excludes these items, was $5.19 in 2019 and $4.34 in 2018 (see "Non-GAAP Income and Non-GAAP EPS" below).

Pricing

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. Changes to the U.S. health care system as part of health care reform, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, have contributed to pricing pressure. In several international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. In addition, the Company's revenue performance in 2019 was negatively affected by other cost-reduction measures taken by governments and other third-parties to lower health care costs. The Company anticipates all of these actions and additional actions in the future will continue to negatively affect revenue performance.

Operating Results

Sales

($ in millions)	**2019**	**% Change**	**% Change Excluding Exchange**	2018	% Change	% Change Excluding Exchange	2017
United States	**$ 20,325**	**12%**	**12%**	$ 18,212	5%	5%	$ 17,424
International	**26,515**	**10%**	**13%**	24,083	6%	6%	22,698
Total	**$ 46,840**	**11%**	**13%**	$ 42,294	5%	5%	$ 40,122

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

Worldwide sales grew 11% in 2019 driven primarily by higher sales in the oncology franchise reflecting strong growth of *Keytruda*, as well as increased alliance revenue related to Lynparza and Lenvima. Also contributing to revenue growth were higher sales of vaccines, including *Gardasil/Gardasil* 9, *Varivax*, *ProQuad* and *M-M-R* II, as well as increased sales of certain hospital acute care products, including *Bridion.* Higher sales of animal health products also drove revenue growth in 2019.

Sales growth in 2019 was partially offset by the effects of generic competition for cardiovascular products *Zetia* and *Vytorin*, hospital acute care products *Invanz*, *Cubicin* and *Noxafil*, oncology product *Emend*, and products within the diversified brands franchise, as well as biosimilar competition for immunology product *Remicade.* The diversified brands franchise includes certain products that are approaching the expiration of their marketing exclusivity or that are no longer protected by patents in developed markets. Lower sales of diabetes products *Januvia* and *Janumet* and HIV products *Isentress/Isentress HD* also partially offset revenue growth in 2019.

Sales in the United States grew 12% in 2019 driven primarily by higher sales of *Keytruda*, combined sales of *ProQuad*, *M-M-R* II and *Varivax*, and *Bridion*, as well as higher alliance revenue from Lenvima and Lynparza. Revenue growth was partially offset by lower sales of *Januvia, Janumet*, *Invanz*, *Emend*, *Isentress/Isentress HD*, *Cubicin* and *Noxafil*.

International sales grew 10% in 2019. Performance in international markets was led by China, which had total sales of $3.2 billion in 2019, representing growth of 47% compared with 2018, including a 7% unfavorable effect from foreign exchange. The increase in international sales primarily reflects growth in *Keytruda*, *Gardasil/Gardasil* 9, combined sales of *ProQuad*, *M-M-R* II and *Varivax*, as well as higher alliance revenue from Lynparza and Lenvima. Sales growth was partially offset by lower sales of *Zetia*, *Vytorin*, *Zepatier, Remicade*, and products within the diversified brands franchise. International sales represented 57% of total sales in both 2019 and 2018.

See Note 18 to the consolidated financial statements for details on sales of the Company's products. A discussion of performance for select products in the franchises follows.

Pharmaceutical Segment

Oncology

($ in millions)	**2019**	**% Change**	**% Change Excluding Exchange**	2018	% Change	% Change Excluding Exchange	2017
Keytruda	**$ 11,084**	**55 %**	**58 %**	$ 7,171	88 %	88 %	$ 3,809
Alliance Revenue - Lynparza [(1)]	**444**	**137 %**	**141 %**	187	*	*	20
Alliance Revenue - Lenvima [(1)]	**404**	**171 %**	**173 %**	149	N/A	N/A	—
Emend	**388**	**(26)%**	**(24)%**	522	(6)%	(7)%	556

** Calculation not meaningful.*

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

Keytruda is an anti-PD-1 therapy that has been approved for the treatment of multiple malignancies including cervical cancer, classical Hodgkin lymphoma (cHL), esophageal cancer, gastric or gastroesophageal junction adenocarcinoma, HNSCC, hepatocellular carcinoma (HCC), NSCLC, SCLC, melanoma, Merkel cell carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient cancer, primary mediastinal large B-cell lymphoma (PMBCL), RCC and urothelial carcinoma. The *Keytruda* clinical development program includes studies across a broad range of cancer types (see "Research and Development" below).

In January 2020, the FDA approved *Keytruda* as monotherapy for the treatment of certain patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) based on the results of the KEYNOTE-057 trial.

In July 2019, the FDA approved *Keytruda* as monotherapy for the treatment of certain patients with recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus whose tumors express PD-L1 (Combined Positive Score [CPS] ≥10) as determined by an FDA-approved test, based on the results of the KEYNOTE-181 and KEYNOTE-180 trials.

In June 2019, the FDA approved *Keytruda* as monotherapy or in combination with chemotherapy for the first-line treatment of patients with metastatic or unresectable, recurrent HNSCC based on results from the pivotal Phase 3 KEYNOTE-048 trial. *Keytruda* was initially approved for HNSCC under the FDA's accelerated approval process based on data from the Phase 1b KEYNOTE-012 trial. In accordance with the accelerated approval process, continued approval was contingent upon verification and description of clinical benefit, which has now been demonstrated in KEYNOTE-048 and has resulted in the FDA converting the accelerated approval to a full (regular) approval. *Keytruda* was approved for these indications by the EC in November 2019 and by Japan's Ministry of Health, Labour and Welfare (MHLW) in December 2019.

Also in June 2019, the FDA approved *Keytruda* as monotherapy for the treatment of certain patients with metastatic SCLC based on pooled data from the KEYNOTE-158 (cohort G) and KEYNOTE-028 (cohort C1) clinical trials.

In April 2019, the FDA approved *Keytruda* in combination with Inlyta (axitinib), a tyrosine kinase inhibitor, for the first-line treatment of patients with advanced RCC, the most common type of kidney cancer, based on findings from the pivotal Phase 3 KEYNOTE-426 trial. *Keytruda* was approved for this indication by the EC in September 2019 and by Japan's MHLW in December 2019.

Also in April 2019, the FDA approved an expanded label for *Keytruda* as monotherapy for the first-line treatment of patients with NSCLC expressing PD-L1 (Tumor Proportion Score [TPS] ≥1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations, in stage III disease where patients are not candidates for surgical resection or definitive chemoradiation, and in metastatic disease. The approval was based on results from the Phase 3 KEYNOTE-042 trial.

In September 2019, the FDA approved the combination of *Keytruda* plus Lenvima for the treatment of certain patients with advanced endometrial carcinoma that is not MSI-H or mismatch repair deficient.

In March 2019, the EC approved *Keytruda* in combination with carboplatin and either paclitaxel or nab-paclitaxel for the first-line treatment of adults with metastatic squamous NSCLC based on data from the Phase 3 KEYNOTE-407 trial. *Keytruda* was approved for this indication by the FDA in October 2018.

In April 2019, the EC approved a new extended dosing schedule of 400 mg every six weeks (Q6W) delivered as an intravenous infusion over 30 minutes for all approved monotherapy indications in the EU. The Q6W dose is available in addition to the formerly approved dose of *Keytruda* 200 mg every three weeks (Q3W) infused over 30 minutes.

Additionally, in 2019, *Keytruda* received the following approvals from China's National Medical Products Administration (NMPA): in combination with pemetrexed and platinum chemotherapy for the first-line treatment of patients with metastatic nonsquamous NSCLC, with no EGFR or ALK genomic tumor aberrations, based on data from the pivotal Phase 3 KEYNOTE-189 trial; as monotherapy for the first-line treatment of patients with locally advanced or metastatic NSCLC whose tumors express PD-L1 as determined by a NMPA-approved test, with no EGFR or ALK genomic tumor aberrations, based on the results from the Phase 3 KEYNOTE-042 trial; and in combination with carboplatin and paclitaxel for the first-line treatment of patients with metastatic squamous NSCLC based on findings from the pivotal Phase 3 KEYNOTE-407 trial.

Global sales of *Keytruda* grew 55% in 2019 driven by higher demand as the Company continues to launch *Keytruda* with multiple new indications globally. Sales in the United States continue to build across the multiple approved indications, in particular for the treatment of NSCLC as monotherapy and in combination with chemotherapy for both nonsquamous and squamous metastatic NSCLC, along with uptake in the recently launched RCC and adjuvant melanoma indications. Other indications contributing to U.S. sales growth include HNSCC, urothelial carcinoma, melanoma, and MSI-H cancer. *Keytruda* sales growth in international markets was driven primarily by performance in Europe, Japan and China reflecting increased use in the treatment of NSCLC, as well as for the more recently approved indications as described above.

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

Pursuant to a re-pricing rule, the Japanese government reduced the price of *Keytruda* by 17.5% effective February 2020. Additionally, *Keytruda* will be subject to another significant price reduction in April 2020 under a provision of the Japanese pricing rules.

Lynparza, an oral poly (ADP-ribose) polymerase (PARP) inhibitor being developed as part of a collaboration with AstraZeneca entered into in July 2017 (see Note 4 to the consolidated financial statements), is approved for the treatment of certain types of advanced ovarian, breast and pancreatic cancers. The increase in alliance revenue related to Lynparza in 2019 was driven primarily by expanded use in the United States, the EU, Japan and China reflecting in part the ongoing launch of new indications. Lynparza received approval for the treatment of certain types of advanced ovarian cancer in the United States in December 2018, in the EU and in Japan in June 2019, and in China in December 2019 based on the results of the Phase 3 SOLO-1 trial. Also, in April 2019, the EC approved Lynparza for the treatment of certain adult patients with advanced breast cancer based on the results of the Phase 3 OlympiAD trial. Additionally, in December 2019, the FDA approved Lynparza for the maintenance treatment of certain adult patients with advanced pancreatic cancer based on the results of the Phase 3 POLO trial.

Lenvima, an oral receptor tyrosine kinase inhibitor being developed as part of a collaboration with Eisai entered into in March 2018 (see Note 4 to the consolidated financial statements), is approved for the treatment of certain types of thyroid cancer, HCC, and in combination with evorolimus for certain patients with RCC. Additionally, in September 2019, the FDA approved the combination of *Keytruda* plus Lenvima for the treatment of certain patients with advanced endometrial carcinoma that is not MSI-H or mismatch repair deficient. This marks the first U.S. approval for the combination of *Keytruda* plus Lenvima. The increase in alliance revenue related to Lenvima in 2019 reflects strong performance in the treatment of HCC following recent worldwide launches, as well as a full year of collaboration activity in 2019.

Global sales of *Emend*, for the prevention of chemotherapy-induced and post-operative nausea and vomiting, declined 26% in 2019 driven primarily by lower demand and pricing in the United States due to competition, including recent generic competition for *Emend* for Injection following U.S. patent expiry in September 2019. The patent that provided U.S. market exclusivity for *Emend* expired in 2015 and the patent that provided market exclusivity in most major European markets expired in May 2019. Additionally, *Emend* for Injection will lose market exclusivity in major European markets in August 2020. The Company anticipates that sales of *Emend* for Injection in these markets will decline significantly thereafter.

Vaccines

($ in millions)	**2019**	**% Change**	**% Change Excluding Exchange**	2018	% Change	% Change Excluding Exchange	2017
Gardasil/Gardasil 9	**$ 3,737**	**19%**	**21%**	$ 3,151	37%	36%	$ 2,308
ProQuad	**756**	**27%**	**29%**	593	12%	12%	528
M-M-R II	**549**	**28%**	**29%**	430	13%	12%	382
Varivax	**970**	**25%**	**28%**	774	1%	1%	767
RotaTeq	**791**	**9%**	**10%**	728	6%	6%	686

Worldwide sales of *Gardasil/Gardasil* 9, vaccines to help prevent certain cancers and other diseases caused by certain types of HPV, grew 19% in 2019 driven primarily by higher demand in the Asia Pacific region, particularly in China, and higher demand in certain European markets reflecting increased vaccination rates for both boys and girls. Growth was partially offset by lower sales in the United States. The U.S. sales decline was driven by the borrowing of *Gardasil* 9 doses from the U.S. Centers for Disease and Control Prevention (CDC) Pediatric Vaccine Stockpile, offset in part by higher demand and pricing.

In 2019, the Company borrowed doses of *Gardasil* 9 from the CDC Pediatric Vaccine Stockpile. The borrowing reduced sales in 2019 by approximately $120 million and the Company recognized a corresponding liability. During 2018, the Company replenished doses borrowed from the CDC Pediatric Vaccine Stockpile in 2017 resulting in the recognition of sales of $125 million in 2018 and a reversal of the liability related to that borrowing.

The decision of Japan's MHLW to suspend the active recommendation for HPV vaccination is still under review.

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

Global sales of *ProQuad*, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, grew 27% in 2019 driven primarily by higher volumes and pricing in the United States, as well as volume growth in the EU largely reflecting a competitor supply issue.

Worldwide sales of *M-M-R* II, a vaccine to help protect against measles, mumps and rubella, grew 28% in 2019 driven primarily by higher sales in the United Sates reflecting increased demand due to measles outbreaks, as well as higher pricing. The Company anticipates that U.S. sales of *M-M-R* II will decline in 2020 driven by lower expected demand related to fewer measles outbreaks.

Global sales of *Varivax,* a vaccine to help prevent chickenpox (varicella), grew 25% in 2019 driven primarily by government tenders in Latin America, as well as higher pricing and volume growth in the United States. *Varivax* sales are expected to decline in 2020 due in part to the timing of government tenders and competition in select Latin American markets.

Global sales of *RotaTeq,* a vaccine to help protect against rotavirus gastroenteritis in infants and children, grew 9% in 2019 driven primarily by continued uptake from the launch in China and higher volumes in the United States, partially offset by lower volumes in Latin America.

In December 2019, the FDA approved *Ervebo* for the prevention of disease caused by *Zaire ebolavirus* in individuals 18 years of age and older. As previously announced, Merck is working to initiate manufacturing of licensed doses and expects these doses to start becoming available in approximately the third quarter of 2020. Merck is working closely with the U.S. government, the World Health Organization (WHO), UNICEF, and Gavi (the Vaccine Alliance) to plan for how eventual, licensed doses will support future public health preparedness and response efforts against *Zaire ebolavirus* disease. Merck is not seeking to profit from sales of this vaccine; rather, to ensure the vaccine is sustainable by recovering manufacturing and operational costs associated with the program. Ervebo was also granted a conditional marking authorization by the EC. Additionally, Merck has made submissions to African country national regulatory authorities in collaboration with the African Vaccine Regulatory Forum that will allow the vaccine to be registered in African countries considered to be at-risk for Ebola outbreaks by the WHO. In February 2020, Merck confirmed that four African countries have approved *Ervebo*. Approvals in additional countries in Africa are anticipated in the near future.

Hospital Acute Care

($ in millions)	**2019**	**% Change**	**% Change Excluding Exchange**	2018	% Change	% Change Excluding Exchange	2017
Bridion	**$ 1,131**	**23 %**	**26 %**	$ 917	30 %	30 %	$ 704
Noxafil	**662**	**(11)%**	**(7)%**	742	17 %	15 %	636
Invanz	**263**	**(47)%**	**(44)%**	496	(18)%	(17)%	602
Cubicin	**257**	**(30)%**	**(28)%**	367	(4)%	(5)%	382

Global sales of *Bridion*, for the reversal of two types of neuromuscular blocking agents used during surgery, grew 23% in 2019 driven by higher demand globally, particularly in the United States.

Worldwide sales of *Noxafil*, for the prevention of invasive fungal infections, declined 11% in 2019 driven primarily by generic competition in the United States. The patent that provided U.S. market exclusivity for certain forms of *Noxafil* representing the majority of U.S. *Noxafil* sales expired in July 2019. Accordingly, the Company is experiencing a decline in U.S. *Noxafil* sales as a result of generic competition and expects the decline to continue. Additionally, the patent for *Noxafil* expired in a number of major European markets in December 2019. As a result, the Company anticipates sales of *Noxafil* in these markets will decline significantly in future periods.

Global sales of *Invanz*, for the treatment of certain infections, declined 47% in 2019 driven by generic competition in the United States. The patent that provided U.S. market exclusivity for *Invanz* expired in November 2017 and generic competition began in the second half of 2018. The Company subsequently experienced a significant decline in *Invanz* sales in the United States as a result of this generic competition and has since lost most of its U.S. *Invanz* sales.

Global sales of *Cubicin*, an I.V. antibiotic for complicated skin and skin structure infections or bacteremia when caused by designated susceptible organisms, declined 30% in 2019 resulting primarily from ongoing generic competition in the United States following expiration of the U.S. composition patent for *Cubicin* in 2016.

In 2019, the FDA and EC approved expanded indications for *Zerbaxa* for the treatment of HABP/VABP caused by certain susceptible Gram-negative microorganisms based on the results of the pivotal Phase 3 ASPECT-NP trial. *Zerbaxa* was previously approved in the United States and EU for the treatment of adults with certain complicated urinary tract and intra-abdominal infections.

In July 2019, the FDA approved *Recarbrio* for injection, a new combination antibacterial for the treatment of adults who have limited or no alternative treatment options with complicated urinary tract infections and complicated intra-abdominal infections caused by certain susceptible Gram-negative microorganisms. *Recarbrio* was approved by the EC in February 2020. Merck anticipates making *Recarbrio* available in the first half of 2020.

In January 2020, the FDA approved *Dificid* (fidaxomicin) for oral suspension and *Dificid* tablets for the treatment of *Clostridioides* (formerly *Clostridium*) *difficile*-associated diarrhea in children aged six months and older.

Immunology

($ in millions)	2019	% Change	% Change Excluding Exchange	2018	% Change	% Change Excluding Exchange	2017
Simponi	**$ 830**	**(7)%**	**(2)%**	$ 893	9 %	5 %	$ 819
Remicade	**411**	**(29)%**	**(25)%**	582	(31)%	(33)%	837

Sales of *Simponi*, a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), declined 7% in 2019 driven by the unfavorable effect of foreign exchange and lower pricing in Europe. Sales of *Simponi* are being unfavorably affected by the launch of biosimilars for a competing product. The Company expects this competition will continue to unfavorably affect sales of *Simponi*.

Sales of *Remicade,* a treatment for inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), declined 29% in 2019 driven by ongoing biosimilar competition in the Company's marketing territories. The Company lost market exclusivity for *Remicade* in major European markets in 2015 and no longer has market exclusivity in any of its marketing territories. The Company is experiencing pricing and volume declines in these markets as a result of biosimilar competition and expects the declines to continue.

Virology

($ in millions)	2019	% Change	% Change Excluding Exchange	2018	% Change	% Change Excluding Exchange	2017
Isentress/Isentress HD	**$ 975**	**(15)%**	**(10)%**	$ 1,140	(5)%	(5)%	$ 1,204

Worldwide sales of *Isentress/Isentress HD*, an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, declined 15% in 2019 primarily reflecting lower demand in the United States and in the EU due to competitive pressure.

In September 2019, the FDA approved supplemental New Drug Applications (NDA) for *Pifeltro* (doravirine) in combination with other antiretroviral agents, and for *Delstrigo* (doravirine/lamivudine/tenofovir disoproxil fumarate) as a complete regimen, that expand their indications to include adult patients with HIV-1 infection who are virologically suppressed on a stable antiretroviral regimen.

Cardiovascular

($ in millions)	2019	% Change	% Change Excluding Exchange	2018	% Change	% Change Excluding Exchange	2017
Zetia/Vytorin	**$ 874**	**(35)%**	**(34)%**	$ 1,355	(35)%	(38)%	$ 2,095
Atozet	**391**	**13 %**	**18 %**	347	54 %	48 %	225
Rosuzet	**120**	**107 %**	**115 %**	58	12 %	9 %	52
Adempas	**419**	**27 %**	**30 %**	329	10 %	7 %	300

Combined global sales of *Zetia* (marketed in most countries outside the United States as *Ezetrol*) and *Vytorin* (marketed outside the United States as *Inegy*), medicines for lowering LDL cholesterol, declined 35% in 2019 driven primarily by lower sales in the EU. The EU patents for *Ezetrol* and *Inegy* expired in April 2018 and April 2019, respectively. Accordingly, the Company is experiencing sales declines in these markets as a result of generic competition and expects the declines to continue. The sales decline was also attributable to loss of exclusivity in Australia. Merck lost market exclusivity in the United States for *Zetia* in 2016 and *Vytorin* in 2017 and subsequently lost nearly all U.S. sales of these products as a result of generic competition.

Sales of *Atozet* (marketed outside of the United States), a medicine for lowering LDL cholesterol, grew 13% in 2019, primarily driven by higher demand in the EU and in Korea.

Sales of *Rosuzet* (marketed outside of the United States), a medicine for lowering LDL cholesterol, more than doubled in 2019, primarily driven by the launch in Japan, as well as higher demand in Korea.

Adempas, a cardiovascular drug for the treatment of pulmonary arterial hypertension, is part of a worldwide clinical development collaboration with Bayer AG (Bayer) to market and develop soluble guanylate cyclase (sGC) modulators including Adempas (see Note 4 to the consolidated financial statements). The increase in alliance revenue of 27% in 2019 was driven both by higher profits from Bayer and higher sales of Adempas in Merck's marketing territories.

Diabetes

($ in millions)	**2019**	**% Change**	**% Change Excluding Exchange**	2018	% Change	% Change Excluding Exchange	2017
Januvia/Janumet	**$ 5,524**	**(7)%**	**(4)%**	$ 5,914	—%	(1)%	$ 5,896

Worldwide combined sales of *Januvia* and *Janumet*, medicines that help lower blood sugar levels in adults with type 2 diabetes, declined 7% in 2019 as a result of continued pricing pressure in the United States, partially offset by higher demand in most international markets. The Company expects U.S. pricing pressure to continue. The patents that provide market exclusivity for *Januvia* and *Janumet* in the United States expire in July 2022 (although six-month pediatric exclusivity may extend this date). The patent that provides market exclusivity for *Januvia* in the EU expires in July 2022 (although pediatric exclusivity may extend this date to September 2022). The supplementary patent certificate that provides market exclusivity for *Janumet* in the EU expires in April 2023. The Company anticipates sales of *Januvia* and *Janumet* in these markets will decline substantially after these patent expiries.

Women's Health

($ in millions)	**2019**	**% Change**	**% Change Excluding Exchange**	2018	% Change	% Change Excluding Exchange	2017
NuvaRing	**$ 879**	**(3)%**	**(2)%**	$ 902	19%	18%	$ 761
Implanon/Nexplanon	**787**	12 %	**14 %**	703	2%	3%	686

Worldwide sales of *NuvaRing*, a vaginal contraceptive product, declined 3% in 2019 driven primarily by lower demand in the EU due to generic competition, largely offset by higher sales in the United States reflecting higher pricing that was partially offset by lower demand. The patent that provided U.S. market exclusivity for *NuvaRing* expired in April 2018 and generic competition began in December 2019. The Company anticipates a rapid and substantial decline in U.S. *NuvaRing* sales in 2020 as a result of this generic competition.

Worldwide sales of *Implanon/Nexplanon*, a single-rod subdermal contraceptive implant, grew 12% in 2019, primarily driven by higher demand and pricing in the United States.

Biosimilars

($ in millions)	**2019**	**% Change**	**% Change Excluding Exchange**	2018	% Change	% Change Excluding Exchange	2017
Biosimilars	$ 252	*	*	$ 64	*	*	$ 5

** Calculation not meaningful.*

Biosimilar products are marketed by the Company pursuant to an agreement with Samsung Bioepis Co., Ltd. (Samsung) to develop and commercialize multiple pre-specified biosimilar candidates. Currently, the Company markets Renflexis (infliximab-abda), a tumor necrosis factor (TNF) antagonist biosimilar to Remicade (infliximab) for the treatment of certain inflammatory diseases; Ontruzant (trastuzumab-dttb), a human epidermal growth factor receptor 2 (HER2)/ neu receptor antagonist biosimilar to Herceptin (trastuzumab) for the treatment of HER2-positive breast cancer and HER2 overexpressing gastric cancer; and Brenzys (etanercept biosimilar), a TNF antagonist biosimilar to Enbrel for the treatment of certain inflammatory diseases. Merck's commercialization territories under the agreement vary by product. Sale growth of biosimilars in 2019 was driven by continued uptake of Renflexis in United States since launch in 2017, continued uptake of Ontruzant in the EU since launch in 2018, and the launch of Brenzys in Brazil in 2019.

Animal Health Segment

($ in millions)	2019	% Change	% Change Excluding Exchange	2018	% Change	% Change Excluding Exchange	2017
Livestock	**$ 2,784**	**6%**	**11%**	$ 2,630	6%	7%	$ 2,484
Companion Animal	**1,609**	**2%**	**5%**	1,582	14%	13%	1,391

Sales of livestock products grew 6% in 2019 predominantly due to products obtained in the April 2019 acquisition of Antelliq, a leader in digital animal identification, traceability and monitoring solutions (see Note 3 to the consolidated financial statements). Growth in sales of livestock products was also driven by higher demand for aqua and swine products. Sales of companion animal products grew 2% in 2019 driven primarily by higher demand for the *Bravecto* line of products for parasitic control.

Costs, Expenses and Other

($ in millions)	2019	Change	2018	Change	2017
Cost of sales	**$ 14,112**	**4%**	$ 13,509	5%	$ 12,912
Selling, general and administrative	**10,615**	**5%**	10,102	—%	10,074
Research and development	**9,872**	**1%**	9,752	-6%	10,339
Restructuring costs	**638**	**1%**	632	-19%	776
Other (income) expense, net	**139**	*****	(402)	-20%	(500)
	$ 35,376	**5%**	$ 33,593	—%	$ 33,601

** Greater than 100%.*

Cost of Sales

Cost of sales was $14.1 billion in 2019 compared with $13.5 billion in 2018. Cost of sales includes the amortization of intangible assets recorded in connection with business acquisitions, which totaled $1.4 billion in 2019 compared with $2.7 billion in 2018. Cost of sales also includes the amortization of amounts capitalized in connection with collaborations of $464 million in 2019 compared with $347 million in 2018 (see Note 8 to the consolidated financial statements). Additionally, costs in 2019 include intangible asset impairment charges of $705 million related to marketed products recorded in connection with business acquisitions (see Note 8 to the consolidated financial statements). The Company may recognize additional non-cash impairment charges in the future related to intangible assets that were measured at fair value and capitalized in connection with business acquisitions and such charges could be material. Costs in 2018 include a $423 million charge related to the termination of a collaboration agreement with Samsung for insulin glargine (see Note 3 to the consolidated financial statements). Also included in cost of sales are expenses associated with restructuring activities which amounted to $251 million in 2019 compared with $21 million in 2018, primarily reflecting accelerated depreciation and asset write-offs related to the planned sale or closure of manufacturing facilities. Separation costs associated with manufacturing-related headcount reductions have been incurred and are reflected in *Restructuring costs* as discussed below.

Gross margin was 69.9% in 2019 compared with 68.1% in 2018. The gross margin improvement in 2019 reflects the charge recorded in 2018 in connection with the termination of the collaboration agreement with Samsung (noted above), favorable product mix, and lower amortization of intangible assets (noted above). These improvements in gross margin were partially offset by unfavorable manufacturing variances, inventory write-offs, pricing pressure, and higher restructuring costs.

Selling, General and Administrative

Selling, general and administrative (SG&A) expenses were $10.6 billion in 2019, an increase of 5% compared with 2018, driven primarily by higher administrative costs, acquisition and divestiture-related costs (largely related to the acquisition of Antelliq), promotional expenses primarily in support of strategic brands, and restructuring costs, partially offset by the favorable effect of foreign exchange and lower selling costs. SG&A expenses in 2019 include restructuring costs of $34 million related primarily to accelerated depreciation for facilities to be closed or divested. Separation costs associated with sales force reductions have been incurred and are reflected in *Restructuring costs* as discussed below. SG&A expenses include acquisition and divestiture-related costs of $126 million in 2019 compared

with $32 million in 2018, consisting of integration, transaction, and certain other costs related to business acquisitions and divestitures.

Research and Development

Research and development (R&D) expenses were $9.9 billion in 2019, an increase of 1% compared with 2018. The increase was driven primarily by a $993 million charge in 2019 for the acquisition of Peloton (see Note 3 to the consolidated financial statements), as well as higher expenses related to clinical development and increased investment in discovery research and early drug development. The increase in R&D expenses in 2019 was partially offset by a $1.4 billion charge in 2018 related to the formation of an oncology collaboration with Eisai (see Note 4 to the consolidated financial statements), a $344 million charge in 2018 related to the acquisition of Viralytics Limited (Viralytics) (see Note 3 to the consolidated financial statements), and the favorable effect of foreign exchange.

R&D expenses are comprised of the costs directly incurred by Merck Research Laboratories (MRL), the Company's research and development division that focuses on human health-related activities, which were $6.1 billion in 2019 compared with $5.6 billion in 2018. Also included in R&D expenses are Animal Health research costs, licensing costs and costs incurred by other divisions in support of R&D activities, including depreciation, production and general and administrative, which in the aggregate were $2.6 billion in 2019 and $2.3 billion in 2018. R&D expenses also include in-process research and development (IPR&D) impairment charges of $172 million and $152 million in 2019 and 2018, respectively (see Note 8 to the consolidated financial statements). The Company may recognize additional non-cash impairment charges in the future related to the cancellation or delay of other pipeline programs that were measured at fair value and capitalized in connection with business acquisitions and such charges could be material. In addition, R&D expenses include expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration recorded in connection with business acquisitions. During 2019 and 2018, the Company recorded a net reduction in expenses of $39 million and $54 million, respectively, related to changes in these estimates.

Restructuring Costs

In early 2019, Merck approved a new global restructuring program (Restructuring Program) as part of a worldwide initiative focused on further optimizing the Company's manufacturing and supply network, as well as reducing its global real estate footprint. This program is a continuation of the Company's plant rationalization, builds on prior restructuring programs and does not include any actions associated with the planned spin-off of NewCo. As the Company continues to evaluate its global footprint and overall operating model, it has subsequently identified additional actions under the Restructuring Program, and could identify further actions over time. The actions currently contemplated under the Restructuring Program are expected to be substantially completed by the end of 2023, with the cumulative pretax costs to be incurred by the Company to implement the program now estimated to be approximately $2.5 billion. The Company expects to record charges of approximately $800 million in 2020 related to the Restructuring Program. The Company anticipates the actions under the Restructuring Program to result in annual net cost savings of approximately $900 million by the end of 2023. Actions under previous global restructuring programs have been substantially completed.

Restructuring costs, primarily representing separation and other related costs associated with these restructuring activities, were $638 million in 2019 and $632 million in 2018. Separation costs incurred were associated with actual headcount reductions, as well as estimated expenses under existing severance programs for headcount reductions that were probable and could be reasonably estimated. Also included in restructuring costs are asset abandonment, facility shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation plan costs. For segment reporting, restructuring costs are unallocated expenses.

Additional costs associated with the Company's restructuring activities are included in *Cost of sales*, *Selling, general and administrative* and *Research and development*. The Company recorded aggregate pretax costs of $927 million in 2019 and $658 million in 2018 related to restructuring program activities (see Note 5 to the consolidated financial statements).

Other (Income) Expense, Net

For details on the components of Other (income) expense, net, see Note 14 to the consolidated financial statements.

Segment Profits

($ in millions)	**2019**	2018	2017
Pharmaceutical segment profits	**$ 28,324**	$ 24,871	$ 23,018
Animal Health segment profits	**1,609**	1,659	1,552
Other non-reportable segment profits	**(7)**	103	275
Other	**(18,462)**	(17,932)	(18,324)
Income Before Taxes	**$ 11,464**	$ 8,701	$ 6,521

Pharmaceutical segment profits are comprised of segment sales less standard costs, as well as SG&A expenses directly incurred by the segment. Animal Health segment profits are comprised of segment sales, less all cost of sales, as well as SG&A and R&D expenses directly incurred by the segment. For internal management reporting presented to the chief operating decision maker, Merck does not allocate the remaining cost of sales not included in segment profits as described above, research and development expenses incurred by MRL, or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. Also excluded from the determination of segment profits are costs related to restructuring activities and acquisition and divestiture-related costs, including amortization of purchase accounting adjustments, intangible asset impairment charges and changes in the estimated fair value measurement of liabilities for contingent consideration. Additionally, segment profits do not reflect other expenses from corporate and manufacturing cost centers and other miscellaneous income or expense. These unallocated items are reflected in "Other" in the above table. Also included in "Other" are miscellaneous corporate profits (losses), as well as operating profits (losses) related to third-party manufacturing sales. During 2019, as a result of changes to the Company's internal reporting structure, certain costs that were previously included in the Pharmaceutical segment are now being included as part of non-segment expenses within MRL. Prior period Pharmaceutical segment profits have been recast to reflect these changes on a comparable basis.

Pharmaceutical segment profits grew 14% in 2019 compared with 2018 driven primarily by higher sales, as well as lower selling costs. Animal Health segment profits declined 3% in 2019 driven primarily by unfavorable product mix, higher investments in selling and product development, and the unfavorable effect of foreign exchange, partially offset by higher sales.

Taxes on Income

The effective income tax rates of 14.7% in 2019 and 28.8% in 2018 reflect the impacts of acquisition and divestiture-related costs, restructuring costs and the beneficial impact of foreign earnings, including product mix. The effective income tax rate in 2019 also reflects the favorable impact of a $364 million net tax benefit related to the settlement of certain federal income tax matters (see Note 15 to the consolidated financial statements) and the reversal of tax reserves established in connection with the 2014 divestiture of Merck's Consumer Care (MCC) business due to the lapse in the statute of limitations. In addition, the effective income tax rate in 2019 reflects the unfavorable impacts of a charge for the acquisition of Peloton for which no tax benefit was recognized and charges of $117 million related to the finalization of treasury regulations for the transition tax associated with the 2017 enactment of U.S. tax legislation known as the Tax Cuts and Jobs Act (TCJA) (see Note 15 to the consolidated financial statements). The effective income tax rate in 2018 includes measurement-period adjustments to the provisional amounts recorded in 2017 associated with the enactment of the TCJA, including $124 million related to the transition tax. In addition, the effective income tax rate for 2018 reflects the unfavorable impacts of a charge recorded in connection with the formation of a collaboration with Eisai and a charge related to the termination of a collaboration agreement with Samsung for which no tax benefit was recognized.

Net (Loss) Income Attributable to Noncontrolling Interests

Net (loss) income attributable to noncontrolling interests was $(66) million in 2019 compared with $(27) million in 2018. The losses in 2019 and 2018 were driven primarily by the portion of goodwill impairment charges related to certain business in the Healthcare Services segment that are attributable to noncontrolling interests.

Net Income and Earnings per Common Share

Net income attributable to Merck & Co., Inc. was $9.8 billion in 2019 and $6.2 billion in 2018. EPS was $3.81 in 2019 and $2.32 in 2018.

Non-GAAP Income and Non-GAAP EPS

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

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

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

($ in millions except per share amounts)	**2019**	2018	2017
Income before taxes as reported under GAAP	**$ 11,464**	$ 8,701	$ 6,521
Increase (decrease) for excluded items:			
Acquisition and divestiture-related costs	**2,681**	3,066	3,760
Restructuring costs	**927**	658	927
Other items:			
Charge for the acquisition of Peloton	**993**	—	—
Charge related to the formation of an oncology collaboration with Eisai	**—**	1,400	—
Charge related to the termination of a collaboration with Samsung	**—**	423	—
Charge for the acquisition of Viralytics	**—**	344	—
Charge related to the formation of an oncology collaboration with AstraZeneca	**—**	—	2,350
Other	**55**	(57)	(16)
Non-GAAP income before taxes	**16,120**	14,535	13,542
Taxes on income as reported under GAAP	**1,687**	2,508	4,103
Estimated tax benefit on excluded items [1]	**695**	535	785
Net tax charge related to the enactment of the TCJA and subsequent finalization of related treasury regulations [2]	**(117)**	(160)	(2,625)
Net tax benefit from the settlement of certain federal income tax matters	**364**	—	234
Tax benefit from the reversal of tax reserves related to the divestiture of MCC	**86**	—	—
Tax benefit related to the settlement of a state income tax matter	**—**	—	88
Non-GAAP taxes on income	**2,715**	2,883	2,585
Non-GAAP net income	**13,405**	11,652	10,957
Less: Net (loss) income attributable to noncontrolling interests as reported under GAAP	**(66)**	(27)	24
Acquisition and divestiture-related costs attributable to noncontrolling interests	**(89)**	(58)	—
Non-GAAP net income attributable to noncontrolling interests	**23**	31	24
Non-GAAP net income attributable to Merck & Co., Inc.	**$ 13,382**	$ 11,621	$ 10,933
EPS assuming dilution as reported under GAAP	**$ 3.81**	$ 2.32	$ 0.87
EPS difference	**1.38**	2.02	3.11
Non-GAAP EPS assuming dilution	**$ 5.19**	$ 4.34	$ 3.98

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

[2] *Amount in 2017 was provisional (see Note 15 to the consolidated financial statements).*

Acquisition and Divestiture-Related Costs

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

Restructuring Costs

Non-GAAP income and non-GAAP EPS exclude costs related to restructuring actions (see Note 5 to the consolidated financial statements). These amounts include employee separation costs and accelerated depreciation associated with facilities to be closed or divested. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the asset, based upon the anticipated date the site

will be closed or divested or the equipment disposed of, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. Restructuring costs also include asset abandonment, facility shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation costs.

Certain Other Items

These items are adjusted for after they are evaluated on an individual basis considering their quantitative and qualitative aspects. Typically, these consist of items that are unusual in nature, significant to the results of a particular period or not indicative of future operating results. Excluded from non-GAAP income and non-GAAP EPS in 2019 is a charge for the acquisition of Peloton (see Note 3 to the consolidated financial statements), tax charges related to the finalization of U.S. treasury regulations related to the TCJA, a net tax benefit related to the settlement of certain federal income tax matters, and a tax benefit related to the reversal of tax reserves established in connection with the 2014 divestiture of MCC (see Note 15 to the consolidated financial statements). Excluded from non-GAAP income and non-GAAP EPS in 2018 is a charge related to the formation of a collaboration with Eisai (see Note 4 to the consolidated financial statements), a charge related to the termination of a collaboration agreement with Samsung for insulin glargine (see Note 3 to the consolidated financial statements), a charge for the acquisition of Viralytics (see Note 3 to the consolidated financial statements), and measurement-period adjustments related to the provisional amounts recorded for the TCJA (see Note 15 to the consolidated financial statements). Excluded from non-GAAP income and non-GAAP EPS in 2017 is a charge related to the formation of a collaboration with AstraZeneca (see Note 4 to the consolidated financial statements), as well as a provisional net tax charge related to the enactment of the TCJA, a net tax benefit related to the settlement of certain federal income tax matters and a tax benefit related to the settlement of a state income tax matter (see Note 15 to the consolidated financial statements).

Research and Development

A chart reflecting the Company's current research pipeline as of February 21, 2020 is set forth in Item 1. "Business — Research and Development" above.

Research and Development Update

The Company currently has several candidates under regulatory review in the United States and internationally.

Keytruda is an anti-PD-1 therapy approved for the treatment of many cancers that is in clinical development for expanded indications. These approvals were the result of a broad clinical development program that currently consists of more than 1,000 clinical trials, including more than 600 trials that combine *Keytruda* with other cancer treatments. These studies encompass more than 30 cancer types including: biliary tract, cervical, colorectal, cutaneous squamous cell, endometrial, gastric, head and neck, hepatocellular, Hodgkin lymphoma, non-Hodgkin lymphoma, melanoma, mesothelioma, nasopharyngeal, non-small-cell lung, ovarian, PMBCL, prostate, renal, small-cell lung, triple-negative breast and urothelial, many of which are currently in Phase 3 clinical development. Further trials are being planned for other cancers.

Keytruda is under review in the EU as monotherapy for the first-line treatment of patients with stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC, and whose tumors express PD-L1 (TPS ≥1%) with no EGFR or ALK genomic tumor aberrations based on results from the Phase 3 KEYNOTE-042 trial.

Keytruda is under review in Japan as monotherapy and in combination with chemotherapy for the first-line treatment of advanced gastric or gastroesophageal junction adenocarcinoma based on results from the pivotal Phase 3 KEYNOTE-062 trial.

Keytruda is also under review in Japan as monotherapy for the second-line treatment of advanced or metastatic esophageal or esophagogastric junction carcinoma based on the results of the Phase 3 KEYNOTE-181 trial. Merck has made the decision to withdraw its Type II variation application for *Keytruda* for this indication in the EU.

In October 2019, the FDA accepted a supplemental Biologics License Application (BLA) seeking use of *Keytruda* for the treatment of patients with recurrent and/or metastatic cutaneous squamous cell carcinoma (cSCC) that

is not curable by surgery or radiation based on the results of the KEYNOTE-629 trial. The FDA set a Prescription Drug User Fee Act (PDUFA) date of June 29, 2020.

In February 2020, Merck announced the FDA issued a Complete Response Letter regarding Merck's supplemental BLAs seeking to update the dosing frequency for *Keytruda* to include a 400 mg dose infused over 30 minutes every-six-weeks (Q6W) option in multiple indications. The submitted applications are based on pharmacokinetic modeling and simulation data presented at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting. These data supported the EC approval of 400 mg Q6W dosing for *Keytruda* monotherapy indications in March 2019. Merck is reviewing the letter and will discuss next steps with the FDA.

Additionally, *Keytruda* has received Breakthrough Therapy designation from the FDA in combination with neoadjuvant chemotherapy for the treatment of high-risk, early-stage triple-negative breast cancer (TNBC) and in combination with enfortumab vedotin, in the first-line setting for the treatment of patients with unresectable locally advanced or metastatic urothelial cancer who are not eligible for cisplatin-containing chemotherapy. The FDA's Breakthrough Therapy designation is intended to expedite the development and review of a candidate that is planned for use, alone or in combination, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

In September 2019, Merck announced results from the pivotal neoadjuvant/adjuvant Phase 3 KEYNOTE-522 trial in patients with early-stage TNBC. The trial investigated a regimen of neoadjuvant *Keytruda* plus chemotherapy, followed by adjuvant *Keytruda* as monotherapy (the *Keytruda* regimen) compared with a regimen of neoadjuvant chemotherapy followed by adjuvant placebo (the chemotherapy-placebo regimen). Interim findings were presented at the European Society for Medical Oncology (ESMO) 2019 Congress. In the neoadjuvant phase, *Keytruda* plus chemotherapy resulted in a statistically significant increase in pathological complete response (pCR) versus chemotherapy in patients with early-stage TNBC. The improvement seen when adding *Keytruda* to neoadjuvant chemotherapy was observed regardless of PD-L1 expression. In the other dual primary endpoint of event-free-survival (EFS), with a median follow-up of 15.5 months, the *Keytruda* regimen reduced the risk of progression in the neoadjuvant phase and recurrence in the adjuvant phase compared with the chemotherapy-placebo regimen. Merck continues to discuss interim analysis data from KEYNOTE-522 with regulatory authorities. The *Keytruda* breast cancer clinical development program encompasses several internal and external collaborative studies.

In February 2020, Merck announced that the pivotal Phase 3 KEYNOTE-355 trial investigating *Keytruda* in combination with chemotherapy met one of its dual primary endpoints of progression-free survival (PFS) in patients with metastatic triple-negative breast cancer (mTNBC) whose tumors expressed PD-L1 (CPS ≥10). Based on an interim analysis conducted by an independent Data Monitoring Committee (DMC), first-line treatment with *Keytruda* in combination with chemotherapy (nab-paclitaxel, paclitaxel or gemcitabine/carboplatin) demonstrated a statistically significant and clinically meaningful improvement in PFS compared to chemotherapy alone in these patients. Based on the recommendation of the DMC, the trial will continue without changes to evaluate the other dual primary endpoint of overall survival (OS).

In May 2019, Merck announced that the Phase 3 KEYNOTE-119 trial evaluating *Keytruda* as monotherapy for the second- or third-line treatment of patients with metastatic TNBC did not meet its pre-specified primary endpoint of superior OS compared to chemotherapy. Other endpoints were not formally tested per the study protocol because the primary endpoint of OS was not met.

In June 2019, Merck announced full results from the pivotal Phase 3 KEYNOTE-062 trial evaluating *Keytruda* as monotherapy and in combination with chemotherapy for the first-line treatment of advanced gastric or gastroesophageal junction adenocarcinoma. In the monotherapy arm of the study, *Keytruda* met a primary endpoint by demonstrating noninferiority to chemotherapy, the current standard of care, for OS in patients whose tumors expressed PD-L1 (CPS ≥1). In the combination arm of KEYNOTE-062, *Keytruda* plus chemotherapy was not found to be statistically superior for OS (CPS ≥1 or CPS ≥10) or PFS (CPS ≥1) compared with chemotherapy alone. Results were presented at the 2019 ASCO Annual Meeting. In September 2017, the FDA approved *Keytruda* as a third-line treatment for previously treated patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction cancer whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test. KEYNOTE-062 was a potential confirmatory trial for this accelerated, third-line approval. In addition to KEYNOTE-062, additional first-line, Phase

3 studies in Merck's gastric clinical program include KEYNOTE-811 and KEYNOTE-859, as well as KEYNOTE-585 in the neoadjuvant and adjuvant treatment setting.

In January 2020, Merck announced that the Phase 3 KEYNOTE-604 trial investigating *Keytruda* in combination with chemotherapy met one of its dual primary endpoints of PFS in the first-line treatment of patients with extensive stage SCLC. At the final analysis of the study, there was also an improvement in OS for patients treated with *Keytruda* in combination with chemotherapy compared to chemotherapy alone; however, these OS results did not meet statistical significance per the pre-specified statistical plan. Results will be presented at an upcoming medical meeting and discussed with regulatory authorities.

Lynparza is an oral PARP inhibitor currently approved for certain types of advanced ovarian, breast and pancreatic cancers being co-developed for multiple cancer types as part of a collaboration with AstraZeneca (see Note 4 to the consolidated financial statements).

Lynparza is under review in the EU as a first-line maintenance monotherapy for patients with g*BRCA*m metastatic pancreatic cancer whose disease has not progressed following first-line platinum-based chemotherapy. Lynparza was approved for this indication by the FDA in December 2019 based on results from the Phase 3 POLO trial. A decision from the European Medicines Agency (EMA) is expected in the second half of 2020.

In January 2020, the FDA accepted a supplemental NDA for Lynparza in combination with bevacizumab for the maintenance treatment of women with advanced ovarian cancer whose disease showed a complete or partial response to first-line treatment with platinum-based chemotherapy and bevacizumab based on the results from the pivotal Phase 3 PAOLA-1 trial. A PDUFA date is set for the second quarter of 2020. This indication is also under review in the EU.

In January 2020, the FDA accepted for Priority Review a supplemental NDA for Lynparza for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) and deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutations, who have progressed following prior treatment with a new hormonal agent based on positive results from the Phase 3 PROfound trial. A PDUFA date is set for the second quarter of 2020. This indication is also under review in the EU.

In June 2019, Merck and AstraZeneca presented full results from the Phase 3 SOLO-3 trial which evaluated Lynparza, compared to chemotherapy, for the treatment of platinum-sensitive relapsed patients with g*BRCA*m advanced ovarian cancer, who have received two or more prior lines of chemotherapy. The results from the trial showed a statistically-significant and clinically-meaningful improvement in objective response rate (ORR) in the Lynparza arm compared to the chemotherapy arm. The key secondary endpoint of PFS was also significantly increased in the Lynparza arm compared to the chemotherapy arm. The results were presented at the 2019 ASCO Annual Meeting.

MK-5618, selumetinib, is a MEK 1/2 inhibitor being co-developed as part of a strategic collaboration with AstraZeneca (see Note 4 to the consolidated financial statements). Selumetinib is under Priority Review with the FDA as a potential new medicine for pediatric patients aged three years and older with neurofibromatosis type 1 (NF1) and symptomatic, inoperable plexiform neurofibromas. This regulatory submission was based on positive results from the National Cancer Institute Cancer Therapy Evaluation Program-sponsored SPRINT Phase 2 Stratum 1 trial. A PDUFA date is set for the second quarter of 2020.

V503 is under review in Japan for an initial indication in females for the prevention of certain HPV-related diseases and precursors.

In February 2020, the FDA accepted for Priority Review a supplemental BLA for *Gardasil* 9 for the prevention of certain head and neck cancers caused by vaccine-type HPV in females and males 9 through 45 years of age. The FDA set a PDUFA date of June 2020.

In addition to the candidates under regulatory review, the Company has several drug candidates in Phase 3 clinical development in addition to the *Keytruda* programs discussed above.

Lynparza, in addition to the indications under review discussed above, is in Phase 3 development in combination with *Keytruda* for the treatment of NSCLC.

Lenvima is an orally available tyrosine kinase inhibitor currently approved for certain types of thyroid cancer, HCC, and in combination for certain patients with RCC being co-developed as part of a strategic collaboration with Eisai (see Note 4 to the consolidated financial statements). Pursuant to the agreement, the companies will jointly

initiate clinical studies evaluating the *Keytruda*/Lenvima combination in six types of cancer (endometrial cancer, NSCLC, HCC, HNSCC, bladder cancer and melanoma), as well as a basket trial targeting multiple cancer types. The FDA granted Breakthrough Therapy designation for *Keytruda* in combination with Lenvima both for the potential treatment of patients with advanced and/or metastatic RCC and for the potential treatment of patients with unresectable HCC not amenable to locoregional treatment.

MK-7264, gefapixant, is a selective, non-narcotic, orally-administered P2X3-receptor antagonist being investigated in Phase 3 trials for the treatment of refractory, chronic cough and in a Phase 2 trial for the treatment of women with endometriosis-related pain.

MK-1242, vericiguat, is a sGC stimulator for the potential treatment of patients with worsening chronic heart failure being developed as part of a worldwide strategic collaboration between Merck and Bayer (see Note 4 to the consolidated financial statements). Vericiguat is being studied in patients suffering from chronic heart failure with reduced ejection fraction (Phase 3 clinical trial) and from chronic heart failure with preserved ejection fraction (Phase 2 clinical trial). In November 2019, Merck announced that the Phase 3 VICTORIA study evaluating the efficacy and safety of vericiguat met the primary efficacy endpoint. Vericiguat reduced the risk of the composite endpoint of heart failure hospitalization or cardiovascular death in patients with worsening chronic heart failure with reduced ejection fraction compared to placebo when given in combination with available heart failure therapies. The results of the VICTORIA study will be presented at an upcoming medical meeting in 2020.

V114 is an investigational polyvalent conjugate vaccine for the prevention of pneumococcal disease. In June 2018, Merck initiated the first Phase 3 study in the adult population for the prevention of invasive pneumococcal disease. Currently six Phase 3 adult studies are ongoing, including studies in healthy adults 50 years of age or older, adults with risk factors for pneumococcal disease, those infected with HIV, and those who are recipients of allogeneic hematopoietic stem cell transplant. In October 2018, Merck began the first Phase 3 study in the pediatric population. Currently, eight studies are ongoing, including studies in healthy infants and in children afflicted with sickle cell disease. V114 has received Breakthrough Therapy designation from the FDA for the prevention of invasive pneumococcal disease caused by the vaccine serotypes in pediatric patients (6 weeks to 18 years of age) and in adults.

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

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

Acquired In-Process Research and Development

In connection with business acquisitions, the Company has recorded the fair value of in-process research projects which, at the time of acquisition, had not yet reached technological feasibility. At December 31, 2019, the balance of IPR&D was $1.0 billion.

The IPR&D projects that remain in development are subject to the inherent risks and uncertainties in drug development and it is possible that the Company will not be able to successfully develop and complete the IPR&D programs and profitably commercialize the underlying product candidates. The time periods to receive approvals from the FDA and other regulatory agencies are subject to uncertainty. Significant delays in the approval process, or the Company's failure to obtain approval at all, would delay or prevent the Company from realizing revenues from these products. Additionally, if certain of the IPR&D programs fail or are abandoned during development, then the Company will not realize the future cash flows it has estimated and recorded as IPR&D as of the acquisition date. If such

circumstances were to occur, the Company's future operating results could be adversely affected and the Company may recognize impairment charges and such charges could be material.

In 2019, 2018, and 2017 the Company recorded IPR&D impairment charges within *Research and development* expenses of $172 million, $152 million and $483 million, respectively (see Note 8 to the consolidated financial statements).

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

Acquisitions, Research Collaborations and License Agreements

Merck continues to remain focused on pursuing opportunities that have the potential to drive both near- and long-term growth. Certain recent transactions are described below. Merck is actively monitoring the landscape for growth opportunities that meet the Company's strategic criteria.

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

In July 2019, Merck acquired Peloton, a clinical-stage biopharmaceutical company focused on the development of novel small molecule therapeutic candidates targeting hypoxia-inducible factor-2α (HIF-2α) for the treatment of patients with cancer and other non-oncology diseases. Peloton's lead candidate, MK-6482 (formerly PT2977), is a novel oral HIF-2α inhibitor in late-stage development for renal cell carcinoma. Merck made an upfront payment of $1.2 billion in cash; additionally, former Peloton shareholders will be eligible to receive $50 million upon U.S. regulatory approval, $50 million upon first commercial sale in the United States, and up to $1.05 billion of sales-based milestones. The transaction was accounted for as an acquisition of an asset. Merck recorded cash of $157 million, deferred tax liabilities of $52 million, and other net liabilities of $4 million at the acquisition date and *Research and development* expenses of $993 million in 2019 related to the transaction.

In January 2020, Merck acquired ArQule, Inc. (ArQule), a publicly traded biopharmaceutical company focused on kinase inhibitor discovery and development for the treatment of patients with cancer and other diseases for $2.7 billion. ArQule's lead investigational candidate, MK-1026 (formerly ARQ 531), is a novel, oral Bruton's tyrosine kinase (BTK) inhibitor currently in a Phase 2 dose expansion study for the treatment of B-cell malignancies. The Company is in the process of determining the preliminary fair value of assets acquired, liabilities assumed and total consideration transferred in this transaction, which will be accounted for as an acquisition of a business.

Capital Expenditures

Capital expenditures were $3.5 billion in 2019, $2.6 billion in 2018 and $1.9 billion in 2017. Expenditures in the United States were $1.9 billion in 2019, $1.5 billion in 2018 and $1.2 billion in 2017. The increased capital expenditures in 2019 reflect investment in new capital projects focused primarily on increasing manufacturing capacity for Merck's key products. As previously announced, the Company plans to invest more than $19 billion in new capital projects from 2019-2023.

Depreciation expense was $1.7 billion in 2019, $1.4 billion in 2018 and $1.5 billion in 2017, of which $1.2 billion in 2019, $1.0 billion in 2018 and $1.0 billion in 2017, related to locations in the United States. Total depreciation expense in 2019 and 2017 included accelerated depreciation of $233 million and $60 million, respectively, associated with restructuring activities (see Note 5 to the consolidated financial statements).

Analysis of Liquidity and Capital Resources

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

Selected Data

($ in millions)	**2019**	2018	2017
Working capital	**$ 5,263**	$ 3,669	$ 6,152
Total debt to total liabilities and equity	**31.2%**	30.4%	27.8%
Cash provided by operations to total debt	**0.5:1**	0.4:1	0.3:1

Cash provided by operating activities was $13.4 billion in 2019 compared with $10.9 billion in 2018, reflecting stronger operating performance and increased accounts receivable factoring as discussed below. Cash provided by operating activities continues to be the Company's primary source of funds to finance operating needs, capital expenditures, treasury stock purchases and dividends paid to shareholders.

Cash used in investing activities was $2.6 billion in 2019 compared with cash provided by investing activities of $4.3 billion in 2018. The change was driven primarily by lower proceeds from the sales of securities and other investments, the acquisitions of Antelliq and Peloton in 2019, and higher capital expenditures, partially offset by lower purchases of securities and other investments.

Cash used in financing activities was $8.9 billion in 2019 compared with $13.2 billion in 2018. The lower use of cash in financing activities was driven primarily by proceeds from the issuance of debt and lower purchases of treasury stock reflecting the accelerated share repurchase (ASR) program in 2018 as discussed below, as well as lower payments on debt, partially offset by the repayment of short-term borrowings, higher dividends paid to shareholders and lower proceeds from the exercise of stock options.

The Company has accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable (see Note 6 to the consolidated financial statements). The Company factored $2.7 billion and $1.1 billion of accounts receivable in the fourth quarter of 2019 and 2018, respectively, under these factoring arrangements, which reduced outstanding accounts receivable. The cash received from the financial institutions is reported within operating activities in the Consolidated Statement of Cash Flows. In certain of these factoring arrangements, for ease of administration, the Company will collect customer payments related to the factored receivables, which it then remits to the financial institutions. At December 31, 2019, the Company had collected $256 million on behalf of the financial institutions, which was remitted to them in January 2020. The net cash flows from these collections are reported as financing activities in the Consolidated Statement of Cash Flows.

The Company's contractual obligations as of December 31, 2019 are as follows:

Payments Due by Period

($ in millions)	Total	2020	2021—2022	2023—2024	Thereafter
Purchase obligations [1]	$ 3,167	$ 1,097	$ 1,108	$ 421	$ 541
Loans payable and current portion of long-term debt	3,612	3,612	—	—	—
Long-term debt	22,779	—	4,515	3,058	15,206
Interest related to debt obligations	10,021	760	1,372	1,189	6,700
Unrecognized tax benefits [2]	49	49	—	—	—
Transition tax related to the enactment of the TCJA [3]	3,397	390	781	1,181	1,045
Milestone payments related to collaborations [4]	400	400	—	—	—
Leases [5]	1,012	254	354	202	202
	$ 44,437	$ 6,562	$ 8,130	$ 6,051	$ 23,694

[1] *Includes future inventory purchases the Company has committed to in connection with certain divestitures.*

[2] *As of December 31, 2019, the Company's Consolidated Balance Sheet reflects liabilities for unrecognized tax benefits, interest and penalties of $1.5 billion, including $49 million reflected as a current liability. Due to the high degree of uncertainty regarding the timing of future cash outflows of liabilities for unrecognized tax benefits beyond one year, a reasonable estimate of the period of cash settlement for years beyond 2020 cannot be made.*

[3] *In connection with the enactment of the TCJA, the Company is required to pay a one-time transition tax, which the Company has elected to pay over a period of eight years through 2025 as permitted under the TCJA (see Note 15 to the consolidated financial statements).*

[4] *Reflects payments under collaborative agreements for sales-based milestones that were achieved in 2019 (and therefore deemed to be contractual obligations) but not paid until January 2020 (see Note 4 to the consolidated financial statements).*

[5] *Amounts exclude reasonably certain lease renewals that have not yet been executed (see Note 9 to the consolidated financial statements).*

Purchase obligations are enforceable and legally binding obligations for purchases of goods and services including minimum inventory contracts, research and development and advertising. Amounts do not include contingent milestone payments related to collaborative arrangements or acquisitions as they are not considered contractual obligations until the successful achievement of developmental, regulatory approval or commercial milestones. At December 31, 2019, the Company has recognized liabilities for contingent sales-based milestone payments related to collaborations with AstraZeneca, Eisai and Bayer where payment remains subject to the achievement of the related sales milestone aggregating $1.4 billion (see Note 4 to the consolidated financial statements). Excluded from research and development obligations are potential future funding commitments of up to approximately $60 million for investments in research venture capital funds. Loans payable and current portion of long-term debt reflects $226 million of long-dated notes that are subject to repayment at the option of the holders. Required funding obligations for 2020 relating to the Company's pension and other postretirement benefit plans are not expected to be material. However, the Company currently anticipates contributing approximately $100 million to its U.S. pension plans, $150 million to its international pension plans and $15 million to its other postretirement benefit plans during 2020.

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

In December 2018, the Company exercised a make-whole provision on its $1.25 billion, 5.00% notes due 2019 and repaid this debt.

In November 2017, the Company launched tender offers for certain outstanding notes and debentures. The Company paid $810 million in aggregate consideration (applicable purchase price together with accrued interest) to redeem $585 million principal amount of debt that was validly tendered in connection with the tender offers.

The Company has a $6.0 billion credit facility that matures in June 2024. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

In March 2018, the Company filed a securities registration statement with the U.S. Securities and Exchange Commission (SEC) under the automatic shelf registration process available to "well-known seasoned issuers" which is effective for three years.

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

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

In November 2019, Merck's Board of Directors declared a quarterly dividend of $0.61 per share on the Company's outstanding common stock that was paid in January 2020. In January 2020, the Board of Directors declared a quarterly dividend of $0.61 per share on the Company's common stock for the second quarter of 2020 payable in April 2020.

In October 2018, Merck's Board of Directors authorized purchases of up to $10 billion of Merck's common stock for its treasury. The treasury stock purchase authorization has no time limit and will be made over time in open-market transactions, block transactions, on or off an exchange, or in privately negotiated transactions. The Company spent $4.8 billion to purchase 59 million shares of its common stock for its treasury during 2019. In addition, the Company received 7.7 million shares in settlement of ASR agreements as discussed below. As of December 31, 2019, the Company's remaining share repurchase authorization was $7.2 billion. The Company purchased $9.1 billion and $4.0 billion of its common stock during 2018 and 2017, respectively, under authorized share repurchase programs.

On October 25, 2018, the Company entered into ASR agreements with two third-party financial institutions (Dealers). Under the ASR agreements, Merck agreed to purchase $5 billion of Merck's common stock, in total, with an initial delivery of 56.7 million shares of Merck's common stock, based on the then-current market price, made by the Dealers to Merck, and payments of $5 billion made by Merck to the Dealers on October 29, 2018, which were funded with existing cash and investments, as well as short-term borrowings. Upon settlement of the ASR agreements in April 2019, Merck received an additional 7.7 million shares as determined by the average daily volume weighted-average price of Merck's common stock during the term of the ASR program, less a negotiated discount, bringing the total shares received by Merck under this program to 64.4 million.

Financial Instruments Market Risk Disclosures

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

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

Foreign Currency Risk Management

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

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

Because Merck principally sells foreign currency in its revenue hedging program, a uniform weakening of the U.S. dollar would yield the largest overall potential loss in the market value of these hedge instruments. The market value of Merck's hedges would have declined by an estimated $456 million and $441 million at December 31, 2019 and 2018, respectively, from a uniform 10% weakening of the U.S. dollar. The market value was determined using a foreign exchange option pricing model and holding all factors except exchange rates constant. Although not predictive in nature, the Company believes that a 10% threshold reflects reasonably possible near-term changes in Merck's major foreign currency exposures relative to the U.S. dollar. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

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

A sensitivity analysis to changes in the value of the U.S. dollar on foreign currency denominated derivatives, investments and monetary assets and liabilities indicated that if the U.S. dollar uniformly weakened by 10% against

all currency exposures of the Company at December 31, 2019 and 2018, *Income before taxes* would have declined by approximately $110 million and $134 million in 2019 and 2018, respectively. Because the Company was in a net short (payable) position relative to its major foreign currencies after consideration of forward contracts, a uniform weakening of the U.S. dollar will yield the largest overall potential net loss in earnings due to exchange. This measurement assumes that a change in one foreign currency relative to the U.S. dollar would not affect other foreign currencies relative to the U.S. dollar. Although not predictive in nature, the Company believes that a 10% threshold reflects reasonably possible near-term changes in Merck's major foreign currency exposures relative to the U.S. dollar. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

The economy of Argentina was determined to be hyperinflationary in 2018; consequently, in accordance with U.S. GAAP, the Company began remeasuring its monetary assets and liabilities for those operations in earnings. The impact to the Company's results was immaterial.

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

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

Interest Rate Risk Management

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

At December 31, 2019, the Company was a party to 19 pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes as detailed in the table below.

($ in millions)	**2019**		
Debt Instrument	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
1.85% notes due 2020	$ 1,250	5	$ 1,250
3.875% notes due 2021	1,150	5	1,150
2.40% notes due 2022	1,000	4	1,000
2.35% notes due 2022	1,250	5	1,250

The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in the benchmark London Interbank Offered Rate (LIBOR) swap rate. The fair value changes in the notes attributable to changes in the LIBOR swap rate are recorded in interest expense along with the offsetting fair value changes in the swap contracts. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

The Company's investment portfolio includes cash equivalents and short-term investments, the market values of which are not significantly affected by changes in interest rates. The market value of the Company's medium- to long-term fixed-rate investments is modestly affected by changes in U.S. interest rates. Changes in medium- to long-term U.S. interest rates have a more significant impact on the market value of the Company's fixed-rate borrowings, which generally have longer maturities. A sensitivity analysis to measure potential changes in the market value of

Merck's investments and debt from a change in interest rates indicated that a one percentage point increase in interest rates at December 31, 2019 and 2018 would have positively affected the net aggregate market value of these instruments by $2.0 billion and $1.2 billion, respectively. A one percentage point decrease at December 31, 2019 and 2018 would have negatively affected the net aggregate market value by $2.2 billion and $1.4 billion, respectively. The fair value of Merck's debt was determined using pricing models reflecting one percentage point shifts in the appropriate yield curves. The fair values of Merck's investments were determined using a combination of pricing and duration models.

Critical Accounting Policies

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

Acquisitions and Dispositions

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

In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the acquisition at their respective fair values with limited exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are generally recognized at fair value. If fair value cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Accordingly, the Company may be required to value assets at fair value measures that do not reflect the Company's intended use of those assets. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in the Company's consolidated financial statements after the date of the acquisition. The fair values of intangible assets, including acquired IPR&D, are determined utilizing information available near the acquisition date based on expectations and assumptions that are deemed reasonable by management. Given the considerable judgment involved in determining fair values, the Company typically obtains assistance from third-party valuation specialists for significant items. Amounts allocated to acquired IPR&D are capitalized and accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, Merck will make a determination as to the then-useful life of the intangible asset, generally determined by the period in which the substantial majority of the cash flows are expected to be generated, and begin amortization. Certain of the Company's business acquisitions involve the potential for future payment of consideration that is contingent upon the achievement of performance milestones, including product development milestones and royalty payments on future product sales. The fair value of contingent consideration liabilities is determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date, at each reporting period until the contingency is resolved, the contingent consideration liability is

remeasured at current fair value with changes (either expense or income) recorded in earnings. Changes in any of the inputs may result in a significantly different fair value adjustment.

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

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

The fair values of identifiable intangible assets related to IPR&D are also determined using an income approach, through which fair value is estimated based on each asset's probability-adjusted future net cash flows, which reflect the different stages of development of each product and the associated probability of successful completion. The net cash flows are then discounted to present value using an appropriate discount rate.

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

Revenue Recognition

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

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

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

In the United States, sales discounts are issued to customers at the point-of-sale, through an intermediary wholesaler (known as chargebacks), or in the form of rebates. Additionally, sales are generally made with a limited right of return under certain conditions. Revenues are recorded net of provisions for sales discounts and returns, which are established at the time of sale. In addition, revenues are recorded net of time value of money discounts if collection of accounts receivable is expected to be in excess of one year.

The U.S. provision for aggregate customer discounts covers chargebacks and rebates. Chargebacks are discounts that occur when a contracted customer purchases through an intermediary wholesaler. The contracted customer generally purchases product from the wholesaler at its contracted price plus a mark-up. The wholesaler, in turn, charges

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

The Company continually monitors its provision for aggregate customer discounts. There were no material adjustments to estimates associated with the aggregate customer discount provision in 2019, 2018 or 2017.

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

($ in millions)	**2019**	2018
Balance January 1	**$ 2,630**	$ 2,551
Current provision	**11,999**	10,837
Adjustments to prior years	**(230)**	(117)
Payments	**(11,963)**	(10,641)
Balance December 31	**$ 2,436**	$ 2,630

Accruals for chargebacks are reflected as a direct reduction to accounts receivable and accruals for rebates as current liabilities. The accrued balances relative to these provisions included in *Accounts receivable* and *Accrued and other current liabilities* were $233 million and $2.2 billion, respectively, at December 31, 2019 and were $245 million and $2.4 billion, respectively, at December 31, 2018.

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

The Company maintains a returns policy that allows its U.S. pharmaceutical customers to return product within a specified period prior to and subsequent to the expiration date (generally, three to six months before and 12 months after product expiration). The estimate of the provision for returns is based upon historical experience with actual returns. Additionally, the Company considers factors such as levels of inventory in the distribution channel, product dating and expiration period, whether products have been discontinued, entrance in the market of generic competition, changes in formularies or launch of over-the-counter products, among others. The product returns provision for U.S. pharmaceutical sales as a percentage of U.S. net pharmaceutical sales was 1.1% in 2019, 1.6% in 2018 and 2.1% in 2017. Outside of the United States, returns are only allowed in certain countries on a limited basis.

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

Through its distribution programs with U.S. wholesalers, the Company encourages wholesalers to align purchases with underlying demand and maintain inventories below specified levels. The terms of the programs allow the wholesalers to earn fees upon providing visibility into their inventory levels, as well as by achieving certain performance parameters such as inventory management, customer service levels, reducing shortage claims and reducing

product returns. Information provided through the wholesaler distribution programs includes items such as sales trends, inventory on-hand, on-order quantity and product returns.

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

Inventories Produced in Preparation for Product Launches

The Company capitalizes inventories produced in preparation for product launches sufficient to support estimated initial market demand. Typically, capitalization of such inventory does not begin until the related product candidates are in Phase 3 clinical trials and are considered to have a high probability of regulatory approval. The Company monitors the status of each respective product within the regulatory approval process; however, the Company generally does not disclose specific timing for regulatory approval. If the Company is aware of any specific risks or contingencies other than the normal regulatory approval process or if there are any specific issues identified during the research process relating to safety, efficacy, manufacturing, marketing or labeling, the related inventory would generally not be capitalized. Expiry dates of the inventory are affected by the stage of completion. The Company manages the levels of inventory at each stage to optimize the shelf life of the inventory in relation to anticipated market demand in order to avoid product expiry issues. For inventories that are capitalized, anticipated future sales and shelf lives support the realization of the inventory value as the inventory shelf life is sufficient to meet initial product launch requirements. Inventories produced in preparation for product launches capitalized at December 31, 2019 and 2018 were $168 million and $7 million, respectively.

Contingencies and Environmental Liabilities

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property and commercial litigation, as well as certain additional matters including governmental and environmental matters (see Note 10 to the consolidated financial statements). The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. For product liability claims, a portion of the overall accrual is actuarially determined and considers such factors as past experience, number of claims reported and estimates of claims incurred but not yet reported. Individually significant contingent losses are accrued when probable and reasonably estimable.

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of December 31, 2019 and 2018 of approximately $240 million and $245 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

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

The Company is also remediating environmental contamination resulting from past industrial activity at certain of its sites and takes an active role in identifying and accruing for these costs. In the past, Merck performed a worldwide survey to assess all sites for potential contamination resulting from past industrial activities. Where

assessment indicated that physical investigation was warranted, such investigation was performed, providing a better evaluation of the need for remedial action. Where such need was identified, remedial action was then initiated. As definitive information became available during the course of investigations and/or remedial efforts at each site, estimates were refined and accruals were established or adjusted accordingly. These estimates and related accruals continue to be refined annually.

The Company believes that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on the Company. Expenditures for remediation and environmental liabilities were $19 million in 2019 and are estimated at $47 million in the aggregate for the years 2020 through 2024. In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $67 million and $71 million at December 31, 2019 and 2018, respectively. These liabilities are undiscounted, do not consider potential recoveries from other parties and will be paid out over the periods of remediation for the applicable sites, which are expected to occur primarily over the next 15 years. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed $58 million in the aggregate. Management also does not believe that these expenditures should result in a material adverse effect on the Company's financial condition, results of operations or liquidity for any year.

Share-Based Compensation

The Company expenses all share-based payment awards to employees, including grants of stock options, over the requisite service period based on the grant date fair value of the awards. The Company determines the fair value of certain share-based awards using the Black-Scholes option-pricing model which uses both historical and current market data to estimate the fair value. This method incorporates various assumptions such as the risk-free interest rate, expected volatility, expected dividend yield and expected life of the options. Total pretax share-based compensation expense was $417 million in 2019, $348 million in 2018 and $312 million in 2017. At December 31, 2019, there was $603 million of total pretax unrecognized compensation expense related to nonvested stock option, restricted stock unit and performance share unit awards which will be recognized over a weighted average period of 1.9 years. For segment reporting, share-based compensation costs are unallocated expenses.

Pensions and Other Postretirement Benefit Plans

Net periodic benefit cost for pension plans totaled $137 million in 2019, $195 million in 2018 and $201 million in 2017. Net periodic benefit (credit) for other postretirement benefit plans was $(49) million in 2019, $(45) million in 2018 and $(60) million in 2017. Pension and other postretirement benefit plan information for financial reporting purposes is calculated using actuarial assumptions including a discount rate for plan benefit obligations and an expected rate of return on plan assets. The changes in net periodic benefit cost year over year for pension plans are largely attributable to changes in the discount rate affecting net loss amortization.

The Company reassesses its benefit plan assumptions on a regular basis. For both the pension and other postretirement benefit plans, the discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due. The discount rates for the Company's U.S. pension and other postretirement benefit plans ranged from 3.20% to 3.50% at December 31, 2019, compared with a range of 4.00% to 4.40% at December 31, 2018.

The expected rate of return for both the pension and other postretirement benefit plans represents the average rate of return to be earned on plan assets over the period the benefits included in the benefit obligation are to be paid. In developing the expected rate of return, the Company considers long-term compound annualized returns of historical market data, current market conditions and actual returns on the Company's plan assets. Using this reference information, the Company develops forward-looking return expectations for each asset category and a weighted-average expected long-term rate of return for a target portfolio allocated across these investment categories. The expected portfolio performance reflects the contribution of active management as appropriate. For 2020, the expected rate of return for the Company's U.S. pension and other postretirement benefit plans will range from 7.00% to 7.30%, compared to a range of 7.70% to 8.10% in 2019. The decrease reflects lower expected asset returns and a modest shift in asset allocation.

The Company has established investment guidelines for its U.S. pension and other postretirement plans to create an asset allocation that is expected to deliver a rate of return sufficient to meet the long-term obligation of each plan, given an acceptable level of risk. The target investment portfolio of the Company's U.S. pension and other

postretirement benefit plans is allocated 30% to 45% in U.S. equities, 15% to 30% in international equities, 35% to 45% in fixed-income investments, and up to 5% in cash and other investments. The portfolio's equity weighting is consistent with the long-term nature of the plans' benefit obligations. The expected annual standard deviation of returns of the target portfolio, which approximates 10%, reflects both the equity allocation and the diversification benefits among the asset classes in which the portfolio invests. For non-U.S. pension plans, the targeted investment portfolio varies based on the duration of pension liabilities and local government rules and regulations. Although a significant percentage of plan assets are invested in U.S. equities, concentration risk is mitigated through the use of strategies that are diversified within management guidelines.

Actuarial assumptions are based upon management's best estimates and judgment. A reasonably possible change of plus (minus) 25 basis points in the discount rate assumption, with other assumptions held constant, would have had an estimated $70 million favorable (unfavorable) impact on the Company's net periodic benefit cost in 2019. A reasonably possible change of plus (minus) 25 basis points in the expected rate of return assumption, with other assumptions held constant, would have had an estimated $50 million favorable (unfavorable) impact on Merck's net periodic benefit cost in 2019. Required funding obligations for 2020 relating to the Company's pension and other postretirement benefit plans are not expected to be material. The preceding hypothetical changes in the discount rate and expected rate of return assumptions would not impact the Company's funding requirements.

Net loss amounts, which reflect experience differentials primarily relating to differences between expected and actual returns on plan assets as well as the effects of changes in actuarial assumptions, are recorded as a component of *AOCI*. Expected returns for pension plans are based on a calculated market-related value of assets. Under this methodology, asset gains/losses resulting from actual returns that differ from the Company's expected returns are recognized in the market-related value of assets ratably over a five-year period. Also, net loss amounts in *AOCI* in excess of certain thresholds are amortized into net periodic benefit cost over the average remaining service life of employees.

Restructuring Costs

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

Impairments of Long-Lived Assets

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

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

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

likely than not that the fair value of a reporting unit is less than its carrying amount, a quantitative fair value test is performed. If the carrying value of a reporting unit is greater than its fair value, a goodwill impairment charge will be recorded for the difference (up to the carrying value of goodwill).

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

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

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

Impairments of Investments

The Company reviews its investments in marketable debt securities for impairments based on the determination of whether the decline in market value of the investment below the carrying value is other-than-temporary. The Company considers available evidence in evaluating potential impairments of its investments in marketable debt securities, including the duration and extent to which fair value is less than cost. Changes in fair value that are considered temporary are reported net of tax in *OCI*. An other-than-temporary impairment has occurred if the Company does not expect to recover the entire amortized cost basis of the marketable debt security. If the Company does not intend to sell the impaired debt security, and it is not more likely than not it will be required to sell the debt security before the recovery of its amortized cost basis, the amount of the other-than-temporary impairment recognized in earnings, recorded in *Other (income) expense, net*, is limited to the portion attributed to credit loss. The remaining portion of the other-than-temporary impairment related to other factors is recognized in *OCI*.

Investments in publicly traded equity securities are reported at fair value determined using quoted market prices in active markets for identical assets or quoted prices for similar assets or other inputs that are observable or can be corroborated by observable market data. Changes in fair value are included in *Other (income) expense, net*. Investments in equity securities without readily determinable fair values are recorded at cost, plus or minus subsequent observable price changes in orderly transactions for identical or similar investments, minus impairments. Such adjustments are recognized in *Other (income) expense, net*. Realized gains and losses for equity securities are included in *Other (income) expense, net*.

Taxes on Income

The Company's effective tax rate is based on pretax income, statutory tax rates and tax planning opportunities available in the various jurisdictions in which the Company operates. An estimated effective tax rate for a year is applied to the Company's quarterly operating results. In the event that there is a significant unusual or one-time item recognized, or expected to be recognized, in the Company's quarterly operating results, the tax attributable to that item would be separately calculated and recorded at the same time as the unusual or one-time item. The Company considers the resolution of prior year tax matters to be such items. Significant judgment is required in determining the Company's tax provision and in evaluating its tax positions. The recognition and measurement of a tax position is based on management's best judgment given the facts, circumstances and information available at the reporting date. The Company evaluates tax positions to determine whether the benefits of tax positions are more likely than not of being sustained upon audit based on the technical merits of the tax position. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely

of being realized upon ultimate settlement in the financial statements. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit in the financial statements. If the more likely than not threshold is not met in the period for which a tax position is taken, the Company may subsequently recognize the benefit of that tax position if the tax matter is effectively settled, the statute of limitations expires, or if the more likely than not threshold is met in a subsequent period (see Note 15 to the consolidated financial statements).

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

Recently Issued Accounting Standards

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

Cautionary Factors That May Affect Future Results

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

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

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

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

Item 8. Financial Statements and Supplementary Data.

(a) Financial Statements

The consolidated balance sheet of Merck & Co., Inc. and subsidiaries as of December 31, 2019 and 2018, and the related consolidated statements of income, of comprehensive income, of equity and of cash flows for each of the three years in the period ended December 31, 2019, the notes to consolidated financial statements, and the report dated February 26, 2020 of PricewaterhouseCoopers LLP, independent registered public accounting firm, are as follows:

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

	2019	2018	2017
Sales	**$ 46,840**	$ 42,294	$ 40,122
Costs, Expenses and Other			
Cost of sales	**14,112**	13,509	12,912
Selling, general and administrative	**10,615**	10,102	10,074
Research and development	**9,872**	9,752	10,339
Restructuring costs	**638**	632	776
Other (income) expense, net	**139**	(402)	(500)
	35,376	33,593	33,601
Income Before Taxes	**11,464**	8,701	6,521
Taxes on Income	**1,687**	2,508	4,103
Net Income	**9,777**	6,193	2,418
Less: Net (Loss) Income Attributable to Noncontrolling Interests	**(66)**	(27)	24
Net Income Attributable to Merck & Co., Inc.	**$ 9,843**	$ 6,220	$ 2,394
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	**$ 3.84**	$ 2.34	$ 0.88
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	**$ 3.81**	$ 2.32	$ 0.87

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

	2019	2018	2017
Net Income Attributable to Merck & Co., Inc.	**$ 9,843**	$ 6,220	$ 2,394
Other Comprehensive (Loss) Income Net of Taxes:			
Net unrealized (loss) gain on derivatives, net of reclassifications	**(135)**	297	(446)
Net unrealized gain (loss) on investments, net of reclassifications	**96**	(10)	(58)
Benefit plan net (loss) gain and prior service (cost) credit, net of amortization	**(705)**	(425)	419
Cumulative translation adjustment	**96**	(223)	401
	(648)	(361)	316
Comprehensive Income Attributable to Merck & Co., Inc.	**$ 9,195**	$ 5,859	$ 2,710

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

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

	2019	2018
Assets		
Current Assets		
Cash and cash equivalents	**$ 9,676**	$ 7,965
Short-term investments	**774**	899
Accounts receivable (net of allowance for doubtful accounts of $86 in 2019 and $119 in 2018)	**6,778**	7,071
Inventories (excludes inventories of $1,480 in 2019 and $1,417 in 2018 classified in Other assets - see Note 7)	**5,978**	5,440
Other current assets	**4,277**	4,500
Total current assets	**27,483**	25,875
Investments	**1,469**	6,233
Property, Plant and Equipment (at cost)		
Land	**343**	333
Buildings	**11,989**	11,486
Machinery, equipment and office furnishings	**15,394**	14,441
Construction in progress	**5,013**	3,355
	32,739	29,615
Less: accumulated depreciation	**17,686**	16,324
	15,053	13,291
Goodwill	**19,425**	18,253
Other Intangibles, Net	**14,196**	13,104
Other Assets	**6,771**	5,881
	$ 84,397	$ 82,637
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	**$ 3,610**	$ 5,308
Trade accounts payable	**3,738**	3,318
Accrued and other current liabilities	**12,549**	10,151
Income taxes payable	**736**	1,971
Dividends payable	**1,587**	1,458
Total current liabilities	**22,220**	22,206
Long-Term Debt	**22,736**	19,806
Deferred Income Taxes	**1,470**	1,702
Other Noncurrent Liabilities	**11,970**	12,041
Merck & Co., Inc. Stockholders' Equity		
Common stock, $0.50 par value Authorized - 6,500,000,000 shares Issued - 3,577,103,522 shares in 2019 and 2018	**1,788**	1,788
Other paid-in capital	**39,660**	38,808
Retained earnings	**46,602**	42,579
Accumulated other comprehensive loss	**(6,193)**	(5,545)
	81,857	77,630
Less treasury stock, at cost: 1,038,087,496 shares in 2019 and 984,543,979 shares in 2018	**55,950**	50,929
Total Merck & Co., Inc. stockholders' equity	**25,907**	26,701
Noncontrolling Interests	**94**	181
Total equity	**26,001**	26,882
	$ 84,397	$ 82,637

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

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

	Common Stock	Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock	Non-controlling Interests	Total
Balance January 1, 2017	$1,788	$39,939	$ 44,133	$ (5,226)	$(40,546)	$ 220	$ 40,308
Net income attributable to Merck & Co., Inc.	—	—	2,394	—	—	—	2,394
Other comprehensive income, net of taxes	—	—	—	316	—	—	316
Cash dividends declared on common stock ($1.89 per share)	—	—	(5,177)	—	—	—	(5,177)
Treasury stock shares purchased	—	—	—	—	(4,014)	—	(4,014)
Acquisition of Vallée S.A.	—	—	—	—	—	7	7
Net income attributable to noncontrolling interests	—	—	—	—	—	24	24
Distributions attributable to noncontrolling interests	—	—	—	—	—	(18)	(18)
Share-based compensation plans and other	—	(37)	—	—	766	—	729
Balance December 31, 2017	1,788	39,902	41,350	(4,910)	(43,794)	233	34,569
Net income attributable to Merck & Co., Inc.	—	—	6,220	—	—	—	6,220
Adoption of new accounting standards	—	—	322	(274)	—	—	48
Other comprehensive loss, net of taxes	—	—	—	(361)	—	—	(361)
Cash dividends declared on common stock ($1.99 per share)	—	—	(5,313)	—	—	—	(5,313)
Treasury stock shares purchased	—	(1,000)	—	—	(8,091)	—	(9,091)
Net loss attributable to noncontrolling interests	—	—	—	—	—	(27)	(27)
Distributions attributable to noncontrolling interests	—	—	—	—	—	(25)	(25)
Share-based compensation plans and other	—	(94)	—	—	956	—	862
Balance December 31, 2018	1,788	38,808	42,579	(5,545)	(50,929)	181	26,882
Net income attributable to Merck & Co., Inc.	**—**	**—**	**9,843**	**—**	**—**	**—**	**9,843**
Other comprehensive loss, net of taxes	**—**	**—**	**—**	**(648)**	**—**	**—**	**(648)**
Cash dividends declared on common stock ($2.26 per share)	**—**	**—**	**(5,820)**	**—**	**—**	**—**	**(5,820)**
Treasury stock shares purchased	**—**	**1,000**	**—**	**—**	**(5,780)**	**—**	**(4,780)**
Net loss attributable to noncontrolling interests	**—**	**—**	**—**	**—**	**—**	**(66)**	**(66)**
Distributions attributable to noncontrolling interests	**—**	**—**	**—**	**—**	**—**	**(21)**	**(21)**
Share-based compensation plans and other	**—**	**(148)**	**—**	**—**	**759**	**—**	**611**
Balance December 31, 2019	**$ 1,788**	**$39,660**	**$ 46,602**	**$ (6,193)**	**$(55,950)**	**$ 94**	**$ 26,001**

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

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

	2019	2018	2017
Cash Flows from Operating Activities			
Net income	**$ 9,777**	$ 6,193	$ 2,418
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	**3,652**	4,519	4,676
Intangible asset impairment charges	**1,040**	296	646
Charge for the acquisition of Peloton Therapeutics, Inc.	**993**	—	—
Charge for future payments related to collaboration license options	**—**	650	500
Provisional charge for one-time transition tax related to the enactment of U.S. tax legislation	**—**	—	5,347
Deferred income taxes	**(556)**	(509)	(2,621)
Share-based compensation	**417**	348	312
Other	**184**	978	190
Net changes in assets and liabilities:			
Accounts receivable	**294**	(418)	297
Inventories	**(508)**	(911)	(145)
Trade accounts payable	**399**	230	254
Accrued and other current liabilities	**376**	(341)	(922)
Income taxes payable	**(2,359)**	827	(3,291)
Noncurrent liabilities	**(237)**	(266)	(123)
Other	**(32)**	(674)	(1,087)
Net Cash Provided by Operating Activities	**13,440**	10,922	6,451
Cash Flows from Investing Activities			
Capital expenditures	**(3,473)**	(2,615)	(1,888)
Purchases of securities and other investments	**(3,202)**	(7,994)	(10,739)
Proceeds from sales of securities and other investments	**8,622**	15,252	15,664
Acquisition of Antelliq Corporation, net of cash acquired	**(3,620)**	—	—
Acquisition of Peloton Therapeutics, Inc., net of cash acquired	**(1,040)**	—	—
Other acquisitions, net of cash acquired	**(294)**	(431)	(396)
Other	**378**	102	38
Net Cash (Used in) Provided by Investing Activities	**(2,629)**	4,314	2,679
Cash Flows from Financing Activities			
Net change in short-term borrowings	**(3,710)**	5,124	(26)
Payments on debt	**—**	(4,287)	(1,103)
Proceeds from issuance of debt	**4,958**	—	—
Purchases of treasury stock	**(4,780)**	(9,091)	(4,014)
Dividends paid to stockholders	**(5,695)**	(5,172)	(5,167)
Proceeds from exercise of stock options	**361**	591	499
Other	**5**	(325)	(195)
Net Cash Used in Financing Activities	**(8,861)**	(13,160)	(10,006)
Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash	**17**	(205)	457
Net Increase (Decrease) in Cash, Cash Equivalents and Restricted Cash	**1,967**	1,871	(419)
Cash, Cash Equivalents and Restricted Cash at Beginning of Year (includes $2 million of restricted cash at January 1, 2019 included in Other Assets)	**7,967**	6,096	6,515
Cash, Cash Equivalents and Restricted Cash at End of Year (includes $258 million of restricted cash at December 31, 2019 included in Other Assets - see Note 6)	**$ 9,934**	$ 7,967	$ 6,096

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

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

1. Nature of Operations

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

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

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

The Healthcare Services segment provides services and solutions that focus on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company has recently sold certain businesses in the Healthcare Services segment and is in the process of divesting the remaining businesses.

The Alliances segment primarily includes activity from the Company's relationship with AstraZeneca LP related to sales of Nexium and Prilosec, which concluded in 2018.

Planned Spin-Off of Women's Health, Legacy Brands and Biosimilars into New Company

In February 2020, Merck announced its intention to spin-off products from its women's health, trusted legacy brands and biosimilars businesses into a new, yet-to-be-named, independent, publicly traded company (NewCo) through a distribution of NewCo's publicly traded stock to Company shareholders. The distribution is expected to qualify as tax-free to the Company and its shareholders for U.S. federal income tax purposes. The legacy brands included in the transaction consist of dermatology, pain, respiratory, and select cardiovascular products including *Zetia* and *Vytorin*, as well as the rest of Merck's diversified brands franchise. Merck's existing research pipeline programs will continue to be owned and developed within Merck as planned. NewCo will have development capabilities initially focused on late-stage development and life-cycle management, and is expected over time to develop research capabilities in selected therapeutic areas. The spin-off is expected to be completed in the first half of 2021, subject to market and certain other conditions. Subsequent to the spin-off, the historical results of the woman's health, legacy brands and biosimilars businesses will be reflected as discontinued operations in the Company's consolidated financial statements.

2. Summary of Accounting Policies

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

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

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

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

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

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

Investments in publicly traded equity securities are reported at fair value determined using quoted market prices in active markets for identical assets or quoted prices for similar assets or other inputs that are observable or can be corroborated by observable market data. Changes in fair value are included in *Other (income) expense, net*.

Investments in equity securities without readily determinable fair values are recorded at cost, plus or minus subsequent observable price changes in orderly transactions for identical or similar investments, minus impairments. Such adjustments are recognized in *Other (income) expense, net*. Realized gains and losses for equity securities are included in *Other (income) expense, net*.

Revenue Recognition — On January 1, 2018, the Company adopted ASU 2014-09, *Revenue from Contracts with Customers*, and subsequent amendments (ASC 606 or new guidance), using the modified retrospective method. Comparative information for prior periods has not been restated and continues to be reported under the accounting standards in effect for those periods.

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

The vast majority of revenues from sales of products are recognized at a point in time when control of the goods is transferred to the customer, which the Company has determined is when title and risks and rewards of ownership transfer to the customer and the Company is entitled to payment. The Company recognizes revenue from the sales of vaccines to the Federal government for placement into vaccine stockpiles in accordance with Securities and Exchange Commission (SEC) Interpretation, *Commission Guidance Regarding Accounting for Sales of Vaccines and BioTerror Countermeasures to the Federal Government for Placement into the Pediatric Vaccine Stockpile or the Strategic National Stockpile*. This interpretation allows companies to recognize revenue for sales of vaccines into U.S. government stockpiles even though these sales might not meet the criteria for revenue recognition under other accounting guidance. For businesses within the Company's Healthcare Services segment and certain services in the Animal Health segment, revenue is recognized over time, generally ratably over the contract term as services are provided. These service revenues are not material.

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

In the United States, sales discounts are issued to customers at the point-of-sale, through an intermediary wholesaler (known as chargebacks), or in the form of rebates. Additionally, sales are generally made with a limited right of return under certain conditions. Revenues are recorded net of provisions for sales discounts and returns, which are established at the time of sale. In addition, revenues are recorded net of time value of money discounts if collection of accounts receivable is expected to be in excess of one year.

The U.S. provision for aggregate customer discounts covering chargebacks and rebates was $11.8 billion in 2019, $10.7 billion in 2018 and $10.7 billion in 2017. Chargebacks are discounts that occur when a contracted customer purchases through an intermediary wholesaler. The contracted customer generally purchases product from the wholesaler at its contracted price plus a mark-up. The wholesaler, in turn, charges the Company back for the difference between the price initially paid by the wholesaler and the contract price paid to the wholesaler by the customer. The provision for chargebacks is based on expected sell-through levels by the Company's wholesale customers to contracted customers, as well as estimated wholesaler inventory levels. Rebates are amounts owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. The Company uses historical customer segment utilization mix, sales forecasts, changes to product mix and price, inventory levels in the distribution channel, government pricing calculations and prior payment history in order to estimate the expected provision. Amounts accrued for aggregate customer discounts are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal and state agencies, and other customers to the amounts accrued. The accrued balances relative to the provisions for chargebacks and rebates included in *Accounts*

receivable and *Accrued and other current liabilities* were $233 million and $2.2 billion, respectively, at December 31, 2019 and were $245 million and $2.4 billion, respectively, at December 31, 2018.

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

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

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

Depreciation — Depreciation is provided over the estimated useful lives of the assets, principally using the straight-line method. For tax purposes, accelerated tax methods are used. The estimated useful lives primarily range from 25 to 45 years for *Buildings*, and from 3 to 15 years for *Machinery, equipment and office furnishings*. Depreciation expense was $1.7 billion in 2019, $1.4 billion in 2018 and $1.5 billion in 2017.

Advertising and Promotion Costs — Advertising and promotion costs are expensed as incurred. The Company recorded advertising and promotion expenses of $2.1 billion, $2.1 billion and $2.2 billion in 2019, 2018 and 2017, respectively.

Software Capitalization — The Company capitalizes certain costs incurred in connection with obtaining or developing internal-use software including external direct costs of material and services, and payroll costs for employees directly involved with the software development. These costs are included in *Property, plant and equipment*. In addition, the Company capitalizes certain costs incurred to implement a cloud computing arrangement that is considered a service agreement, which are included in *Other Assets*. Capitalized software costs are amortized beginning when the software project is substantially complete and the asset is ready for its intended use. Capitalized software costs associated with projects that are being amortized over 6 to 10 years (including the Company's on-going multi-year implementation of an enterprise-wide resource planning system) were $548 million and $439 million, net of accumulated amortization at December 31, 2019 and 2018, respectively. All other capitalized software costs are being amortized over periods ranging from 3 to 5 years. Costs incurred during the preliminary project stage and post-implementation stage, as well as maintenance and training costs, are expensed as incurred.

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

Acquired Intangibles — Acquired intangibles include products and product rights, licenses, trade names and patents, which are initially recorded at fair value, assigned an estimated useful life, and amortized primarily on a straight-line basis over their estimated useful lives ranging from 2 to 24 years (see Note 8). The Company periodically evaluates whether current facts or circumstances indicate that the carrying values of its acquired intangibles may not

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

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

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

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

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

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

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

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

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

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

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

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

Recently Adopted Accounting Standards — In February 2016, the Financial Accounting Standards Board (FASB) issued new accounting guidance for the accounting and reporting of leases (ASU 2016-02) and subsequently issued several updates to the new guidance (ASC 842 or new leasing guidance). The new leasing guidance requires

that lessees recognize a right-of-use asset and a lease liability for each of its leases (other than leases that meet the definition of a short-term lease). Leases are classified as either operating or finance. Operating leases result in straight-line expense in the income statement (similar to previous operating leases), while finance leases result in more expense being recognized in the earlier years of the lease term (similar to previous capital leases). The Company adopted the new standard on January 1, 2019 using a modified retrospective approach. Merck elected the transition method that allows for application of the standard at the adoption date rather than at the beginning of the earliest comparative period presented in the financial statements. The Company also elected available practical expedients. Upon adoption, the Company recognized $1.1 billion of additional assets and related liabilities on its consolidated balance sheet (see Note 9). The adoption of the new leasing guidance did not impact the Company's consolidated statements of income or of cash flows.

In April 2018, the FASB issued new guidance on the accounting for costs incurred to implement a cloud computing arrangement that is considered a service arrangement. The new guidance requires the capitalization of such costs, aligning it with the accounting for costs associated with developing or obtaining internal-use software. The Company adopted the new standard in the third quarter of 2019 using prospective application for eligible costs, which were immaterial.

In August 2018, the FASB issued new guidance modifying the disclosure requirements for employers that sponsor defined benefit pension or other postretirement plans. The new guidance removes disclosures that no longer are considered cost beneficial, clarifies the specific requirements of certain disclosures, and adds disclosure requirements identified as relevant. The Company elected to early adopt the new guidance in 2019 on a retrospective basis resulting in minor changes to its employee benefit plan disclosures (see Note 13).

Also, in August 2018, the FASB issued new guidance on fair value measurements that adds, removes, and modifies certain disclosure requirements. The Company elected to early adopt the new guidance in 2019 resulting in minor changes to its fair value disclosures (see Note 6).

Recently Issued Accounting Standards Not Yet Adopted — In June 2016, the FASB issued new guidance on the accounting for credit losses on financial instruments. The new guidance introduces an expected loss model for estimating credit losses, replacing the incurred loss model. The new guidance also changes the impairment model for available-for-sale debt securities, requiring the use of an allowance to record estimated credit losses (and subsequent recoveries). The Company adopted the new guidance effective January 1, 2020. There was no impact to the Company's consolidated financial statements upon adoption.

In November 2018, the FASB issued new guidance for collaborative arrangements intended to reduce diversity in practice by clarifying whether certain transactions between collaborative arrangement participants should be accounted for under revenue recognition guidance (ASC 606). The Company adopted the new guidance effective January 1, 2020, which will result in minor changes to the footnote presentation of information related to the Company's collaborative arrangements.

In December 2019, the FASB issued amended guidance on the accounting and reporting of income taxes. The guidance is intended to simplify the accounting for income taxes by removing exceptions related to certain intraperiod tax allocations and deferred tax liabilities; clarifying guidance primarily related to evaluating the step-up tax basis for goodwill in a business combination; and reflecting enacted changes in tax laws or rates in the annual effective tax rate. The amended guidance is effective for interim and annual periods in 2021. Early adoption is permitted. The application of the amendments in the new guidance are to be applied on a retrospective basis, on a modified retrospective basis through a cumulative-effect adjustment to retained earnings or prospectively, depending on the amendment. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In January 2020, the FASB issued new guidance intended to clarify certain interactions between accounting standards related to equity securities, equity method investments and certain derivatives. The guidance addresses accounting for the transition into and out of the equity method of accounting and measuring certain purchased options and forward contracts to acquire investments. The new guidance is effective for interim and annual periods in 2021 and is to be applied prospectively. Early adoption is permitted. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

3. Acquisitions, Divestitures, Research Collaborations and License Agreements

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

Recently Completed Transaction

In January 2020, Merck acquired ArQule, Inc. (ArQule), a publicly traded biopharmaceutical company focused on kinase inhibitor discovery and development for the treatment of patients with cancer and other diseases for $2.7 billion. ArQule's lead investigational candidate, MK-1026 (formerly ARQ 531), is a novel, oral Bruton's tyrosine kinase (BTK) inhibitor currently in a Phase 2 dose expansion study for the treatment of B-cell malignancies. The Company is in the process of determining the preliminary fair value of assets acquired, liabilities assumed and total consideration transferred in this transaction, which will be accounted for as an acquisition of a business.

2019 Transactions

In July 2019, Merck acquired Peloton Therapeutics, Inc. (Peloton), a clinical-stage biopharmaceutical company focused on the development of novel small molecule therapeutic candidates targeting hypoxia-inducible factor-2α (HIF-2α) for the treatment of patients with cancer and other non-oncology diseases. Peloton's lead candidate, MK-6482 (formerly PT2977), is a novel oral HIF-2α inhibitor in late-stage development for renal cell carcinoma. Merck made an upfront payment of $1.2 billion in cash; additionally, former Peloton shareholders will be eligible to receive $50 million upon U.S. regulatory approval, $50 million upon first commercial sale in the United States, and up to $1.05 billion of sales-based milestones. The transaction was accounted for as an acquisition of an asset. Merck recorded cash of $157 million, deferred tax liabilities of $52 million, and other net liabilities of $4 million at the acquisition date and *Research and development* expenses of $993 million in 2019 related to the transaction.

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

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

($ in millions)	April 1, 2019
Cash and cash equivalents	$ 31
Accounts receivable	73
Inventories	95
Property, plant and equipment	62
Identifiable intangible assets (useful lives ranging from 18-24 years) [(1)]	2,689
Deferred income tax liabilities	(520)
Other assets and liabilities, net	(81)
Total identifiable net assets	2,349
Goodwill [(2)]	1,302
Consideration transferred	$ 3,651

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

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

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

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

2018 Transactions

In 2018, the Company recorded an aggregate charge of $423 million within *Cost of sales* in conjunction with the termination of a collaboration agreement entered into in 2014 with Samsung Bioepis Co., Ltd. (Samsung) for insulin glargine. The charge reflects a termination payment of $155 million, which represents the reimbursement of all fees previously paid by Samsung to Merck under the agreement, plus interest, as well as the release of Merck's ongoing obligations under the agreement. The charge also included fixed asset abandonment charges of $137 million, inventory write-offs of $122 million, as well as other related costs of $9 million. The termination of this agreement has no impact on the Company's other collaboration with Samsung.

In June 2018, Merck acquired Viralytics Limited (Viralytics), an Australian publicly traded company focused on oncolytic immunotherapy treatments for a range of cancers, for AUD 502 million ($378 million). The transaction provided Merck with full rights to V937 (formerly CVA21), Viralytics's investigational oncolytic immunotherapy. V937 is based on Viralytics's proprietary formulation of an oncolytic virus (Coxsackievirus Type A21) that has been shown to preferentially infect and kill cancer cells. V937 is currently being evaluated in multiple clinical trials, both as an intratumoral and intravenous agent, including in combination with *Keytruda*. Under a previous agreement between Merck and Viralytics, a study is investigating the use of the *Keytruda* and V937 combination in melanoma, prostate, lung and bladder cancers. The transaction was accounted for as an acquisition of an asset. Merck recorded net assets of $34 million (primarily cash) at the acquisition date and *Research and development* expenses of $344 million in 2018 related to the transaction. There are no future contingent payments associated with the acquisition.

In March 2018, Merck and Eisai Co., Ltd. (Eisai) entered into a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima, an orally available tyrosine kinase inhibitor discovered by Eisai (see Note 4).

2017 Transactions

In October 2017, Merck acquired Rigontec GmbH (Rigontec), a leader in accessing the retinoic acid-inducible gene I pathway, part of the innate immune system, as a novel and distinct approach in cancer immunotherapy to induce both immediate and long-term anti-tumor immunity. Rigontec's lead candidate, MK-4621 (formerly RGT100), is in development for the treatment in patients with various tumors. Under the terms of the agreement, Merck made an upfront cash payment of €119 million ($140 million) and may make additional contingent payments of up to €349 million (of which €184 million are related to the achievement of research milestones and regulatory approvals and €165 million are related to the achievement of commercial targets). The transaction was accounted for as an acquisition of an asset and the upfront payment is reflected within *Research and development* expenses in 2017.

In July 2017, Merck and AstraZeneca PLC (AstraZeneca) entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza for multiple cancer types (see Note 4).

In March 2017, Merck acquired a controlling interest in Vallée S.A. (Vallée), a leading privately held producer of animal health products in Brazil. Vallée has an extensive portfolio of products spanning parasiticides, anti-infectives and vaccines that include products for livestock, horses, and companion animals. Under the terms of the agreement, Merck acquired 93.5% of the shares of Vallée for $358 million. Of the total purchase price, $176 million was placed into escrow pending resolution of certain contingent items. The transaction was accounted for as an acquisition of a business. Merck recognized intangible assets of $297 million related to currently marketed products, net deferred tax liabilities of $102 million, other net assets of $32 million and noncontrolling interest of $25 million. In addition, the Company recorded liabilities of $37 million for contingencies identified at the acquisition date and corresponding

indemnification assets of $37 million, representing the amounts to be reimbursed to Merck if and when the contingent liabilities are paid. The excess of the consideration transferred over the fair value of net assets acquired of $156 million was recorded as goodwill. The goodwill was allocated to the Animal Health segment and is not deductible for tax purposes. The estimated fair values of identifiable intangible assets related to currently marketed products were determined using an income approach. Actual cash flows are likely to be different than those assumed. The intangible assets related to currently marketed products are being amortized over their estimated useful lives of 15 years. In the fourth quarter of 2017, Merck acquired an additional 4.5% interest in Vallée for $18 million, which reduced the noncontrolling interest related to Vallée.

Remicade/Simponi

In 1998, a subsidiary of Schering-Plough entered into a licensing agreement with Centocor Ortho Biotech Inc. (Centocor), a Johnson & Johnson (J&J) company, to market *Remicade,* which is prescribed for the treatment of inflammatory diseases. In 2005, Schering-Plough's subsidiary exercised an option under its contract with Centocor for license rights to develop and commercialize *Simponi*, a fully human monoclonal antibody. The Company has marketing rights to both products throughout Europe, Russia and Turkey. *Remicade* lost market exclusivity in major European markets in 2015 and the Company no longer has market exclusivity in any of its marketing territories. The Company continues to have market exclusivity for *Simponi* in all of its marketing territories. All profits derived from Merck's distribution of the two products in these countries are equally divided between Merck and J&J.

4. Collaborative Arrangements

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

AstraZeneca

In July 2017, Merck and AstraZeneca PLC (AstraZeneca) entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza for multiple cancer types. Lynparza is an oral poly (ADP-ribose) polymerase (PARP) inhibitor currently approved for certain types of ovarian and breast cancer. The companies are jointly developing and commercializing Lynparza, both as monotherapy and in combination trials with other potential medicines. Independently, Merck and AstraZeneca will develop and commercialize Lynparza in combinations with their respective PD-1 and PD-L1 medicines, *Keytruda* and Imfinzi. The companies will also jointly develop and commercialize AstraZeneca's selumetinib, an oral, potent, selective inhibitor of MEK, part of the mitogen-activated protein kinase (MAPK) pathway, currently being developed for multiple indications. Under the terms of the agreement, AstraZeneca and Merck will share the development and commercialization costs for Lynparza and selumetinib monotherapy and non-PD-L1/PD-1 combination therapy opportunities.

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

As part of the agreement, Merck made an upfront payment to AstraZeneca of $1.6 billion in 2017 and made payments of $750 million over a multi-year period for certain license options (of which $250 million was paid in December 2017, $400 million was paid in December 2018 and $100 million was paid in December 2019). The Company recorded an aggregate charge of $2.35 billion in *Research and development* expenses in 2017 related to the upfront payment and license option payments. In addition, the agreement provides for additional contingent payments from Merck to AstraZeneca related to the successful achievement of sales-based and regulatory milestones.

In 2019, Merck determined it was probable that annual sales of Lynparza in the future would trigger a $300 million sales-based milestone payment from Merck to AstraZeneca. Accordingly, in 2019, Merck recorded a $300

million liability and a corresponding increase to the intangible asset related to Lynparza. Prior to 2019, Merck accrued sales-based milestone payments aggregating $700 million, of which $200 million and $250 million was paid to AstraZeneca in 2019 and 2018, respectively, and the remainder of $250 million was paid in January 2020. Potential future sales-based milestone payments of $3.1 billion have not yet been accrued as they are not deemed by the Company to be probable at this time.

In 2019, Lynparza received regulatory approval in the European Union (EU) both as a monotherapy for the treatment of certain adult patients with advanced breast cancer and as a monotherapy for the maintenance treatment of certain adult patients with *BRCA*-mutated advanced ovarian cancer. Each of these approvals triggered a $30 million capitalized milestone payment from Merck to AstraZeneca. In 2018, Lynparza received regulatory approvals triggering capitalized milestone payments of $140 million in the aggregate from Merck to AstraZeneca. Potential future regulatory milestone payments of $1.7 billion remain under the agreement.

The intangible asset balance related to Lynparza (which includes capitalized sales-based and regulatory milestone payments) was $955 million at December 31, 2019 and is included in *Other Intangibles, Net* on the Consolidated Balance Sheet. The amount is being amortized over its estimated useful life through 2028 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

Years Ended December 31	**2019**	2018	2017
Alliance revenue	**$ 444**	$ 187	$ 20
Cost of sales [1]	**148**	93	4
Selling, general and administrative	**138**	48	1
Research and development [2]	**168**	152	2,419

December 31	**2019**	2018
Receivables from AstraZeneca included in *Other current assets*	$ 128	$ 52
Payables to AstraZeneca included in *Accrued and other current liabilities* [3]	577	405
Payables to AstraZeneca included *Other Noncurrent Liabilities* [3]	—	250

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

[2] *Amount for 2017 includes $2.35 billion related to the upfront payment and license option payments.*

[3] *Includes accrued milestone payments.*

Eisai

In March 2018, Merck and Eisai announced a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima, an orally available tyrosine kinase inhibitor discovered by Eisai. Under the agreement, Merck and Eisai will develop and commercialize Lenvima jointly, both as monotherapy and in combination with Merck's *Keytruda*. Eisai records Lenvima product sales globally (Eisai is the principal on Lenvima sales transactions), and Merck and Eisai share gross profits equally. Merck records its share of Lenvima product sales, net of cost of sales and commercialization costs, as alliance revenue. Expenses incurred during co-development, including for studies evaluating Lenvima as monotherapy, are shared equally by the two companies and reflected in *Research and development* expenses.

Under the agreement, Merck made an upfront payment to Eisai of $750 million and will make payments of up to $650 million for certain option rights through 2021 (of which $325 million was paid in March 2019, $200 million is expected to be paid in March 2020 and $125 million is expected to be paid in March 2021). The Company recorded an aggregate charge of $1.4 billion in *Research and development* expenses in 2018 related to the upfront payment and future option payments. In addition, the agreement provides for additional contingent payments from Merck to Eisai related to the successful achievement of sales-based and regulatory milestones.

In 2019, Merck determined it was probable that annual sales of Lenvima in the future would trigger sales-based milestone payments from Merck to Eisai aggregating $682 million. Accordingly, in 2019, Merck recorded $682 million of liabilities and corresponding increases to the intangible asset related to Lenvima. In 2018, Merck accrued sales-based milestone payments aggregating $268 million related to Lenvima. Of these amounts, $50 million was paid

to Eisai in 2019 and an additional $150 million was paid in January 2020. Potential future sales-based milestone payments of $3.0 billion have not yet been accrued as they are not deemed by the Company to be probable at this time.

In 2018, Lenvima received regulatory approvals triggering capitalized milestone payments of $250 million in the aggregate from Merck to Eisai. Potential future regulatory milestone payments of $135 million remain under the agreement.

The intangible asset balance related to Lenvima (which includes capitalized sales-based and regulatory milestone payments) was $956 million at December 31, 2019 and is included in *Other Intangibles, Net* on the Consolidated Balance Sheet. The amount is being amortized over its estimated useful life through 2026 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

Years Ended December 31	**2019**	2018
Alliance revenue	**$ 404**	$ 149
Cost of sales [(1)]	**206**	39
Selling, general and administrative	**80**	13
Research and development [(2)]	**189**	1,489

December 31	**2019**	2018
Receivables from Eisai included in *Other current assets*	**$ 150**	$ 71
Payables to Eisai included in *Accrued and other current liabilities* [(3)]	**700**	375
Payables to Eisai included in *Other Noncurrent Liabilities* [(3)]	**525**	543

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

[(2)] *Amount for 2018 includes $1.4 billion related to the upfront payment and option payments.*

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

Bayer AG

In 2014, the Company entered into a worldwide clinical development collaboration with Bayer AG (Bayer) to market and develop soluble guanylate cyclase (sGC) modulators including Bayer's Adempas, which is approved to treat pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension. The two companies have implemented a joint development and commercialization strategy. The collaboration also includes clinical development of Bayer's vericiguat, which is in Phase 3 trials for worsening heart failure, as well as opt-in rights for other early-stage sGC compounds in development by Bayer. Merck in turn made available its early-stage sGC compounds under similar terms. Under the agreement, Bayer leads commercialization of Adempas in the Americas, while Merck leads commercialization in the rest of the world. For vericiguat and other potential opt-in products, Bayer will lead commercialization in the rest of world and Merck will lead in the Americas. For all products and candidates included in the agreement, both companies will share in development costs and profits on sales and will have the right to co-promote in territories where they are not the lead. Revenue from Adempas includes sales in Merck's marketing territories, as well as Merck's share of profits from the sale of Adempas in Bayer's marketing territories. In addition, the agreement provides for additional contingent payments from Merck to Bayer related to the successful achievement of sales-based milestones.

In 2018, Merck determined it was probable that annual worldwide sales of Adempas in the future would trigger a $375 million sales-based milestone payment from Merck to Bayer. Accordingly, Merck recorded a $375 million liability and a corresponding increase to the intangible asset related to Adempas. In 2018, the Company made a $350 million milestone payment to Bayer, which was accrued for in 2016 when Merck deemed the payment to be probable. There is an additional $400 million potential future sales-based milestone payment that has not yet been accrued as it is not deemed by the Company to be probable at this time.

The intangible asset balance related to Adempas (which includes the acquired intangible asset balance, as well as capitalized sales-based milestone payments) was $883 million at December 31, 2019 and is included in *Other Intangibles, Net* on the Consolidated Balance Sheet. The amount is being amortized over its estimated useful life through 2027 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

Years Ended December 31	**2019**	2018	2017
Net product sales recorded by Merck	**$ 215**	$ 190	$ 149
Merck's profit share from sales in Bayer's marketing territories	**204**	139	151
Total sales	**419**	329	300
Cost of sales [1]	**113**	216	99
Selling, general and administrative	**41**	35	27
Research and development	**126**	127	101

December 31	**2019**	2018
Receivables from Bayer included in *Other current assets*	**$ 49**	$ 32
Payables to Bayer included in *Other Noncurrent Liabilities* [2]	**375**	375

[1] *Includes amortization of intangible assets.*

[2] *Represents accrued milestone payment.*

5. Restructuring

In early 2019, Merck approved a new global restructuring program (Restructuring Program) as part of a worldwide initiative focused on further optimizing the Company's manufacturing and supply network, as well as reducing its global real estate footprint. This program is a continuation of the Company's plant rationalization, builds on prior restructuring programs and does not include any actions associated with the planned spin-off of NewCo. As the Company continues to evaluate its global footprint and overall operating model, it has subsequently identified additional actions under the Restructuring Program, and could identify further actions over time. The actions currently contemplated under the Restructuring Program are expected to be substantially completed by the end of 2023, with the cumulative pretax costs to be incurred by the Company to implement the program now estimated to be approximately $2.5 billion. The Company estimates that approximately 60% of the cumulative pretax costs will result in cash outlays, primarily related to employee separation expense and facility shut-down costs. Approximately 40% of the cumulative pretax costs will be non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested. The Company expects to record charges of approximately $800 million in 2020 related to the Restructuring Program. Actions under previous global restructuring programs have been substantially completed.

The Company recorded total pretax costs of $927 million in 2019, $658 million in 2018 and $927 million in 2017 related to restructuring program activities. For segment reporting, restructuring charges are unallocated expenses.

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

	Separation Costs	Accelerated Depreciation	Other	Total
Year Ended December 31, 2019				
Cost of sales	**$ —**	**$ 198**	**$ 53**	**$ 251**
Selling, general and administrative	**—**	**33**	**1**	**34**
Research and development	**—**	**2**	**2**	**4**
Restructuring costs	**572**	**—**	**66**	**638**
	$ 572	**$ 233**	**$ 122**	**$ 927**
Year Ended December 31, 2018				
Cost of sales	$ —	$ 10	$ 11	$ 21
Selling, general and administrative	—	2	1	3
Research and development	—	(13)	15	2
Restructuring costs	473	—	159	632
	$ 473	$ (1)	$ 186	$ 658
Year Ended December 31, 2017				
Cost of sales	$ —	$ 52	$ 86	$ 138
Selling, general and administrative	—	2	—	2
Research and development	—	6	5	11
Restructuring costs	552	—	224	776
	$ 552	$ 60	$ 315	$ 927

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

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

Other activity in 2019, 2018 and 2017 includes asset abandonment, facility shut-down and other related costs, as well as pretax gains and losses resulting from the sales of facilities and related assets. Additionally, other activity includes certain employee-related costs associated with pension and other postretirement benefit plans (see Note 13) and share-based compensation.

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

	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2018	$ 619	$ —	$ 128	$ 747
Expenses	473	(1)	186	658
(Payments) receipts, net	(649)	—	(238)	(887)
Non-cash activity	—	1	15	16
Restructuring reserves December 31, 2018	443	—	91	534
Expenses	**572**	**233**	**122**	**927**
(Payments) receipts, net	**(325)**	**—**	**(136)**	**(461)**
Non-cash activity	**—**	**(233)**	**(8)**	**(241)**
Restructuring reserves December 31, 2019 [(1)]	**$ 690**	**$ —**	**$ 69**	**$ 759**

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

6. Financial Instruments

Derivative Instruments and Hedging Activities

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

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

Foreign Currency Risk Management

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

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

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

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

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

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

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

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

	Amount of Pretax (Gain) Loss Recognized in Other Comprehensive Income[1]			Amount of Pretax (Gain) Loss Recognized in *Other (income) expense, net* for Amounts Excluded from Effectiveness Testing		
Years Ended December 31	**2019**	2018	2017	**2019**	2018	2017
Net Investment Hedging Relationships						
Foreign exchange contracts	**$ (10)**	$ (18)	$ —	**$ (31)**	$ (11)	$ —
Euro-denominated notes	**(75)**	(183)	520	**—**	—	—

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

Interest Rate Risk Management

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

At December 31, 2019, the Company was a party to 19 pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes as detailed in the table below.

	2019		
Debt Instrument	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
1.85% notes due 2020	$ 1,250	5	$ 1,250
3.875% notes due 2021	1,150	5	1,150
2.40% notes due 2022	1,000	4	1,000
2.35% notes due 2022	1,250	5	1,250

The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in the benchmark London Interbank Offered Rate (LIBOR) swap rate. The fair value changes in the notes attributable to changes in the LIBOR swap rate are recorded in interest expense along with the offsetting fair value changes in the swap contracts. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

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

	Carrying Amount of Hedged Liabilities		Cumulative Amount of Fair Value Hedging Adjustment Increase (Decrease) Included in the Carrying Amount	
	2019	2018	**2019**	2018
Balance Sheet Line Item in which Hedged Item is Included				
Loans payable and current portion of long-term debt	**$ 1,249**	$ —	**$ (1)**	$ —
Long-Term Debt	**3,409**	4,560	**14**	(82)

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

		2019			2018		
		Fair Value of Derivative			Fair Value of Derivative		
	Balance Sheet Caption	**Asset**	**Liability**	**U.S. Dollar Notional**	Asset	Liability	U.S. Dollar Notional
Derivatives Designated as Hedging Instruments							
Interest rate swap contracts	Other Assets	**$ 15**	**$ —**	**$ 3,400**	$ —	$ —	$ —
Interest rate swap contracts	Accrued and other current liabilities	**—**	**1**	**1,250**	—	—	—
Interest rate swap contracts	Other Noncurrent Liabilities	**—**	**—**	**—**	—	81	4,650
Foreign exchange contracts	Other current assets	**152**	**—**	**6,117**	263	—	6,222
Foreign exchange contracts	Other Assets	**55**	**—**	**2,160**	75	—	2,655
Foreign exchange contracts	Accrued and other current liabilities	**—**	**22**	**1,748**	—	7	774
Foreign exchange contracts	Other Noncurrent Liabilities	**—**	**1**	**53**	—	1	89
		$ 222	**$ 24**	**$ 14,728**	$ 338	$ 89	$ 14,390
Derivatives Not Designated as Hedging Instruments							
Foreign exchange contracts	Other current assets	**$ 66**	**$ —**	**$ 7,245**	$ 116	$ —	$ 5,430
Foreign exchange contracts	Accrued and other current liabilities	**—**	**73**	**8,693**	—	71	9,922
		$ 66	**$ 73**	**$ 15,938**	$ 116	$ 71	$ 15,352
		$ 288	**$ 97**	**$ 30,666**	$ 454	$ 160	$ 29,742

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

	2019		2018	
	Asset	**Liability**	Asset	Liability
Gross amounts recognized in the consolidated balance sheet	**$ 288**	**$ 97**	$ 454	$ 160
Gross amounts subject to offset in master netting arrangements not offset in the consolidated balance sheet	**(84)**	**(84)**	(121)	(121)
Cash collateral received	**(34)**	**—**	(107)	—
Net amounts	**$ 170**	**$ 13**	$ 226	$ 39

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

	Sales			Other (income) expense, net [1]			Other comprehensive income (loss)		
Years Ended December 31	**2019**	2018	2017	**2019**	2018	2017	**2019**	2018	2017
Financial Statement Line Items in which Effects of Fair Value or Cash Flow Hedges are Recorded	**$ 46,840**	$ 42,294	$ 40,122	**$ 139**	(402)	(500)	**$ (648)**	$ (361)	$ 316
(Gain) loss on fair value hedging relationships									
Interest rate swap contracts									
Hedged items	**—**	—	—	**95**	(27)	(48)	**—**	—	—
Derivatives designated as hedging instruments	**—**	—	—	**(65)**	50	12	**—**	—	—
Impact of cash flow hedging relationships									
Foreign exchange contracts									
Amount of gain (loss) recognized in *OCI* on derivatives	**—**	—	—	**—**	—	—	**87**	228	(562)
(Decrease) increase in *Sales* as a result of *AOCI* reclassifications	**255**	(160)	138	**—**	—	—	**(255)**	160	(138)
Interest rate contracts									
Amount of gain recognized in *Other (income) expense, net* on derivatives	**—**	—	—	**(4)**	(4)	(3)	**—**	—	—
Amount of loss recognized in *OCI* on derivatives	**—**	—	—	**—**	—	—	**(6)**	(4)	(3)

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

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

		Amount of Derivative Pretax (Gain) Loss Recognized in Income		
Years Ended December 31	Income Statement Caption	**2019**	2018	2017
Derivatives Not Designated as Hedging Instruments				
Foreign exchange contracts [1]	Other (income) expense, net	**$ 174**	$ (260)	$ 110
Foreign exchange contracts [2]	Sales	**1**	(8)	(3)

[1] *These derivative contracts mitigate changes in the value of remeasured foreign currency denominated monetary assets and liabilities attributable to changes in foreign currency exchange rates.*

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

At December 31, 2019, the Company estimates $31 million of pretax net unrealized gains on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from *AOCI* to *Sales*. The amount ultimately reclassified to *Sales* may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.

Investments in Debt and Equity Securities

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

	2019				2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$ 668	$ —	$ —	$ 668	$ —	$ —	$ —	$ —
Corporate notes and bonds	608	13	—	621	4,985	3	(68)	4,920
U.S. government and agency securities	266	3	—	269	895	2	(5)	892
Asset-backed securities	226	1	—	227	1,285	1	(11)	1,275
Foreign government bonds	—	—	—	—	167	—	(1)	166
Mortgage-backed securities	—	—	—	—	8	—	—	8
Total debt securities	1,768	17	—	1,785	7,340	6	(85)	7,261
Publicly traded equity securities [(1)]				838				456
Total debt and publicly traded equity securities				$ 2,623				$ 7,717

[(1)] *Unrealized net gains recognized in* Other (income) expense, net *on equity securities still held at December 31, 2019 were $160 million during 2019. Unrealized net losses recognized in* Other (income) expense, net *on equity securities still held at December 31, 2018 were $35 million during 2018.*

At December 31, 2019 and 2018, the Company also had $420 million and $568 million, respectively, of equity investments without readily determinable fair values included in *Other Assets*. During 2019 and 2018, the Company recognized unrealized gains of $20 million and $167 million, respectively, in *Other (income) expense, net*, on certain of these equity investments based on favorable observable price changes from transactions involving similar investments of the same investee. In addition, during 2019 and 2018, the Company recognized unrealized losses of $13 million and $26 million, respectively, in *Other (income) expense, net*, related to certain of these investments based on unfavorable observable price changes. Cumulative unrealized gains and cumulative unrealized losses based on observable prices changes for investments in equity investments without readily determinable fair values were $109 million and $21 million, respectively.

Available-for-sale debt securities included in *Short-term investments* totaled $749 million at December 31, 2019. Of the remaining debt securities, $933 million mature within five years. At December 31, 2019 and 2018, there were no debt securities pledged as collateral.

Fair Value Measurements

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

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

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

Level 3 — Unobservable inputs that are supported by little or no market activity. Level 3 assets or liabilities are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as assets or liabilities for which the determination of fair value requires significant judgment or estimation. If the inputs used to measure the financial assets and liabilities fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

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

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

	Fair Value Measurements Using				Fair Value Measurements Using			
	Level 1	**Level 2**	**Level 3**	**Total**	Level 1	Level 2	Level 3	Total
		2019				2018		
Assets								
Investments								
Commercial paper	**$ —**	**$ 668**	**$ —**	**$ 668**	$ —	$ —	$ —	$ —
Corporate notes and bonds	**—**	**621**	**—**	**621**	—	4,835	—	4,835
Asset-backed securities [1]	**—**	**227**	**—**	**227**	—	1,253	—	1,253
U.S. government and agency securities	**—**	**209**	**—**	**209**	—	731	—	731
Foreign government bonds	**—**	**—**	**—**	**—**	—	166	—	166
Publicly traded equity securities	**518**	**—**	**—**	**518**	147	—	—	147
	518	**1,725**	**—**	**2,243**	147	6,985	—	7,132
Other assets [2]								
U.S. government and agency securities	**60**	**—**	**—**	**60**	55	106	—	161
Corporate notes and bonds	**—**	**—**	**—**	**—**	—	85	—	85
Asset-backed securities [1]	**—**	**—**	**—**	**—**	—	22	—	22
Mortgage-backed securities	**—**	**—**	**—**	**—**	—	8	—	8
Publicly traded equity securities	**320**	**—**	**—**	**320**	309	—	—	309
	380	**—**	**—**	**380**	364	221	—	585
Derivative assets [3]								
Forward exchange contracts	**—**	**169**	**—**	**169**	—	241	—	241
Purchased currency options	**—**	**104**	**—**	**104**	—	213	—	213
Interest rate swaps	**—**	**15**	**—**	**15**	—	—	—	—
	—	**288**	**—**	**288**	—	454	—	454
Total assets	**$ 898**	**$ 2,013**	**$ —**	**$ 2,911**	$ 511	$ 7,660	$ —	$ 8,171
Liabilities								
Other liabilities								
Contingent consideration	**$ —**	**$ —**	**$ 767**	**$ 767**	$ —	$ —	$ 788	$ 788
Derivative liabilities [3]								
Forward exchange contracts	**—**	**95**	**—**	**95**	—	74	—	74
Interest rate swaps	**—**	**1**	**—**	**1**	—	81	—	81
Written currency options	**—**	**1**	**—**	**1**	—	5	—	5
	—	**97**	**—**	**97**	—	160	—	160
Total liabilities	**$ —**	**$ 97**	**$ 767**	**$ 864**	$ —	$ 160	$ 788	$ 948

[1] *Primarily all of the asset-backed securities are highly-rated (Standard & Poor's rating of AAA and Moody's Investors Service rating of Aaa), secured primarily by auto loan, credit card and student loan receivables, with weighted-average lives of primarily 5 years or less.*

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

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

As of December 31, 2019, *Cash and cash equivalents* of $9.7 billion include $8.9 billion of cash equivalents (which would be considered Level 2 in the fair value hierarchy).

Contingent Consideration

Summarized information about the changes in liabilities for contingent consideration associated with business acquisitions is as follows:

	2019	2018
Fair value January 1	**$ 788**	$ 935
Changes in estimated fair value [1]	**64**	89
Additions	**—**	8
Payments	**(85)**	(244)
Fair value December 31 [2][3]	**$ 767**	$ 788

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

[2] *Balance at December 31, 2019 includes $114 million recorded as a current liability for amounts expected to be paid within the next 12 months.*

[3] *At December 31, 2019 and 2018, $625 million and $614 million, respectively, of the liabilities relate to the termination of the SPMSD joint venture in 2016. As part of the termination, Merck recorded a liability for contingent future royalty payments of 11.5% on net sales of all Merck products that were previously sold by the joint venture through December 31, 2024. The fair value of this liability is determined utilizing the estimated amount and timing of projected cash flows and a risk-adjusted discount rate of 8% is used to present value the cash flows.*

The changes in the estimated fair value of liabilities for contingent consideration in 2019 and 2018 were largely attributable to increases in the liabilities recorded in connection with the termination of the Sanofi Pasteur MSD (SPMSD) joint venture in 2016. In 2018, these increases were partially offset by the reversal of a liability related to the discontinuation of a program obtained in connection with the acquisition of SmartCells (see Note 8). The payments of contingent consideration in both years relate to the SPMSD termination liabilities described above. The payments of contingent consideration in 2018 also include $175 million related to the achievement of a clinical development milestone for MK-7264 (gefapixant), a program obtained in connection with the acquisition of Afferent Pharmaceuticals.

Other Fair Value Measurements

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

The estimated fair value of loans payable and long-term debt (including current portion) at December 31, 2019, was $28.8 billion compared with a carrying value of $26.3 billion and at December 31, 2018, was $25.6 billion compared with a carrying value of $25.1 billion. Fair value was estimated using recent observable market prices and would be considered Level 2 in the fair value hierarchy.

Concentrations of Credit Risk

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

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

The Company's customers with the largest accounts receivable balances are: McKesson Corporation, AmerisourceBergen Corporation and Cardinal Health, Inc., which represented, in aggregate, approximately 35% of total accounts receivable at December 31, 2019. The Company monitors the creditworthiness of its customers to which it grants credit terms in the normal course of business. Bad debts have been minimal. The Company does not normally require collateral or other security to support credit sales.

The Company has accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable. In 2019, the Company expanded its factoring arrangements in China and entered into factoring agreements to sell accounts receivable from the Company's major U.S. distributors. The Company factored

$2.7 billion and $1.1 billion of accounts receivable in the fourth quarter of 2019 and 2018, respectively, under these factoring arrangements, which reduced outstanding accounts receivable. The cash received from the financial institutions is reported within operating activities in the Consolidated Statement of Cash Flows. In certain of these factoring arrangements, for ease of administration, the Company will collect customer payments related to the factored receivables, which it then remits to the financial institutions. At December 31, 2019, the Company had collected $256 million on behalf of the financial institutions, which is reflected as restricted cash in *Other current assets* and the related obligation to remit the cash within *Accrued and other current liabilities*. The Company remitted the cash to the financial institutions in January 2020. The net cash flows relating to these collections are reported as financing activities in the Consolidated Statement of Cash Flows. The costs of factoring such accounts receivable were *de minimis*.

Derivative financial instruments are executed under International Swaps and Derivatives Association master agreements. The master agreements with several of the Company's financial institution counterparties also include credit support annexes. These annexes contain provisions that require collateral to be exchanged depending on the value of the derivative assets and liabilities, the Company's credit rating, and the credit rating of the counterparty. Cash collateral received by the Company from various counterparties was $34 million and $107 million at December 31, 2019 and 2018, respectively. The obligation to return such collateral is recorded in *Accrued and other current liabilities*. No cash collateral was advanced by the Company to counterparties as of December 31, 2019 or 2018.

7. Inventories

Inventories at December 31 consisted of:

	2019	2018
Finished goods	**$ 1,772**	$ 1,658
Raw materials and work in process	**5,650**	5,004
Supplies	**207**	194
Total (approximates current cost)	**7,629**	6,856
(Decrease) increase to LIFO cost	**(171)**	1
	$ 7,458	$ 6,857
Recognized as:		
Inventories	**$ 5,978**	$ 5,440
Other assets	**1,480**	1,417

Inventories valued under the LIFO method comprised approximately $2.6 billion and $2.5 billion at December 31, 2019 and 2018, respectively. Amounts recognized as *Other assets* are comprised almost entirely of raw materials and work in process inventories. At December 31, 2019 and 2018, these amounts included $1.3 billion and $1.4 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included $168 million and $7 million at December 31, 2019 and 2018, respectively, of inventories produced in preparation for product launches.

8. Goodwill and Other Intangibles

The following table summarizes goodwill activity by segment:

	Pharmaceutical	Animal Health	All Other	Total
Balance January 1, 2018	$ 16,066	$ 1,877	$ 341	$ 18,284
Acquisitions	—	17	24	41
Impairments	—	—	(144)	(144)
Other [1]	96	(24)	—	72
Balance December 31, 2018 [2]	16,162	1,870	221	18,253
Acquisitions	**19**	**1,322**	**—**	**1,341**
Impairments	**—**	**—**	**(162)**	**(162)**
Other [1]	**—**	**—**	**(7)**	**(7)**
Balance December 31, 2019 [2]	**$ 16,181**	**$ 3,192**	**$ 52**	**$ 19,425**

[1] *Other includes cumulative translation adjustments on goodwill balances and certain other adjustments.*

[2] *Accumulated goodwill impairment losses at December 31, 2019 and 2018 were $531 million and $369 million, respectively.*

The additions to goodwill within the Animal Health segment in 2019 primarily relate to the acquisition of Antelliq (see Note 3). The impairments of goodwill within other non-reportable segments in 2019 and 2018 relate to certain businesses within the Healthcare Services segment.

Other intangibles at December 31 consisted of:

	2019			2018		
	Gross Carrying Amount	**Accumulated Amortization**	**Net**	Gross Carrying Amount	Accumulated Amortization	Net
Products and product rights	**$ 45,947**	**$ 38,852**	**$ 7,095**	$ 46,615	$ 37,585	$ 9,030
Licenses	**3,185**	**824**	**2,361**	2,081	408	1,673
IPR&D	**1,032**	**—**	**1,032**	1,064	—	1,064
Trade names	**2,899**	**217**	**2,682**	209	107	102
Other	**2,261**	**1,235**	**1,026**	2,403	1,168	1,235
	$ 55,324	**$ 41,128**	**$ 14,196**	$ 52,372	$ 39,268	$ 13,104

Acquired intangibles include products and product rights, licenses, trade names and patents, which are initially recorded at fair value, assigned an estimated useful life, and amortized primarily on a straight-line basis over their estimated useful lives. Some of the Company's more significant acquired intangibles, on a net basis, related to human health marketed products (included in products and product rights above) at December 31, 2019 include *Zerbaxa*, $2.4 billion; *Implanon/Nexplanon,* $412 million; *Gardasil/Gardasil* 9, $314 million; *Dificid*, $312 million; *Bridion*, $230 million; *Sivextro*, $171 million; and *Simponi*, $163 million. Additionally, the Company had $2.4 billion of acquired intangibles related to animal health marketed products at December 31, 2019. Some of the Company's more significant intangible assets included in licenses above at December 31, 2019 include Lenvima, $956 million and Lynparza, $955 million as a result of collaborations with Eisai and AstraZeneca (see Note 4). The increase in trade names in 2019 reflects $2.7 billion of intangibles acquired in the Antelliq acquisition in 2019 (see Note 3). The Company has an intangible asset related to Adempas as a result of a collaboration with Bayer (see Note 4) that had a carrying value of $883 million at December 31, 2019 reflected in "Other" in the table above.

In 2019, the Company recorded impairment charges related to marketed products and other intangibles of $705 million within *Cost of sales*. Of this amount, $612 million related to *Sivextro*, a product for the treatment of acute bacterial skin and skin structure infections caused by designated susceptible Gram-positive organisms. As part of a reorganization and reprioritization of its internal sales force, the Company made the decision to cease promotion of *Sivextro* in the U.S. market by the end of 2019. This decision resulted in reduced cash flow projections for *Sivextro*, which indicated that the *Sivextro* intangible asset value was not fully recoverable on an undiscounted cash flows basis. The Company utilized market participant assumptions to determine its best estimate of the fair value of the intangible

asset related to *Sivextro* that, when compared with its related carrying value, resulted in the impairment charge noted above.

In 2017, the Company recorded impairment charges related to marketed products and other intangibles of $58 million. Of this amount, $47 million related to *Intron A*, a treatment for certain types of cancers. Sales of *Intron A* were being adversely affected by the availability of new therapeutic options. In 2017, sales of *Intron A* in the United States eroded more rapidly than previously anticipated by the Company, which led to changes in the cash flow assumptions for *Intron A*. These revisions to cash flows indicated that the *Intron A* intangible asset value was not fully recoverable on an undiscounted cash flows basis. The Company utilized market participant assumptions to determine its best estimate of the fair value of the intangible asset related to *Intron A* that, when compared with its related carrying value, resulted in the impairment charge noted above. The remaining charges in 2017 relate to the impairment of customer relationship, tradename and developed technology intangibles for certain businesses in the Healthcare Services segment.

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

In 2019, the Company recorded $172 million of IPR&D impairment charges within *Research and development* expenses. Of this amount, $155 million relates to the write-off of the intangible asset balance for programs obtained in connection with the acquisition of IOmet Pharma Ltd following a review of clinical trial results conducted by Merck, along with external clinical trial results for similar compounds. The discontinuation of this clinical development program resulted in a reversal of the related liability for contingent consideration of $11 million.

In 2018, the Company recorded $152 million of IPR&D impairment charges. Of this amount, $139 million relates to the write-off of the remaining intangible asset balance for a program obtained in connection with the SmartCells acquisition following a decision to terminate the program due to product development issues. The discontinuation of this clinical development program resulted in a reversal of the related liability for contingent consideration of $60 million (see Note 6).

In 2017, the Company recorded $483 million of IPR&D impairment charges. Of this amount, $240 million resulted from a strategic decision to discontinue the development of the investigational combination regimens MK-3682B (grazoprevir/ruzasvir/uprifosbuvir) and MK-3682C (ruzasvir/uprifosbuvir) for the treatment of chronic hepatitis C virus (HCV) infection. This decision was made based on a review of available Phase 2 efficacy data and in consideration of the evolving marketplace and the growing number of treatment options available for patients with chronic HCV infection, including *Zepatier*, which is marketed by the Company for the treatment of adult patients with chronic HCV infection. As a result of this decision, the Company recorded an IPR&D impairment charge to write-off the remaining intangible asset related to uprifosbuvir. The IPR&D impairment charges in 2017 also include a charge of $226 million to write-off the intangible asset related to verubecestat, an investigational small molecule inhibitor of the beta-site amyloid precursor protein cleaving enzyme 1 (BACE1), resulting from a decision in February 2018 to stop a Phase 3 study evaluating verubecestat in people with prodromal Alzheimer's disease. The decision to stop the study followed a recommendation by the external Data Monitoring Committee (eDMC), which assessed overall benefit/risk during an interim safety analysis. The eDMC concluded that it was unlikely that positive benefit/risk could be established if the trial continued.

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

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

Aggregate amortization expense recorded within *Cost of sales* was $2.0 billion in 2019, $3.1 billion in 2018 and $3.2 billion in 2017. The estimated aggregate amortization expense for each of the next five years is as follows: 2020, $1.6 billion; 2021, $1.5 billion; 2022, $1.5 billion; 2023, $1.5 billion; 2024, $1.4 billion.

9. Loans Payable, Long-Term Debt and Leases

Loans Payable

Loans payable at December 31, 2019 included $1.9 billion of notes due in 2020, $1.4 billion of commercial paper and $226 million of long-dated notes that are subject to repayment at the option of the holders. Loans payable at December 31, 2018 included $5.1 billion of commercial paper and $149 million of long-dated notes that are subject to repayment at the option of the holders. The weighted-average interest rate of commercial paper borrowings was 2.23% and 2.09% for the years ended December 31, 2019 and 2018, respectively.

Long-Term Debt

Long-term debt at December 31 consisted of:

	2019	2018
2.75% notes due 2025	**$ 2,492**	$ 2,490
3.70% notes due 2045	**1,975**	1,974
2.80% notes due 2023	**1,747**	1,745
3.40% notes due 2029	**1,732**	—
4.00% notes due 2049	**1,468**	—
2.35% notes due 2022	**1,248**	1,214
4.15% notes due 2043	**1,238**	1,237
3.875% notes due 2021	**1,151**	1,132
1.125% euro-denominated notes due 2021	**1,113**	1,134
1.875% euro-denominated notes due 2026	**1,107**	1,127
2.40% notes due 2022	**1,010**	983
3.90% notes due 2039	**982**	—
2.90% notes due 2024	**745**	—
6.50% notes due 2033	**722**	726
0.50% euro-denominated notes due 2024	**555**	565
1.375% euro-denominated notes due 2036	**551**	561
2.50% euro-denominated notes due 2034	**550**	560
3.60% notes due 2042	**490**	490
6.55% notes due 2037	**412**	414
5.75% notes due 2036	**338**	338
5.95% debentures due 2028	**306**	306
5.85% notes due 2039	**271**	270
6.40% debentures due 2028	**250**	250
6.30% debentures due 2026	**135**	135
1.85% notes due 2020	**—**	1,231
Floating-rate notes due 2020	**—**	699
Other	**148**	225
	$ 22,736	$ 19,806

Other (as presented in the table above) includes $147 million and $223 million at December 31, 2019 and 2018, respectively, of borrowings at variable rates that resulted in effective interest rates of 2.54% and 2.27% for 2019 and 2018, respectively.

With the exception of the 6.30% debentures due 2026, the notes listed in the table above are redeemable in whole or in part, at Merck's option at any time, at varying redemption prices.

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

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

Certain of the Company's borrowings require that Merck comply with covenants and, at December 31, 2019, the Company was in compliance with these covenants.

The aggregate maturities of long-term debt for each of the next five years are as follows: 2020, $1.9 billion; 2021, $2.3 billion; 2022, $2.3 billion; 2023, $1.7 billion; 2024, $1.3 billion.

The Company has a $6.0 billion credit facility that matures in June 2024. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

Leases

As discussed in Note 1, on January 1, 2019, Merck adopted new guidance for the accounting and reporting of leases. The Company has operating leases primarily for manufacturing facilities, research and development facilities, corporate offices, employee housing, vehicles and certain equipment. As permitted under the transition guidance in ASC 842, the Company elected a package of practical expedients which, among other provisions, allowed the Company to carry forward historical lease classifications. The Company determines if an arrangement is a lease at inception. When evaluating contracts for embedded leases, the Company exercises judgment to determine if there is an explicit or implicit identified asset in the contract and if Merck controls the use of that asset. Embedded leases, primarily associated with contract manufacturing organizations, are immaterial.

Under ASC 842 transition guidance, Merck elected the hindsight practical expedient to determine the lease term for existing leases, which permits companies to consider available information prior to the effective date of the new guidance as to the actual or likely exercise of options to extend or terminate the lease. The lease term includes options to extend or terminate the lease when it is reasonably certain that Merck will exercise that option. Real estate leases for facilities have an average remaining lease term of eight years, which include options to extend the leases for up to four years where applicable. Vehicle leases are generally in effect for four years. The Company has made an accounting policy election not to record short-term leases (leases with an initial term of 12 months or less) on the balance sheet; however, Merck currently has no short-term leases.

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

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

Operating lease cost was $339 million in 2019. Cash paid for amounts included in the measurement of operating lease liabilities was $281 million in 2019. Operating lease assets obtained in exchange for lease obligations was $129 million in 2019.

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

December 31		**2019**
Assets		
Other Assets [(1)]	**$**	**1,073**
Liabilities		
Accrued and other current liabilities		**236**
Other Noncurrent Liabilities		**768**
	$	**1,004**
Weighted-average remaining lease term (years)		**7.4**
Weighted-average discount rate		**3.2%**

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

Maturities of operating leases liabilities are as follows:

2020	$ 264
2021	200
2022	168
2023	113
2024	89
Thereafter	297
Total lease payments	1,131
Less: Imputed interest	127
	$ 1,004

At December 31, 2019, the Company had entered into additional real estate operating leases that had not yet commenced. The obligations associated with these leases total $538 million, of which $221 million relates to a lease that will commence in April 2020 and has a lease term of 10 years.

As of December 31, 2018, prior to the adoption of ASC 842, the minimum aggregate rental commitments under noncancellable leases were as follows: 2019, $188 million; 2020, $198 million; 2021, $150 million; 2022, $134 million; 2023, $84 million and thereafter, $243 million.

10. Contingencies and Environmental Liabilities

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

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

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

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

Product Liability Litigation

Fosamax

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Fosamax* (*Fosamax* Litigation). As of December 31, 2019, approximately 3,750 cases are pending against Merck in either federal or state court. Plaintiffs in the vast majority of these cases generally allege that they sustained femur fractures and/or other bone injuries (Femur Fractures) in association with the use of *Fosamax*.

All federal cases involving allegations of Femur Fractures have been or will be transferred to a multidistrict litigation in the District of New Jersey (Femur Fracture MDL). In the only bellwether case tried to date in the Femur Fracture MDL, *Glynn v. Merck*, the jury returned a verdict in Merck's favor. In addition, in June 2013, the Femur Fracture MDL court granted Merck's motion for judgment as a matter of law in the *Glynn* case and held that the plaintiff's failure to warn claim was preempted by federal law.

In August 2013, the Femur Fracture MDL court entered an order requiring plaintiffs in the Femur Fracture MDL to show cause why those cases asserting claims for a femur fracture injury that took place prior to September 14, 2010, should not be dismissed based on the court's preemption decision in the *Glynn* case. Pursuant to the show cause order, in March 2014, the Femur Fracture MDL court dismissed with prejudice approximately 650 cases on preemption grounds. Plaintiffs in approximately 515 of those cases appealed that decision to the U.S. Court of Appeals for the Third Circuit (Third Circuit). In March 2017, the Third Circuit issued a decision reversing the Femur Fracture MDL court's preemption ruling and remanding the appealed cases back to the Femur Fracture MDL court. Merck filed a petition for a writ of certiorari to the U.S. Supreme Court in August 2017, seeking review of the Third Circuit's decision. The Supreme Court granted Merck's petition in June 2018, and in May 2019, the Supreme Court issued its opinion and decided that the Third Circuit had incorrectly concluded that the issue of preemption should be resolved by a jury, and accordingly vacated the judgment of the Third Circuit and remanded the proceedings back to the Third Circuit to address the issue in a manner consistent with the Supreme Court's opinion. On November 15, 2019, the Third Circuit remanded the cases back to the District Court in order to allow that court to determine in the first instance whether the plaintiffs' state law claims are preempted by federal law under the standards described by the Supreme Court in its opinion. On December 13, 2019, the District Court ordered Merck to serve its opening brief on or before February 21, 2020, and plaintiffs to file their responsive brief on or before April 22, 2020. Merck may then file a reply on or before May 22, 2020.

Accordingly, as of December 31, 2019, approximately 970 cases were actively pending in the Femur Fracture MDL.

As of December 31, 2019, approximately 2,510 cases alleging Femur Fractures have been filed in New Jersey state court and are pending before Judge James Hyland in Middlesex County. The parties selected an initial group of cases to be reviewed through fact discovery, and Merck has continued to select additional cases to be reviewed.

As of December 31, 2019, approximately 275 cases alleging Femur Fractures have been filed and are pending in California state court. All of the Femur Fracture cases filed in California state court have been coordinated before a single judge in Orange County, California.

Additionally, there are four Femur Fracture cases pending in other state courts.

Discovery is presently stayed in the Femur Fracture MDL and in the state court in California. Merck intends to defend against these lawsuits.

Januvia/Janumet

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Januvia* and/or *Janumet*. As of December 31, 2019, Merck is aware of approximately 1,380 product users alleging that *Januvia* and/or *Janumet* caused the development of pancreatic cancer and other injuries.

Most claims have been filed in multidistrict litigation before the U.S. District Court for the Southern District of California (MDL). Outside of the MDL, the majority of claims have been filed in coordinated proceedings before the Superior Court of California, County of Los Angeles (California State Court).

In November 2015, the MDL and California State Court-in separate opinions-granted summary judgment to defendants on grounds of federal preemption.

Plaintiffs appealed in both forums. In November 2017, the U.S. Court of Appeals for the Ninth Circuit vacated the judgment and remanded for further discovery. In November 2018, the California state appellate court reversed and remanded on similar grounds. In March 2019, the parties in the MDL and the California coordinated proceeding agreed to coordinate and adopt a schedule for completing discovery on general causation and preemption issues and for renewing summary judgment and *Daubert* motions. Under the stipulated case management schedule, the hearings for *Daubert* and summary judgment motions are expected to take place in June 2020.

As of December 31, 2019, six product users have claims pending against Merck in state courts other than California, including Illinois. In June 2017, the Illinois trial court denied Merck's motion for summary judgment based on federal preemption. Merck appealed, and the Illinois appellate court affirmed in December 2018. Merck filed a petition for leave to appeal to the Illinois Supreme Court in February 2019. In April 2019, the Illinois Supreme Court stayed consideration of the pending petition to appeal until the U.S. Supreme Court issued its opinion in *Merck Sharp & Dohme Corp. v. Albrecht* (relating to the *Fosamax* matter discussed above). Merck filed the opinion in *Albrecht* with the Illinois Supreme Court in June 2019. The petition for leave to appeal was decided on September 25, 2019, in which the Illinois Supreme Court directed the intermediate appellate court to reconsider its earlier ruling. The Illinois Appellate Court issued a favorable decision concluding, consistent with *Albrecht*, that preemption presents a legal question to be resolved by the court.

In addition to the claims noted above, the Company has agreed to toll the statute of limitations for approximately 50 additional claims. The Company intends to continue defending against these lawsuits.

Vioxx

As previously disclosed, Merck is a defendant in a lawsuit brought by the Attorney General of Utah alleging that Merck misrepresented the safety of *Vioxx*. The lawsuit is pending in Utah state court. Utah seeks damages and penalties under the Utah False Claims Act. A bench trial in this matter is currently scheduled for April 20, 2020.

Governmental Proceedings

As previously disclosed, in the fall of 2018, the Company received a records subpoena from the U.S. Attorney's Office for the District of Vermont (VT USAO) pursuant to Section 248 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) relating to an investigation of potential health care offenses. The subpoena sought information relating to any actual or potential business relationship or arrangement Merck has had with Practice Fusion, Inc. (PFI), a cloud-based, electronic health records (EHR) company that was acquired by Allscripts in January 2018. The Company cooperated with the government and responded to that subpoena. Subsequently, on May 21, 2019, Merck received a second records subpoena from the VT USAO that broadened the government's information request by seeking information relating to Merck's relationship with any EHR company. Shortly thereafter, the VT USAO served a Civil Investigation Demand (CID) upon Merck similarly seeking information on the Company's relationships with EHR vendors. The CID explains that the government is conducting a False Claims Act investigation concerning whether Merck and/or PFI submitted claims to federal healthcare programs that violate the Federal Anti-Kickback Statute. Merck is cooperating with the government's investigation.

As previously disclosed, on April 15, 2019, Merck received a set of investigative interrogatories from the California Attorney General's Office pursuant to its investigation of conduct and agreements that allegedly affected or delayed competition to Lantus in the insulin market. The interrogatories seek information concerning Merck's development of an insulin glargine product, and its subsequent termination, as well as Merck's patent litigation against Sanofi S.A. concerning Lantus and the resolution of that litigation. Merck is cooperating with the California Attorney General's investigation.

As previously disclosed, the Company's subsidiaries in China have received and may continue to receive inquiries regarding their operations from various Chinese governmental agencies. Some of these inquiries may be

related to matters involving other multinational pharmaceutical companies, as well as Chinese entities doing business with such companies. The Company's policy is to cooperate with these authorities and to provide responses as appropriate.

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

Commercial and Other Litigation

Zetia Antitrust Litigation

As previously disclosed, Merck, MSD, Schering Corporation and MSP Singapore Company LLC (collectively, the Merck Defendants) are defendants in putative class action and opt-out lawsuits filed in 2018 on behalf of direct and indirect purchasers of *Zetia* alleging violations of federal and state antitrust laws, as well as other state statutory and common law causes of action. The cases have been consolidated for pretrial purposes in a federal multidistrict litigation before Judge Rebecca Beach Smith in the Eastern District of Virginia. In December 2018, the court denied the Merck Defendants' motions to dismiss or stay the direct purchaser putative class actions pending bilateral arbitration. On August 9, 2019, the district court adopted in full the report and recommendation of the magistrate judge with respect to the Merck Defendants' motions to dismiss on non-arbitration issues, thereby granting in part and denying in part Merck Defendants' motions to dismiss. In addition, on June 27, 2019, the representatives of the putative direct purchaser class filed an amended complaint and, on August 1, 2019, retailer opt-out plaintiffs filed an amended complaint. The Merck Defendants moved to dismiss the new allegations in both complaints. On October 15, 2019, the magistrate judge issued a report and recommendation recommending that the district judge grant the motions in their entirety. On December 20, 2019, the district court adopted this report and recommendation in part. The district court granted the Merck Defendants' motion to dismiss to the extent the motion sought dismissal of claims for overcharges paid by entities that purchased generic ezetimibe from Par Pharmaceutical, Inc. (Par Pharmaceutical) and dismissed any claims for such overcharges. Trial is currently scheduled to begin on October 28, 2020.

Rotavirus Vaccines Antitrust Litigation

As previously disclosed, MSD is a defendant in putative class action lawsuits filed in 2018 on behalf of direct purchasers of *RotaTeq*, alleging violations of federal antitrust laws. The cases were consolidated in the Eastern District of Pennsylvania. On January 23, 2019, the court denied MSD's motions to compel arbitration and to dismiss the consolidated complaint. On February 19, 2019, MSD appealed the court's order on arbitration to the Third Circuit. On October 28, 2019, the Third Circuit vacated the district court's order and remanded for limited discovery on the issue of arbitrability, after which MSD may file a renewed motion to compel arbitration.

Sales Force Litigation

As previously disclosed, in May 2013, Ms. Kelli Smith filed a complaint against the Company in the U.S. District Court for the District of New Jersey on behalf of herself and a putative class of female sales representatives and a putative sub-class of female sales representatives with children, claiming (a) discriminatory policies and practices in selection, promotion and advancement, (b) disparate pay, (c) differential treatment, (d) hostile work environment and (e) retaliation under federal and state discrimination laws. In April 2016, the Magistrate Judge granted plaintiffs' request to amend the complaint to add the following: (i) a Company subsidiary as a corporate defendant; (ii) an ERISA claim and (iii) an individual constructive discharge claim for one of the named plaintiffs. Approximately 700 individuals opted-in to this action; the opt-in period has closed. In August 2017, plaintiffs filed their motion to certify a Title VII pay discrimination class and also sought final collective action certification of plaintiffs' Equal Pay Act claim.

On October 1, 2018, the parties entered into an agreement to fully resolve the Smith sales force litigation. As part of the settlement and in exchange for a full and general release of all individual and class claims, the Company agreed to pay $8.5 million. On December 3, 2019, the court approved the settlement.

Qui Tam Litigation

As previously disclosed, in June 2012, the U.S. District Court for the Eastern District of Pennsylvania unsealed a complaint that has been filed against the Company under the federal False Claims Act by two former employees alleging, among other things, that the Company defrauded the U.S. government by falsifying data in connection with a clinical study conducted on the mumps component of the Company's *M-M-R* II vaccine. The complaint alleges the fraud took place between 1999 and 2001. The U.S. government had the right to participate in and take over the prosecution of this lawsuit but notified the court that it declined to exercise that right. The two former employees are pursuing the lawsuit without the involvement of the U.S. government. In addition, as previously disclosed, two putative class action lawsuits on behalf of direct purchasers of the *M-M-R* II vaccine, which charge that the Company misrepresented the efficacy of the *M-M-R* II vaccine in violation of federal antitrust laws and various state consumer protection laws, are pending in the Eastern District of Pennsylvania. In September 2014, the court denied Merck's motion to dismiss the False Claims Act suit and granted in part and denied in part its motion to dismiss the then-pending antitrust suit. As a result, both the False Claims Act suit and the antitrust suits have proceeded into discovery, which is now complete, and the parties have filed and briefed cross-motions for summary judgment, which are currently pending before the Court. The Company continues to defend against these lawsuits.

Merck KGaA Litigation

As previously disclosed, in January 2016, to protect its long-established brand rights in the United States, the Company filed a lawsuit against Merck KGaA, Darmstadt, Germany (KGaA), historically operating as the EMD Group in the United States, alleging it improperly uses the name "Merck" in the United States. KGaA has filed suit against the Company in France, the UK, Germany, Switzerland, Mexico, India, Australia, Singapore, Hong Kong, and China alleging, among other things, unfair competition, trademark infringement and/or corporate name infringement. In the UK, Australia, Singapore, Hong Kong, and India, KGaA also alleges breach of the parties' coexistence agreement. The litigation is ongoing in the United States with no trial date set, and also ongoing in numerous jurisdictions outside of the United States; the Company is defending those suits in each jurisdiction.

Patent Litigation

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

Januvia, Janumet, Janumet XR — In February 2019, Par Pharmaceutical filed suit against the Company in the U.S. District Court for the District of New Jersey, seeking a declaratory judgment of invalidity of a patent owned by the Company covering certain salt and polymorphic forms of sitagliptin that expires in 2026. In response, the Company filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Par Pharmaceutical and additional companies that also indicated an intent to market generic versions of *Januvia*, *Janumet*, and *Janumet XR* following expiration of key patent protection in 2022, but prior to the expiration of the later-granted patent owned by the Company covering certain salt and polymorphic forms of sitagliptin that expires in 2026, and a later granted patent owned by the Company covering the *Janumet* formulation which expires in 2028. Par Pharmaceutical dismissed its case in the U.S. District Court for the District of New Jersey against the Company and will litigate the action in the U.S. District Court for the District of Delaware. The Company filed a patent infringement lawsuit against Mylan Pharmaceuticals Inc. and Mylan Inc. (Mylan) in the Northern District of West Virginia. The Judicial Panel of Multidistrict Litigation entered an order transferring the Company's lawsuit against Mylan to the U.S. District Court for the District of Delaware for coordinated and consolidated pretrial proceedings with the other cases pending in that district. The U.S. District Court for the District of Delaware has scheduled the lawsuits for a single 3-day trial on invalidity issues in October 2021. The Court will schedule separate 1-day trials on infringement issues if necessary. In October 2019, Mylan filed a petition for *Inter Partes* Review (IPR) at the United States Patent and Trademark Office

(USPTO) seeking invalidity of the 2026 patent. The USPTO has six months from filing to determine whether it will institute the requested IPR proceeding.

Other Litigation

There are various other pending legal proceedings involving the Company, principally product liability and intellectual property lawsuits. While it is not feasible to predict the outcome of such proceedings, in the opinion of the Company, either the likelihood of loss is remote or any reasonably possible loss associated with the resolution of such proceedings is not expected to be material to the Company's financial condition, results of operations or cash flows either individually or in the aggregate.

Legal Defense Reserves

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of December 31, 2019 and 2018 of approximately $240 million and $245 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

Environmental Matters

The Company and its subsidiaries are parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund, and other federal and state equivalents. These proceedings seek to require the operators of hazardous waste disposal facilities, transporters of waste to the sites and generators of hazardous waste disposed of at the sites to clean up the sites or to reimburse the government for cleanup costs. The Company has been made a party to these proceedings as an alleged generator of waste disposed of at the sites. In each case, the government alleges that the defendants are jointly and severally liable for the cleanup costs. Although joint and several liability is alleged, these proceedings are frequently resolved so that the allocation of cleanup costs among the parties more nearly reflects the relative contributions of the parties to the site situation. The Company's potential liability varies greatly from site to site. For some sites the potential liability is *de minimis* and for others the final costs of cleanup have not yet been determined. While it is not feasible to predict the outcome of many of these proceedings brought by federal or state agencies or private litigants, in the opinion of the Company, such proceedings should not ultimately result in any liability which would have a material adverse effect on the financial condition, results of operations or liquidity of the Company. The Company has taken an active role in identifying and accruing for these costs and such amounts do not include any reduction for anticipated recoveries of cleanup costs from former site owners or operators or other recalcitrant potentially responsible parties.

In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $67 million and $71 million at December 31, 2019 and 2018, respectively. These liabilities are undiscounted, do not consider potential recoveries from other parties and will be paid out over the periods of remediation for the applicable sites, which are expected to occur primarily over the next 15 years. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed $58 million in the aggregate. Management also does not believe that these expenditures should result in a material adverse effect on the Company's financial condition, results of operations or liquidity for any year.

11. Equity

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

Capital Stock

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

	2019		2018		2017	
	Common Stock	**Treasury Stock**	Common Stock	Treasury Stock	Common Stock	Treasury Stock
Balance January 1	**3,577**	**985**	3,577	880	3,577	828
Purchases of treasury stock	**—**	**66**	—	122	—	67
Issuances [(1)]	**—**	**(13)**	—	(17)	—	(15)
Balance December 31	**3,577**	**1,038**	3,577	985	3,577	880

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

On October 25, 2018, the Company entered into accelerated share repurchase (ASR) agreements with two third-party financial institutions (Dealers). Under the ASR agreements, Merck agreed to purchase $5 billion of Merck's common stock, in total, with an initial delivery of 56.7 million shares of Merck's common stock, based on the then-current market price, made by the Dealers to Merck, and payments of $5 billion made by Merck to the Dealers on October 29, 2018, which were funded with existing cash and investments, as well as short-term borrowings. The payments to the Dealers were recorded as reductions to shareholders' equity, consisting of a $4 billion increase in treasury stock, which reflected the value of the initial 56.7 million shares received on October 29, 2018, and a $1 billion decrease in other-paid-in capital, which reflected the value of the stock held back by the Dealers pending final settlement. Upon settlement of the ASR agreements in April 2019, Merck received an additional 7.7 million shares as determined by the average daily volume weighted-average price of Merck's common stock during the term of the ASR program, less a negotiated discount, bringing the total shares received by Merck under this program to 64.4 million.

12. Share-Based Compensation Plans

The Company has share-based compensation plans under which the Company grants restricted stock units (RSUs) and performance share units (PSUs) to certain management level employees. In addition, employees and non-employee directors may be granted options to purchase shares of Company common stock at the fair market value at the time of grant. These plans were approved by the Company's shareholders.

At December 31, 2019, 111 million shares collectively were authorized for future grants under the Company's share-based compensation plans. These awards are settled with treasury shares.

Employee stock options are granted to purchase shares of Company stock at the fair market value at the time of grant. These awards generally vest one-third each year over a three-year period, with a contractual term of 7-10 years. RSUs are stock awards that are granted to employees and entitle the holder to shares of common stock as the awards vest. The fair value of the stock option and RSU awards is determined and fixed on the grant date based on the Company's stock price. PSUs are stock awards where the ultimate number of shares issued will be contingent on the Company's performance against a pre-set objective or set of objectives. The fair value of each PSU is determined on the date of grant based on the Company's stock price. For RSUs and PSUs, dividends declared during the vesting period are payable to the employees only upon vesting. Over the PSU performance period, the number of shares of stock that are expected to be issued will be adjusted based on the probability of achievement of a performance target and final compensation expense will be recognized based on the ultimate number of shares issued. RSU and PSU distributions will be in shares of Company stock after the end of the vesting or performance period, subject to the terms applicable to such awards. PSU awards generally vest after three years. Prior to 2018, RSU awards generally vested after three years; beginning with awards granted in 2018, RSU awards generally vest one-third each year over a three-year period.

Total pretax share-based compensation cost recorded in 2019, 2018 and 2017 was $417 million, $348 million and $312 million, respectively, with related income tax benefits of $57 million, $55 million and $57 million, respectively.

The Company uses the Black-Scholes option pricing model for determining the fair value of option grants. In applying this model, the Company uses both historical data and current market data to estimate the fair value of its options. The Black-Scholes model requires several assumptions including expected dividend yield, risk-free interest rate, volatility, and term of the options. The expected dividend yield is based on historical patterns of dividend payments. The risk-free interest rate is based on the rate at grant date of zero-coupon U.S. Treasury Notes with a term equal to the expected term of the option. Expected volatility is estimated using a blend of historical and implied volatility. The historical component is based on historical monthly price changes. The implied volatility is obtained from market data on the Company's traded options. The expected life represents the amount of time that options granted are expected to be outstanding, based on historical and forecasted exercise behavior.

The weighted average exercise price of options granted in 2019, 2018 and 2017 was $80.05, $58.15 and $63.88 per option, respectively. The weighted average fair value of options granted in 2019, 2018 and 2017 was $10.63, $8.26 and $7.04 per option, respectively, and were determined using the following assumptions:

Years Ended December 31	**2019**	2018	2017
Expected dividend yield	**3.2%**	3.4%	3.6%
Risk-free interest rate	**2.4%**	2.9%	2.0%
Expected volatility	**18.7%**	19.1%	17.8%
Expected life (years)	**5.9**	6.1	6.1

Summarized information relative to stock option plan activity (options in thousands) is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2019	23,807	$ 51.89		
Granted	**2,796**	**80.05**		
Exercised	**(8,119)**	**44.48**		
Forfeited	**(616)**	**45.48**		
Outstanding December 31, 2019	**17,868**	**$ 59.88**	**6.48**	**$ 555**
Exercisable December 31, 2019	**11,837**	**$ 55.40**	**5.45**	**$ 421**

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

Years Ended December 31	**2019**	2018	2017
Total intrinsic value of stock options exercised	**$ 295**	$ 348	$ 236
Fair value of stock options vested	**27**	29	30
Cash received from the exercise of stock options	**361**	591	499

A summary of nonvested RSU and PSU activity (shares in thousands) is as follows:

	RSUs		PSUs	
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested January 1, 2019	16,128	$ 58.85	2,039	$ 59.42
Granted	**4,811**	**80.08**	**763**	**83.90**
Vested	**(6,594)**	**55.70**	**(748)**	**57.87**
Forfeited	**(818)**	**64.75**	**(82)**	**66.68**
Nonvested December 31, 2019	**13,527**	**$ 67.58**	**1,972**	**$ 69.18**

At December 31, 2019, there was $603 million of total pretax unrecognized compensation expense related to nonvested stock options, RSU and PSU awards which will be recognized over a weighted average period of 1.9 years. For segment reporting, share-based compensation costs are unallocated expenses.

13. Pension and Other Postretirement Benefit Plans

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

Net Periodic Benefit Cost

The net periodic benefit cost (credit) for pension and other postretirement benefit plans consisted of the following components:

	Pension Benefits								
	U.S.			International			Other Postretirement Benefits		
Years Ended December 31	**2019**	2018	2017	**2019**	2018	2017	**2019**	2018	2017
Service cost	**$ 293**	$ 326	$ 312	**$ 238**	$ 238	$ 252	**$ 48**	$ 57	$ 57
Interest cost	**458**	432	454	**177**	178	172	**69**	69	81
Expected return on plan assets	**(817)**	(851)	(862)	**(426)**	(431)	(393)	**(72)**	(83)	(78)
Amortization of unrecognized prior service cost	**(49)**	(50)	(53)	**(12)**	(13)	(11)	**(78)**	(84)	(98)
Net loss amortization	**151**	232	180	**64**	84	98	**(10)**	1	1
Termination benefits	**31**	19	44	**8**	2	4	**5**	3	8
Curtailments	**14**	10	3	**6**	1	(4)	**(11)**	(8)	(31)
Settlements	**—**	5	—	**1**	13	5	**—**	—	—
Net periodic benefit cost (credit)	**$ 81**	$ 123	$ 78	**$ 56**	$ 72	$ 123	**$ (49)**	$ (45)	$ (60)

The changes in net periodic benefit cost (credit) year over year for pension plans are largely attributable to changes in the discount rate affecting net loss amortization.

In connection with restructuring actions (see Note 5), termination charges were recorded in 2019, 2018 and 2017 on pension and other postretirement benefit plans related to expanded eligibility for certain employees exiting Merck. Also, in connection with these restructuring activities, curtailments were recorded on pension and other postretirement benefit plans and settlements were recorded on certain U.S. and international pension plans as reflected in the table above.

The components of net periodic benefit cost (credit) other than the service cost component are included in *Other (income) expense, net* (see Note 14), with the exception of certain amounts for termination benefits, curtailments and settlements, which are recorded in *Restructuring costs* if the event giving rise to the termination benefits, curtailment or settlement is related to restructuring actions as noted above.

Obligations and Funded Status

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

	Pension Benefits				Other Postretirement Benefits	
	U.S.		International			
	2019	2018	**2019**	2018	**2019**	2018
Fair value of plan assets January 1	**$ 9,648**	$ 10,896	**$ 8,580**	$ 9,339	**$ 968**	$ 1,114
Actual return on plan assets	**2,165**	(810)	**1,505**	(289)	**203**	(72)
Company contributions	**130**	378	**262**	167	**14**	6
Effects of exchange rate changes	**—**	—	**31**	(352)	**—**	—
Benefits paid	**(582)**	(772)	**(230)**	(202)	**(104)**	(80)
Settlements	**—**	(44)	**(12)**	(106)	**—**	—
Other	**—**	—	**27**	23	**21**	—
Fair value of plan assets December 31	**$ 11,361**	$ 9,648	**$ 10,163**	$ 8,580	**$ 1,102**	$ 968
Benefit obligation January 1	**$ 10,620**	$ 11,904	**$ 9,083**	$ 9,483	**$ 1,615**	$ 1,922
Service cost	**293**	326	**238**	238	**48**	57
Interest cost	**458**	432	**177**	178	**69**	69
Actuarial losses (gains) [(1)]	**2,165**	(1,258)	**1,313**	(154)	**21**	(341)
Benefits paid	**(582)**	(772)	**(230)**	(202)	**(104)**	(80)
Effects of exchange rate changes	**—**	—	**4**	(387)	**1**	(6)
Plan amendments	**—**	—	**1**	10	**—**	(9)
Curtailments	**18**	13	**3**	(2)	**—**	—
Termination benefits	**31**	19	**8**	2	**5**	3
Settlements	**—**	(44)	**(12)**	(106)	**—**	—
Other	**—**	—	**27**	23	**18**	—
Benefit obligation December 31	**$ 13,003**	$ 10,620	**$ 10,612**	$ 9,083	**$ 1,673**	$ 1,615
Funded status December 31	**$ (1,642)**	$ (972)	**$ (449)**	$ (503)	**$ (571)**	$ (647)
Recognized as:						
Other Assets	**$ —**	$ —	**$ 837**	$ 659	**$ —**	$ —
Accrued and other current liabilities	**(92)**	(47)	**(18)**	(14)	**(10)**	(10)
Other Noncurrent Liabilities	**(1,550)**	(925)	**(1,268)**	(1,148)	**(561)**	(637)

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

At December 31, 2019 and 2018, the accumulated benefit obligation was $22.8 billion and $19.0 billion, respectively, for all pension plans, of which $12.8 billion and $10.4 billion, respectively, related to U.S. pension plans.

Information related to the funded status of selected pension plans at December 31 is as follows:

	U.S.		International	
	2019	2018	**2019**	2018
Pension plans with a projected benefit obligation in excess of plan assets				
Projected benefit obligation	**$ 13,003**	$ 10,620	**$ 7,421**	$ 6,251
Fair value of plan assets	**11,361**	9,648	**6,135**	5,089
Pension plans with an accumulated benefit obligation in excess of plan assets				
Accumulated benefit obligation	**$ 12,009**	$ 9,702	**$ 2,476**	$ 5,936
Fair value of plan assets	**10,484**	8,966	**1,501**	5,071

Plan Assets

Entities are required to use a fair value hierarchy which maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest:

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

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

Level 3 — Unobservable inputs that are supported by little or no market activity. The Level 3 assets are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as instruments for which the determination of fair value requires significant judgment or estimation. At December 31, 2019 and 2018, $860 million and $826 million, respectively, or approximately 4% and 5%, respectively, of the Company's pension investments were categorized as Level 3 assets.

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

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

	Fair Value Measurements Using					Fair Value Measurements Using				
	Level 1	Level 2	Level 3	NAV [1]	Total	Level 1	Level 2	Level 3	NAV [1]	Total
	2019					2018				
U.S. Pension Plans										
Assets										
Cash and cash equivalents	$ 3	$ —	$ —	$ 236	$ 239	$ 40	$ —	$ —	$ 182	$ 222
Investment funds										
Developed markets equities	205	—	—	3,542	3,747	169	—	—	3,021	3,190
Emerging markets equities	165	—	—	723	888	121	—	—	720	841
Government and agency obligations	—	—	—	173	173	—	—	—	161	161
Corporate obligations	—	—	—	—	—	—	—	—	32	32
Equity securities										
Developed markets	2,451	—	—	—	2,451	2,172	—	—	—	2,172
Fixed income securities										—
Government and agency obligations	—	2,094	—	—	2,094	—	1,509	—	—	1,509
Corporate obligations	—	1,582	—	—	1,582	—	1,246	—	—	1,246
Mortgage and asset-backed securities	—	178	—	—	178	—	262	—	—	262
Other investments	—	—	9	—	9	—	—	13	—	13
Plan assets at fair value	$ 2,824	$ 3,854	$ 9	$ 4,674	$ 11,361	$ 2,502	$ 3,017	$ 13	$ 4,116	$ 9,648
International Pension Plans										
Assets										
Cash and cash equivalents	$ 70	$ 1	$ —	$ 15	$ 86	$ 50	$ 3	$ —	$ 16	$ 69
Investment funds										
Developed markets equities	546	3,761	—	96	4,403	461	3,071	—	75	3,607
Government and agency obligations	462	2,534	—	207	3,203	372	2,082	—	180	2,634
Emerging markets equities	66	96	—	90	252	56	112	—	83	251
Corporate obligations	5	11	—	109	125	4	7	—	94	105
Fixed income obligations	9	6	—	—	15	7	4	—	—	11
Real estate	—	1	—	—	1	—	1	1	—	2
Equity securities										
Developed markets	565	—	—	—	565	544	—	—	—	544
Fixed income securities										
Government and agency obligations	3	376	—	—	379	2	291	—	—	293
Corporate obligations	1	135	—	—	136	1	113	—	—	114
Mortgage and asset-backed securities	—	61	—	—	61	—	55	—	—	55
Other investments										
Insurance contracts [2]	—	65	851	—	916	—	66	811	—	877
Other	—	5	—	16	21	—	4	1	13	18
Plan assets at fair value	$ 1,727	$ 7,052	$ 851	$ 533	$ 10,163	$ 1,497	$ 5,809	$ 813	$ 461	$ 8,580

[1] *Certain investments that were measured at net asset value (NAV) per share or its equivalent have not been classified in the fair value hierarchy. The NAV amounts presented in this table are intended to permit reconciliation of the fair value hierarchy to the fair value of plan assets at December 31, 2019 and 2018.*

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

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

	2019				2018			
	Insurance Contracts	**Real Estate**	**Other**	**Total**	Insurance Contracts	Real Estate	Other	Total
U.S. Pension Plans								
Balance January 1	**$ —**	**$ —**	**$ 13**	**$ 13**	$ —	$ —	$ 15	$ 15
Actual return on plan assets:								
Relating to assets still held at December 31	**—**	**—**	**(8)**	**(8)**	—	—	(3)	(3)
Relating to assets sold during the year	**—**	**—**	**8**	**8**	—	—	4	4
Purchases and sales, net	**—**	**—**	**(4)**	**(4)**	—	—	(3)	(3)
Balance December 31	**$ —**	**$ —**	**$ 9**	**$ 9**	$ —	$ —	$ 13	$ 13
International Pension Plans								
Balance January 1	**$ 811**	**$ 1**	**$ 1**	**$ 813**	$ 470	$ 2	$ 1	$ 473
Actual return on plan assets:								
Relating to assets still held at December 31	**54**	**—**	**—**	**54**	(32)	—	—	(32)
Purchases and sales, net	**(14)**	**(1)**	**(1)**	**(16)**	380	(1)	—	379
Transfers out of Level 3	**—**	**—**	**—**	**—**	(7)	—	—	(7)
Balance December 31	**$ 851**	**$ —**	**$ —**	**$ 851**	$ 811	$ 1	$ 1	$ 813

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

	Fair Value Measurements Using					Fair Value Measurements Using				
	Level 1	**Level 2**	**Level 3**	**NAV [1]**	**Total**	Level 1	Level 2	Level 3	NAV [1]	Total
	2019					2018				
Assets										
Cash and cash equivalents	**$ 52**	**$ —**	**$ —**	**$ 22**	**$ 74**	$ 78	$ —	$ —	$ 16	$ 94
Investment funds										
Developed markets equities	**19**	**—**	**—**	**324**	**343**	16	—	—	279	295
Emerging markets equities	**15**	**—**	**—**	**66**	**81**	12	—	—	67	79
Government and agency obligations	**1**	**—**	**—**	**16**	**17**	1	—	—	15	16
Corporate obligations	**—**	**—**	**—**	**—**	**—**	—	—	—	3	3
Equity securities										—
Developed markets	**225**	**—**	**—**	**—**	**225**	200	—	—	—	200
Fixed income securities										
Government and agency obligations	**—**	**196**	**—**	**—**	**196**	—	141	—	—	141
Corporate obligations	**—**	**149**	**—**	**—**	**149**	—	116	—	—	116
Mortgage and asset-backed securities	**—**	**17**	**—**	**—**	**17**	—	24	—	—	24
Plan assets at fair value	**$ 312**	**$ 362**	**$ —**	**$ 428**	**$ 1,102**	$ 307	$ 281	$ —	$ 380	$ 968

[1] *Certain investments that were measured at net asset value (NAV) per share or its equivalent have not been classified in the fair value hierarchy. The NAV amounts presented in this table are intended to permit reconciliation of the fair value hierarchy to the fair value of plan assets at December 31, 2019 and 2018.*

The Company has established investment guidelines for its U.S. pension and other postretirement plans to create an asset allocation that is expected to deliver a rate of return sufficient to meet the long-term obligation of each plan, given an acceptable level of risk. The target investment portfolio of the Company's U.S. pension and other postretirement benefit plans is allocated 30% to 45% in U.S. equities, 15% to 30% in international equities, 35% to 45% in fixed-income investments, and up to 5% in cash and other investments. The portfolio's equity weighting is consistent with the long-term nature of the plans' benefit obligations. The expected annual standard deviation of returns

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

Expected Contributions

Expected contributions during 2020 are approximately $100 million for U.S. pension plans, approximately $150 million for international pension plans and approximately $15 million for other postretirement benefit plans.

Expected Benefit Payments

Expected benefit payments are as follows:

	U.S. Pension Benefits	International Pension Benefits	Other Postretirement Benefits
2020	$ 747	$ 242	$ 88
2021	717	225	92
2022	710	243	94
2023	718	250	98
2024	708	250	100
2025 — 2029	3,943	1,417	540

Expected benefit payments are based on the same assumptions used to measure the benefit obligations and include estimated future employee service.

Amounts Recognized in Other Comprehensive Income

Net loss amounts reflect experience differentials primarily relating to differences between expected and actual returns on plan assets as well as the effects of changes in actuarial assumptions. Net loss amounts in excess of certain thresholds are amortized into net periodic benefit cost over the average remaining service life of employees. The following amounts were reflected as components of *OCI*:

	Pension Plans						Other Postretirement Benefit Plans		
	U.S.			International					
Years Ended December 31	**2019**	2018	2017	**2019**	2018	2017	**2019**	2018	2017
Net (loss) gain arising during the period	**$ (816)**	$ (397)	$ (19)	**$ (227)**	$ (505)	$ 309	**$ 112**	$ 186	$ 170
Prior service (cost) credit arising during the period	**(4)**	(4)	(13)	**(1)**	(10)	22	**(11)**	2	(31)
	$ (820)	$ (401)	$ (32)	**$ (228)**	$ (515)	$ 331	**$ 101**	$ 188	$ 139
Net loss amortization included in benefit cost	**$ 151**	$ 232	$ 180	**$ 64**	$ 84	$ 98	**$ (10)**	$ 1	$ 1
Prior service credit amortization included in benefit cost	**(49)**	(50)	(53)	**(12)**	(13)	(11)	**(78)**	(84)	(98)
	$ 102	$ 182	$ 127	**$ 52**	$ 71	$ 87	**$ (88)**	$ (83)	$ (97)

Actuarial Assumptions

The Company reassesses its benefit plan assumptions on a regular basis. The weighted average assumptions used in determining U.S. pension and other postretirement benefit plan and international pension plan information are as follows:

	U.S. Pension and Other Postretirement Benefit Plans			International Pension Plans		
December 31	**2019**	2018	2017	**2019**	2018	2017
Net periodic benefit cost						
Discount rate	**4.40%**	3.70%	4.30%	**2.20%**	2.10%	2.20%
Expected rate of return on plan assets	**8.10%**	8.20%	8.70%	**4.90%**	5.10%	5.10%
Salary growth rate	**4.30%**	4.30%	4.30%	**2.80%**	2.90%	2.90%
Interest crediting rate	**3.40%**	3.30%	3.30%	**2.90%**	2.80%	3.00%
Benefit obligation						
Discount rate	**3.40%**	4.40%	3.70%	**1.50%**	2.20%	2.10%
Salary growth rate	**4.20%**	4.30%	4.30%	**2.80%**	2.80%	2.90%
Interest crediting rate	**4.90%**	3.40%	3.30%	**2.80%**	2.90%	2.80%

For both the pension and other postretirement benefit plans, the discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due. The expected rate of return for both the pension and other postretirement benefit plans represents the average rate of return to be earned on plan assets over the period the benefits included in the benefit obligation are to be paid and is determined on a plan basis. The expected rate of return for each plan is developed considering long-term historical returns data, current market conditions, and actual returns on the plan assets. Using this reference information, the long-term return expectations for each asset category and a weighted-average expected return for each plan's target portfolio is developed, according to the allocation among those investment categories. The expected portfolio performance reflects the contribution of active management as appropriate. For 2020, the expected rate of return for the Company's U.S. pension and other postretirement benefit plans will range from 7.00% to 7.30%, as compared to a range of 7.70% to 8.10% in 2019. The decrease reflects lower expected asset returns and a modest shift in asset allocation. The change in the weighted-average expected return on U.S. pension and other postretirement benefit plan assets from 2017 to 2019 is due to the relative weighting of the referenced plans' assets.

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

December 31	**2019**	2018
Health care cost trend rate assumed for next year	**6.8%**	7.0%
Rate to which the cost trend rate is assumed to decline	**4.5%**	4.5%
Year that the trend rate reaches the ultimate trend rate	**2032**	2032

Savings Plans

The Company also maintains defined contribution savings plans in the United States. The Company matches a percentage of each employee's contributions consistent with the provisions of the plan for which the employee is eligible. Total employer contributions to these plans in 2019, 2018 and 2017 were $149 million, $136 million and $131 million, respectively.

14. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

Years Ended December 31	**2019**	2018	2017
Interest income	**$ (274)**	$ (343)	$ (385)
Interest expense	**893**	772	754
Exchange losses (gains)	**187**	145	(11)
Income from investments in equity securities, net [(1)]	**(170)**	(324)	(352)
Net periodic defined benefit plan (credit) cost other than service cost	**(545)**	(512)	(512)
Other, net	**48**	(140)	6
	$ 139	$ (402)	$ (500)

[(1)] *Includes net realized and unrealized gains and losses from investments in equity securities either owned directly or through ownership interests in investment funds.*

Other, net (as presented in the table above) in 2019 includes $162 million of goodwill impairment charges related to certain businesses in the Healthcare Services segment (see Note 8).

Other, net in 2018 includes a gain of $115 million related to the settlement of certain patent litigation, income of $99 million related to AstraZeneca's option exercise in 2014 in connection with the termination of the Company's relationship with AstraZeneca LP (AZLP), and a gain of $85 million resulting from the receipt of a milestone payment for an out-licensed migraine clinical development program. Other, net in 2018 also includes $144 million of goodwill impairment charges related to certain businesses in the Healthcare Services segment (see Note 8), as well as $41 million of charges related to the write-down of assets held for sale to fair value in anticipation of the dissolution of the Company's joint venture with Supera Farma Laboratorios S.A. in Brazil.

Other, net in 2017 includes income of $232 million related to AstraZeneca's option exercise and a $191 million loss on extinguishment of debt.

Interest paid was $841 million in 2019, $777 million in 2018 and $723 million in 2017.

15. Taxes on Income

A reconciliation between the effective tax rate and the U.S. statutory rate is as follows:

	2019		2018		2017	
	Amount	**Tax Rate**	Amount	Tax Rate	Amount	Tax Rate
U.S. statutory rate applied to income before taxes	**$ 2,408**	**21.0%**	$ 1,827	21.0%	$ 2,282	35.0%
Differential arising from:						
Foreign earnings	**(1,020)**	**(8.9)**	(245)	(2.8)	(1,654)	(25.4)
GILTI and the foreign-derived intangible income deduction	**336**	**2.9**	(25)	(0.3)	—	—
Tax settlements	**(403)**	**(3.5)**	(22)	(0.3)	(356)	(5.5)
R&D tax credit	**(118)**	**(1.0)**	(96)	(1.1)	(71)	(1.1)
State taxes	**(2)**	**—**	201	2.3	77	1.2
Acquisition of Peloton	**209**	**1.8**	—	—	—	—
TCJA	**117**	**1.0**	289	3.3	2,625	40.3
Valuation allowances	**113**	**1.0**	269	3.1	632	9.7
Acquisition-related costs, including amortization	**95**	**0.8**	267	3.1	713	10.9
Restructuring	**39**	**0.3**	56	0.6	142	2.2
Other [(1)]	**(87)**	**(0.7)**	(13)	(0.1)	(287)	(4.4)
	$ 1,687	**14.7%**	$ 2,508	28.8%	$ 4,103	62.9%

[(1)] *Other includes the tax effects of losses on foreign subsidiaries and miscellaneous items.*

The Tax Cuts and Jobs Act (TCJA) was enacted in December 2017. Among other provisions, the TCJA reduced the U.S. federal corporate statutory tax rate from 35% to 21% effective January 1, 2018, required companies to pay a one-time transition tax on undistributed earnings of certain foreign subsidiaries, and created new taxes on certain foreign sourced earnings. The Company reflected the impact of the TCJA in its 2017 financial statements. However, since application of certain provisions of the TCJA remained subject to further interpretation, in certain instances the Company made reasonable estimates of the effects of the TCJA, which were since finalized as described below.

The one-time transition tax is based on the Company's post-1986 undistributed earnings and profits (E&P). For a substantial portion of these undistributed E&P, the Company had not previously provided deferred taxes as these earnings were deemed by Merck to be retained indefinitely by subsidiary companies for reinvestment. The Company recorded a provisional amount in 2017 for its one-time transition tax liability of $5.3 billion. This provisional amount was reduced by the reversal of $2.0 billion of deferred taxes that were previously recorded in connection with the merger of Schering-Plough Corporation in 2009 for certain undistributed foreign E&P. On the basis of revised calculations of post-1986 undistributed foreign E&P and finalization of the amounts held in cash or other specified assets, the Company recognized a measurement-period adjustment of $124 million in 2018 related to the transition tax obligation, with a corresponding adjustment to income tax expense during the period, resulting in a revised transition tax obligation of $5.5 billion. In 2019, the Company recorded additional charges of $117 million related to the finalization of treasury regulations associated with the TCJA. As permitted under the TCJA, the Company has elected to pay the one-time transition tax over a period of eight years through 2025. The Company's remaining transition tax liability, which has been reduced by payments and the utilization of foreign tax credits, was $3.4 billion at December 31, 2019, of which $390 million is included in *Income taxes payable* and the remainder of $3.0 billion is included in *Other Noncurrent Liabilities*. In 2017, the Company remeasured its deferred tax assets and liabilities at the new federal statutory tax rate of 21%, which resulted in a provisional deferred tax benefit of $779 million. On the basis of clarifications to the deferred tax benefit calculation, the Company recorded measurement-period adjustments in 2018 of $32 million related to deferred income taxes.

The foreign earnings tax rate differentials in the tax rate reconciliation above primarily reflect the impacts of operations in jurisdictions with different tax rates than the United States, particularly Ireland and Switzerland, as well as Singapore and Puerto Rico which operate under tax incentive grants (which begin to expire in 2022), where the earnings had been indefinitely reinvested, thereby yielding a favorable impact on the effective tax rate compared with the U.S. statutory rate of 21% in 2019 and 2018 and 35% in 2017. The foreign earnings tax rate differentials do not include the impact of intangible asset impairment charges, amortization of purchase accounting adjustments or restructuring costs. These items are presented separately as they each represent a significant, separately disclosed pretax cost or charge, and a substantial portion of each of these items relates to jurisdictions with lower tax rates than the United States. Therefore, the impact of recording these expense items in lower tax rate jurisdictions is an unfavorable impact on the effective tax rate compared to the U.S. statutory rate.

Income before taxes consisted of:

Years Ended December 31	**2019**	2018	2017
Domestic	**$ 439**	$ 3,717	$ 3,483
Foreign	**11,025**	4,984	3,038
	$ 11,464	$ 8,701	$ 6,521

Taxes on income consisted of:

Years Ended December 31	**2019**	2018	2017
Current provision			
Federal	**$ 514**	$ 536	$ 5,585
Foreign	**1,806**	2,281	1,229
State	**(77)**	200	(90)
	2,243	3,017	6,724
Deferred provision			
Federal	**(330)**	(402)	(2,958)
Foreign	**(240)**	(64)	75
State	**14**	(43)	262
	(556)	(509)	(2,621)
	$ 1,687	$ 2,508	$ 4,103

Deferred income taxes at December 31 consisted of:

	2019		2018	
	Assets	**Liabilities**	Assets	Liabilities
Product intangibles and licenses	**$ 442**	**$ 1,778**	$ 720	$ 1,640
Inventory related	**32**	**354**	32	377
Accelerated depreciation	**—**	**594**	—	582
Pensions and other postretirement benefits	**785**	**191**	565	151
Compensation related	**322**	**—**	291	—
Unrecognized tax benefits	**109**	**—**	174	—
Net operating losses and other tax credit carryforwards	**897**	**—**	715	—
Other	**764**	**84**	621	66
Subtotal	**3,351**	**3,001**	3,118	2,816
Valuation allowance	**(1,100)**		(1,348)	
Total deferred taxes	**$ 2,251**	**$ 3,001**	$ 1,770	$ 2,816
Net deferred income taxes		**$ 750**		$ 1,046
Recognized as:				
Other Assets	**$ 719**		$ 656	
Deferred Income Taxes		**$ 1,470**		$ 1,702

The Company has net operating loss (NOL) carryforwards in several jurisdictions. As of December 31, 2019, $762 million of deferred taxes on NOL carryforwards relate to foreign jurisdictions. Valuation allowances of $1.1 billion have been established on these foreign NOL carryforwards and other foreign deferred tax assets. In addition, the Company has $135 million of deferred tax assets relating to various U.S. tax credit carryforwards and NOL carryforwards, all of which are expected to be fully utilized prior to expiry.

Income taxes paid in 2019, 2018 and 2017 were $4.5 billion, $1.5 billion and $4.9 billion, respectively. Tax benefits relating to stock option exercises were $65 million in 2019, $77 million in 2018 and $73 million in 2017.

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

	2019	2018	2017
Balance January 1	**$ 1,893**	$ 1,723	$ 3,494
Additions related to current year positions	**199**	221	146
Additions related to prior year positions	**46**	142	520
Reductions for tax positions of prior years [(1)]	**(454)**	(73)	(1,038)
Settlements [(1)]	**(356)**	(91)	(1,388)
Lapse of statute of limitations [(2)]	**(103)**	(29)	(11)
Balance December 31	**$ 1,225**	$ 1,893	$ 1,723

[(1)] *Amounts reflect the settlements with the IRS as discussed below.*

[(2)] *Amount in 2019 includes $78 million related to the divestiture of Merck's Consumer Care business in 2014.*

If the Company were to recognize the unrecognized tax benefits of $1.2 billion at December 31, 2019, the income tax provision would reflect a favorable net impact of $1.1 billion.

The Company is under examination by numerous tax authorities in various jurisdictions globally. The Company believes that it is reasonably possible that the total amount of unrecognized tax benefits as of December 31, 2019 could decrease by up to approximately $40 million in the next 12 months as a result of various audit closures, settlements or the expiration of the statute of limitations. The ultimate finalization of the Company's examinations with relevant taxing authorities can include formal administrative and legal proceedings, which could have a significant impact on the timing of the reversal of unrecognized tax benefits. The Company believes that its reserves for uncertain tax positions are adequate to cover existing risks or exposures.

Interest and penalties associated with uncertain tax positions amounted to a (benefit) expense of $(101) million in 2019, $51 million in 2018 and $183 million in 2017. These amounts reflect the beneficial impacts of various tax settlements, including those discussed below. Liabilities for accrued interest and penalties were $243 million and $372 million as of December 31, 2019 and 2018, respectively.

In 2019, the Internal Revenue Service (IRS) concluded its examinations of Merck's 2012-2014 U.S. federal income tax returns. As a result, the Company was required to make a payment of $107 million. The Company's reserves for unrecognized tax benefits for the years under examination exceeded the adjustments relating to this examination period and therefore the Company recorded a $364 million net tax benefit in 2019. This net benefit reflects reductions in reserves for unrecognized tax benefits for tax positions relating to the years that were under examination, partially offset by additional reserves for tax positions not previously reserved for.

In 2017, the IRS concluded its examinations of Merck's 2006-2011 U.S. federal income tax returns. As a result, the Company was required to make a payment of approximately $2.8 billion. The Company's reserves for unrecognized tax benefits for the years under examination exceeded the adjustments relating to this examination period and therefore the Company recorded a net $234 million tax benefit in 2017. This net benefit reflects reductions in reserves for unrecognized tax benefits for tax positions relating to the years that were under examination, partially offset by additional reserves for tax positions not previously reserved for, as well as adjustments to reserves for unrecognized tax benefits relating to years which remain open to examination that are affected by this settlement.

The IRS is currently conducting examinations of the Company's tax returns for the years 2015 and 2016. In addition, various state and foreign tax examinations are in progress and for these jurisdictions, the Company's income tax returns are open for examination for the period 2003 through 2019.

16. Earnings per Share

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

Years Ended December 31	**2019**	2018	2017
Net income attributable to Merck & Co., Inc.	**$ 9,843**	$ 6,220	$ 2,394
Average common shares outstanding	**2,565**	2,664	2,730
Common shares issuable [(1)]	**15**	15	18
Average common shares outstanding assuming dilution	**2,580**	2,679	2,748
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	**$ 3.84**	$ 2.34	$ 0.88
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	**$ 3.81**	$ 2.32	$ 0.87

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

In 2019, 2018 and 2017, 2 million, 6 million and 5 million, respectively, of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

17. Other Comprehensive Income (Loss)

Changes in *AOCI* by component are as follows:

	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance January 1, 2017, net of taxes	$ 338	$ (3)	$ (3,206)	$ (2,355)	$ (5,226)
Other comprehensive income (loss) before reclassification adjustments, pretax	(561)	212	438	235	324
Tax	207	(35)	(106)	166	232
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(354)	177	332	401	556
Reclassification adjustments, pretax	(141) (1)	(291) (2)	117 (3)	—	(315)
Tax	49	56	(30)	—	75
Reclassification adjustments, net of taxes	(92)	(235)	87	—	(240)
Other comprehensive income (loss), net of taxes	(446)	(58)	419	401	316
Balance at December 31, 2017, net of taxes	(108)	(61)	(2,787)	(1,954)	(4,910)
Other comprehensive income (loss) before reclassification adjustments, pretax	228	(108)	(728)	(84)	(692)
Tax	(55)	1	169	(139)	(24)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	173	(107)	(559)	(223)	(716)
Reclassification adjustments, pretax	157 (1)	97 (2)	170 (3)	—	424
Tax	(33)	—	(36)	—	(69)
Reclassification adjustments, net of taxes	124	97	134	—	355
Other comprehensive income (loss), net of taxes	297	(10)	(425)	(223)	(361)
Adoption of ASU 2018-02	(23)	1	(344)	100	(266)
Adoption of ASU 2016-01	—	(8)	—	—	(8)
Balance at December 31, 2018, net of taxes	166	(78)	(3,556) (4)	(2,077)	(5,545)
Other comprehensive income (loss) before reclassification adjustments, pretax	**86**	**140**	**(948)**	**112**	**(610)**
Tax	**(15)**	**—**	**192**	**(16)**	**161**
Other comprehensive income (loss) before reclassification adjustments, net of taxes	**71**	**140**	**(756)**	**96**	**(449)**
Reclassification adjustments, pretax	**(261) (1)**	**(44) (2)**	**66 (3)**	**—**	**(239)**
Tax	**55**	**—**	**(15)**	**—**	**40**
Reclassification adjustments, net of taxes	**(206)**	**(44)**	**51**	**—**	**(199)**
Other comprehensive income (loss), net of taxes	**(135)**	**96**	**(705)**	**96**	**(648)**
Balance at December 31, 2019, net of taxes	**$ 31**	**$ 18**	**$ (4,261) (4)**	**$ (1,981)**	**$ (6,193)**

(1) *Relates to foreign currency cash flow hedges that were reclassified from* AOCI *to* Sales.

(2) *Represents net realized (gains) losses on the sales of available-for-sale investments that were reclassified from* AOCI *to* Other (income) expense, net. *In 2017, these amounts included both investments in debt and equity securities; however, as a result of the adoption of ASU 2016-01 in 2018, these amounts relate only to investments in available-for-sale debt securities.*

(3) *Includes net amortization of prior service cost and actuarial gains and losses included in net periodic benefit cost (see Note 13).*

(4) *Includes pension plan net loss of $5.1 billion and $4.4 billion at December 31, 2019 and 2018, respectively, and other postretirement benefit plan net gain of $247 million and $170 million at December 31, 2019 and 2018, respectively, as well as pension plan prior service credit of $263 million and $314 million at December 31, 2019 and 2018, respectively, and other postretirement benefit plan prior service credit of $305 million and $375 million at December 31, 2019 and 2018, respectively.*

18. Segment Reporting

The Company's operations are principally managed on a products basis and include four operating segments, which are the Pharmaceutical, Animal Health, Healthcare Services and Alliances segments. The Pharmaceutical and Animal Health segments are the only reportable segments.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. A large component of pediatric and adolescent vaccine sales are made to the U.S. Centers for Disease Control and Prevention Vaccines for Children program, which is funded by the U.S. government. Additionally, the Company sells vaccines to the Federal government for placement into vaccine stockpiles. During 2019, as a result of changes to the Company's internal reporting structure, certain costs that were previously included in the Pharmaceutical segment are now being included as part of non-segment expenses within Merck Research Laboratories. Prior period Pharmaceutical segment profits have been recast to reflect these changes on a comparable basis.

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

The Healthcare Services segment provides services and solutions that focus on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company has recently sold certain businesses in the Healthcare Services segment and is in the process of divesting the remaining businesses.

The Alliances segment primarily includes activity from the Company's relationship with AstraZeneca LP related to sales of Nexium and Prilosec, which concluded in 2018.

Sales of the Company's products were as follows:

Years Ended December 31	**2019**			2018			2017		
	U.S.	**Int'l**	**Total**	U.S.	Int'l	Total	U.S.	Int'l	Total
Pharmaceutical:									
Oncology									
Keytruda	**$ 6,305**	**$ 4,779**	**$ 11,084**	$ 4,150	$ 3,021	$ 7,171	$ 2,309	$ 1,500	$ 3,809
Alliance revenue - Lynparza [(1)]	**269**	**176**	**444**	127	61	187	—	20	20
Alliance revenue - Lenvima [(1)]	**239**	**165**	**404**	95	54	149	—	—	—
Emend	**183**	**205**	**388**	312	210	522	342	213	556
Vaccines									
Gardasil/Gardasil 9	**1,831**	**1,905**	**3,737**	1,873	1,279	3,151	1,565	743	2,308
ProQuad/M-M-R II/Varivax	**1,683**	**592**	**2,275**	1,430	368	1,798	1,374	303	1,676
Pneumovax 23	**679**	**247**	**926**	627	281	907	581	240	821
RotaTeq	**506**	**284**	**791**	496	232	728	481	204	686
Vaqta	**130**	**108**	**238**	127	112	239	94	124	218
Hospital Acute Care									
Bridion	**533**	**598**	**1,131**	386	531	917	239	465	704
Noxafil	**282**	**380**	**662**	353	389	742	309	327	636
Primaxin	**2**	**271**	**273**	7	258	265	10	270	280
Invanz	**30**	**233**	**263**	253	243	496	361	241	602
Cubicin	**92**	**165**	**257**	191	176	367	189	193	382
Cancidas	**6**	**242**	**249**	12	314	326	20	402	422
Immunology									
Simponi	**—**	**830**	**830**	—	893	893	—	819	819
Remicade	**—**	**411**	**411**	—	582	582	—	837	837
Neuroscience									
Belsomra	**92**	**214**	**306**	96	164	260	98	112	210
Virology									
Isentress/Isentress HD	**398**	**576**	**975**	513	627	1,140	565	639	1,204
Zepatier	**118**	**252**	**370**	8	447	455	771	888	1,660
Cardiovascular									
Zetia	**14**	**575**	**590**	45	813	857	352	992	1,344
Vytorin	**16**	**269**	**285**	10	487	497	124	627	751
Atozet	**—**	**391**	**391**	—	347	347	—	225	225
Adempas	**—**	**419**	**419**	—	329	329	—	300	300
Diabetes									
Januvia	**1,724**	**1,758**	**3,482**	1,969	1,718	3,686	2,153	1,584	3,737
Janumet	**589**	**1,452**	**2,041**	811	1,417	2,228	863	1,296	2,158
Women's Health									
NuvaRing	**742**	**136**	**879**	722	180	902	564	197	761
Implanon/Nexplanon	**568**	**219**	**787**	495	208	703	496	191	686
Diversified Brands									
Singulair	**29**	**669**	**698**	20	688	708	40	692	732
Cozaar/Hyzaar	**24**	**418**	**442**	23	431	453	18	466	484
Nasonex	**9**	**284**	**293**	23	353	376	54	333	387
Arcoxia	**—**	**288**	**288**	—	335	335	—	363	363
Follistim AQ	**103**	**138**	**241**	115	153	268	123	174	298
Other pharmaceutical [(2)]	**1,563**	**3,343**	**4,901**	1,319	3,380	4,705	1,759	3,556	5,314
Total Pharmaceutical segment sales	**18,759**	**22,992**	**41,751**	16,608	21,081	37,689	15,854	19,536	35,390
Animal Health:									
Livestock	**582**	**2,201**	**2,784**	528	2,102	2,630	471	2,013	2,484
Companion Animals	**724**	**885**	**1,609**	710	872	1,582	619	772	1,391
Total Animal Health segment sales	**1,306**	**3,086**	**4,393**	1,238	2,974	4,212	1,090	2,785	3,875
Other segment sales [(3)]	**174**	**1**	**175**	248	2	250	396	1	397
Total segment sales	**20,239**	**26,079**	**46,319**	18,094	24,057	42,151	17,340	22,322	39,662
Other [(4)]	**86**	**436**	**521**	118	26	143	84	376	460
	$ 20,325	**$ 26,515**	**$ 46,840**	$ 18,212	$ 24,083	$ 42,294	$ 17,424	$ 22,698	$ 40,122

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

(1) Alliance revenue represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs (see Note 4).

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

(3) Represents the non-reportable segments of Healthcare Services and Alliances.

(4) Other is primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, as well as third-party manufacturing sales. Other in 2019, 2018 and 2017 also includes approximately $80 million, $95 million and $85 million, respectively, related to the sale of the marketing rights to certain products.

Consolidated sales by geographic area where derived are as follows:

Years Ended December 31	**2019**	2018	2017
United States	**$ 20,325**	$ 18,212	$ 17,424
Europe, Middle East and Africa	**12,707**	12,213	11,478
Japan	**3,583**	3,212	3,122
China	**3,207**	2,184	1,586
Asia Pacific (other than Japan and China)	**2,943**	2,909	2,751
Latin America	**2,469**	2,415	2,339
Other	**1,606**	1,149	1,422
	$ 46,840	$ 42,294	$ 40,122

A reconciliation of segment profits to *Income before taxes* is as follows:

Years Ended December 31	**2019**	2018	2017
Segment profits:			
Pharmaceutical segment	**$ 28,324**	$ 24,871	$ 23,018
Animal Health segment	**1,609**	1,659	1,552
Other segments	**(7)**	103	275
Total segment profits	**29,926**	26,633	24,845
Other profits	**363**	6	26
Unallocated:			
Interest income	**274**	343	385
Interest expense	**(893)**	(772)	(754)
Depreciation and amortization	**(1,573)**	(1,334)	(1,378)
Research and development	**(9,499)**	(9,432)	(10,004)
Amortization of purchase accounting adjustments	**(1,419)**	(2,664)	(3,056)
Restructuring costs	**(638)**	(632)	(776)
Charge related to the termination of a collaboration with Samsung	**—**	(423)	—
Loss on extinguishment of debt	**—**	—	(191)
Other unallocated, net	**(5,077)**	(3,024)	(2,576)
Income Before Taxes	**$ 11,464**	$ 8,701	$ 6,521

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

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

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

Equity (income) loss from affiliates and depreciation and amortization included in segment profits is as follows:

	Pharmaceutical	Animal Health	All Other	Total
Year Ended December 31, 2019				
Included in segment profits:				
Equity (income) loss from affiliates	**$ —**	**$ —**	**$ —**	**$ —**
Depreciation and amortization	**137**	**109**	**10**	**256**
Year Ended December 31, 2018				
Included in segment profits:				
Equity (income) loss from affiliates	$ 4	$ —	$ —	$ 4
Depreciation and amortization	243	82	10	335
Year Ended December 31, 2017				
Included in segment profits:				
Equity (income) loss from affiliates	$ 7	$ —	$ —	$ 7
Depreciation and amortization	125	75	12	212

Property, plant and equipment, net, by geographic area where located is as follows:

December 31	**2019**	2018	2017
United States	**$ 8,974**	$ 8,306	$ 8,070
Europe, Middle East and Africa	**4,767**	3,706	3,151
Asia Pacific (other than Japan and China)	**714**	684	632
Latin America	**266**	264	271
China	**174**	167	150
Japan	**152**	159	158
Other	**6**	5	7
	$ 15,053	$ 13,291	$ 12,439

The Company does not disaggregate assets on a products and services basis for internal management reporting and, therefore, such information is not presented.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Merck & Co., Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheet of Merck & Co., Inc. and its subsidiaries (the "Company") as of December 31, 2019 and 2018, and the related consolidated statements of income, of comprehensive income, of equity and of cash flows for each of the three years in the period ended December 31, 2019, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable

assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Customer Discount Accruals in the U.S. - Medicaid, Managed Care and Medicare Part D Rebates

As described in Note 2 to the consolidated financial statements, the Company records certain variable consideration including discounts, which are estimated at the time of sale generally using the expected value method. Amounts accrued for aggregate customer discounts as of December 31, 2019 in the U.S. are $2.4 billion and are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal and state agencies, and other customers to the amounts accrued. Certain of these discounts take the form of rebates, which are amounts owed based upon definitive contractual agreements or legal requirements with private sector (Managed Care) and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. Management uses historical customer segment utilization mix, sales forecasts, changes to product mix and price, inventory levels in the distribution channel, government pricing calculations and prior payment history in order to estimate the expected provision.

The principal considerations for our determination that performing procedures relating to customer discount accruals in the U.S. - Medicaid, Managed Care, and Medicare Part D rebates is a critical audit matter are that there was significant judgment required by management with significant measurement uncertainty, as the calculation of the rebate accruals includes assumptions related to price and customer segment utilization, pertaining to forecasted customer claims that may not be fully paid until a subsequent period. This in turn led to a high degree of auditor judgment, subjectivity and effort in applying the procedures related to those assumptions.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to customer discount accruals in the U.S. - Medicaid, Managed Care, and Medicare Part D rebates, including management's controls over the assumptions used to estimate the corresponding rebate accruals. These procedures also included, among others, developing an independent estimate of the rebate accruals by utilizing third party data on customer segment utilization, changes to price, the terms of the specific rebate programs, and the historical trend of actual rebate claims paid. The independent estimate was compared to the rebate accruals recorded by management to evaluate the reasonableness of the estimate. Additionally, these procedures included testing actual rebate claims paid and evaluating the contractual terms of the Company's rebate agreements.

PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 26, 2020

We have served as the Company's auditor since 2002.

(b) Supplementary Data

Selected quarterly financial data for 2019 and 2018 are contained in the Condensed Interim Financial Data table below.

Condensed Interim Financial Data (Unaudited)

($ in millions except per share amounts)	4th Q	3rd Q [1]	2nd Q	1st Q [2]
2019 [3]				
Sales	**$ 11,868**	**$ 12,397**	**$ 11,760**	**$ 10,816**
Cost of sales	**3,669**	**3,990**	**3,401**	**3,052**
Selling, general and administrative	**2,888**	**2,589**	**2,712**	**2,425**
Research and development	**2,548**	**3,204**	**2,189**	**1,931**
Restructuring costs	**194**	**232**	**59**	**153**
Other (income) expense, net	**(223)**	**35**	**140**	**188**
Income before taxes	**2,792**	**2,347**	**3,259**	**3,067**
Net income attributable to Merck & Co., Inc.	**2,357**	**1,901**	**2,670**	**2,915**
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	**$ 0.93**	**$ 0.74**	**$ 1.04**	**$ 1.13**
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	**$ 0.92**	**$ 0.74**	**$ 1.03**	**$ 1.12**
2018 [3]				
Sales	$ 10,998	$ 10,794	$ 10,465	$ 10,037
Cost of sales	3,289	3,619	3,417	3,184
Selling, general and administrative	2,643	2,443	2,508	2,508
Research and development	2,214	2,068	2,274	3,196
Restructuring costs	138	171	228	95
Other (income) expense, net	110	(172)	(48)	(291)
Income before taxes	2,604	2,665	2,086	1,345
Net income attributable to Merck & Co., Inc.	1,827	1,950	1,707	736
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	$ 0.70	$ 0.73	$ 0.64	$ 0.27
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	$ 0.69	$ 0.73	$ 0.63	$ 0.27

[1] *Amounts for 2019 include a charge related to the acquisition of Peloton Therapeutics, Inc. (see Note 3).*

[2] *Amounts for 2018 include a charge related to the formation of a collaboration with Eisai (see Note 4).*

[3] *Amounts for 2019 and 2018 reflect acquisition and divestiture-related costs (see Note 8) and the impact of restructuring actions (see Note 5).*

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures. Based on their evaluation, as of the end of the period covered by this Form 10-K, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15 (e) under the Securities Exchange Act of 1934, as amended (the Act)) are effective. For the fourth quarter of 2019, there have been no changes in internal control over financial reporting that materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Act. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control — Integrated Framework* issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2019. PricewaterhouseCoopers LLP, an independent registered public accounting firm, has performed its own assessment of the effectiveness of the Company's internal control over financial reporting and its attestation report is included in this Form 10-K filing.

Management's Report

Management's Responsibility for Financial Statements

Responsibility for the integrity and objectivity of the Company's financial statements rests with management. The financial statements report on management's stewardship of Company assets. These statements are prepared in conformity with generally accepted accounting principles and, accordingly, include amounts that are based on management's best estimates and judgments. Nonfinancial information included in the Annual Report on Form 10-K has also been prepared by management and is consistent with the financial statements.

To assure that financial information is reliable and assets are safeguarded, management maintains an effective system of internal controls and procedures, important elements of which include: careful selection, training and development of operating and financial managers; an organization that provides appropriate division of responsibility; and communications aimed at assuring that Company policies and procedures are understood throughout the organization. A staff of internal auditors regularly monitors the adequacy and application of internal controls on a worldwide basis.

To ensure that personnel continue to understand the system of internal controls and procedures, and policies concerning good and prudent business practices, annually all employees of the Company are required to complete Code of Conduct training. This training reinforces the importance and understanding of internal controls by reviewing key corporate policies, procedures and systems. In addition, the Company has compliance programs, including an ethical business practices program to reinforce the Company's long-standing commitment to high ethical standards in the conduct of its business.

The financial statements and other financial information included in the Annual Report on Form 10-K fairly present, in all material respects, the Company's financial condition, results of operations and cash flows. Our formal certification to the Securities and Exchange Commission is included in this Form 10-K filing.

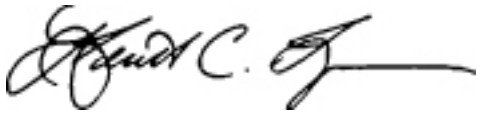
Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control — Integrated Framework* issued in 2013 by the

Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2019.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2019, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.



Kenneth C. Frazier
Chairman, President and Chief Executive Officer

Robert M. Davis
Executive Vice President, Global Services, and Chief Financial Officer

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The required information on directors and nominees is incorporated by reference from the discussion under Proposal 1. Election of Directors of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 26, 2020. Information on executive officers is set forth in Part I of this document on page 35.

The required information on compliance with Section 16(a) of the Securities Exchange Act of 1934, if applicable, is incorporated by reference from the discussion under the heading "Stock Ownership Information" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 26, 2020.

The Company has a Code of Conduct — *Our Values and Standards* applicable to all employees, including the principal executive officer, principal financial officer, principal accounting officer and Controller. The Code of Conduct is available on the Company's website at http://www.msd.com/about/how-we-operate/code-of-conduct/values-and-standards.html. The Company intends to disclose future amendments to certain provisions of the Code of Conduct, and waivers of the Code of Conduct granted to executive officers and directors, if any, on the website within four business days following the date of any amendment or waiver. Every Merck employee is responsible for adhering to business practices that are in accordance with the law and with ethical principles that reflect the highest standards of corporate and individual behavior.

The required information on the identification of the audit committee and the audit committee financial expert is incorporated by reference from the discussion under the heading "Board Meetings and Committees" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 26, 2020.

Item 11. Executive Compensation.

The information required on executive compensation is incorporated by reference from the discussion under the headings "Compensation Discussion and Analysis," "Summary Compensation Table," "All Other Compensation" table, "Grants of Plan-Based Awards" table, "Outstanding Equity Awards" table, "Option Exercises and Stock Vested" table, "Pension Benefits" table, "Nonqualified Deferred Compensation" table, Potential Payments Upon Termination or a Change in Control, including the discussion under the subheadings "Separation" and "Change in Control," as well as all footnote information to the various tables, of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 26, 2020.

The required information on director compensation is incorporated by reference from the discussion under the heading "Director Compensation" and related "Director Compensation" table and "Schedule of Director Fees" table of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 26, 2020.

The required information under the headings "Compensation and Benefits Committee Interlocks and Insider Participation" and "Compensation and Benefits Committee Report" is incorporated by reference from the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 26, 2020.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information with respect to security ownership of certain beneficial owners and management is incorporated by reference from the discussion under the heading "Stock Ownership Information" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 26, 2020.

Equity Compensation Plan Information

The following table summarizes information about the options, warrants and rights and other equity compensation under the Company's equity compensation plans as of the close of business on December 31, 2019. The table does not include information about tax qualified plans such as the Merck U.S. Savings Plan.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders[1]	17,867,551[2]	$ 59.88	110,842,998
Equity compensation plans not approved by security holders	—	—	—
Total	17,867,551	$ 59.88	110,842,998

[1] *Includes options to purchase shares of Company Common Stock and other rights under the following shareholder-approved plans: the Merck & Co., Inc. 2010 and 2019 Incentive Stock Plans, and the Merck & Co., Inc. 2010 Non-Employee Directors Stock Option Plan.*

[2] *Excludes approximately 13,527,086 shares of restricted stock units and 1,927,145 performance share units (assuming maximum payouts) under the Merck Sharp & Dohme 2004, 2007 and 2010 Incentive Stock Plans. Also excludes 197,485 shares of phantom stock deferred under the MSD Employee Deferral Program and 557,132 shares of phantom stock deferred under the Merck & Co., Inc. Plan for Deferred Payment of Directors' Compensation.*

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The required information on transactions with related persons is incorporated by reference from the discussion under the heading "Related Person Transactions" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 26, 2020.

The required information on director independence is incorporated by reference from the discussion under the heading "Independence of Directors" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 26, 2020.

Item 14. Principal Accountant Fees and Services.

The information required for this item is incorporated by reference from the discussion under Proposal 3. Ratification of Appointment of Independent Registered Public Accounting Firm for 2020 beginning with the caption "Pre-Approval Policy for Services of Independent Registered Public Accounting Firm" through "Fees for Services Provided by the Independent Registered Public Accounting Firm" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 26, 2020.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this Form 10-K

1. Financial Statements

Consolidated statement of income for the years ended December 31, 2019, 2018 and 2017

Consolidated statement of comprehensive income for the years ended December 31, 2019, 2018 and 2017

Consolidated balance sheet as of December 31, 2019 and 2018

Consolidated statement of equity for the years ended December 31, 2019, 2018 and 2017

Consolidated statement of cash flows for the years ended December 31, 2019, 2018 and 2017

Notes to consolidated financial statements

Report of PricewaterhouseCoopers LLP, independent registered public accounting firm

2. Financial Statement Schedules

Schedules are omitted because they are either not required or not applicable.

Financial statements of affiliates carried on the equity basis have been omitted because, considered individually or in the aggregate, such affiliates do not constitute a significant subsidiary.

3. Exhibits

Exhibit Number		Description
3.1	—	Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) — Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
3.2	—	By-Laws of Merck & Co., Inc. (effective July 22, 2015) — Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed July 28, 2015 (No. 1-6571)
4.1	—	Indenture, dated as of April 1, 1991, between Merck Sharp & Dohme Corp. (f/k/a Schering Corporation) and U.S. Bank Trust National Association (as successor to Morgan Guaranty Trust Company of New York), as Trustee (the 1991 Indenture) — Incorporated by reference to Exhibit 4 to MSD's Registration Statement on Form S-3 (No. 33-39349)
4.2	—	First Supplemental Indenture to the 1991 Indenture, dated as of October 1, 1997 — Incorporated by reference to Exhibit 4(b) to MSD's Registration Statement on Form S-3 filed September 25, 1997 (No. 333-36383)
4.3	—	Second Supplemental Indenture to the 1991 Indenture, dated November 3, 2009 — Incorporated by reference to Exhibit 4.3 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No.1-6571)
4.4	—	Third Supplemental Indenture to the 1991 Indenture, dated May 1, 2012 — Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the period ended March 31, 2012 (No. 1-6571)
4.5	—	Indenture, dated November 26, 2003, between Merck & Co., Inc. (f/k/a Schering-Plough Corporation) and The Bank of New York as Trustee (the 2003 Indenture) — Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed November 28, 2003 (No. 1-6571)
4.6	—	Second Supplemental Indenture to the 2003 Indenture (including Form of Note), dated November 26, 2003 — Incorporated by reference to Exhibit 4.3 to Schering-Plough's Current Report on Form 8-K filed November 28, 2003 (No. 1-6571)
4.7	—	Third Supplemental Indenture to the 2003 Indenture (including Form of Note), dated September 17, 2007 — Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed September 17, 2007 (No. 1-6571)

Exhibit Number		Description
4.8	—	Fifth Supplemental Indenture to the 2003 Indenture, dated November 3, 2009 — Incorporated by reference to Exhibit 4.4 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
4.9	—	Indenture, dated as of January 6, 2010, between Merck & Co., Inc. and U.S. Bank Trust National Association, as Trustee — Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed December 10, 2010 (No. 1-6571)
4.10	—	2.900% Notes due 2024 Officers' Certificate of the Company dated March 7, 2019, including form of the 2024 Notes - Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed March 7, 2019 (No. 1-6571)
4.11	—	3.400% Notes due 2029 Officers' Certificate of the Company dated March 7, 2019, including form of the 2029 Notes - Incorporated by reference to Exhibit 4.2 to Merck & Co., Inc.'s Current Report on Form 8-K filed March 7, 2019 (No. 1-6571)
4.12	—	3.900% Notes due 2039 Officers' Certificate of the Company dated March 7, 2019, including form of the 2039 Notes - Incorporated by reference to Exhibit 4.3 to Merck & Co., Inc.'s Current Report on Form 8-K filed March 7, 2019 (No. 1-6571)
4.13	—	4.000% Notes due 2049 Officers' Certificate of the Company dated March 7, 2019, including form of the 2049 Notes - Incorporated by reference to Exhibit 4.4 to Merck & Co., Inc.'s Current Report on Form 8-K filed March 7, 2019 (No. 1-6571)
*10.1	—	Merck & Co., Inc. Executive Incentive Plan (as amended and restated effective June 1, 2015) — Incorporated by reference to Merck & Co., Inc.'s Schedule 14A filed April 13, 2015 (No. 1-6571)
*10.2	—	Merck & Co., Inc. Deferral Program Including the Base Salary Deferral Plan (Amended and Restated effective December 1, 2019)
*10.3	—	Merck & Co., Inc. 2010 Incentive Stock Plan (as amended and restated June 1, 2015) — Incorporated by reference to Merck & Co., Inc.'s Schedule 14A filed April 13, 2015 (No. 1-6571)
*10.4	—	Form of stock option terms for 2011 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.2 to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the period ended March 31, 2011 filed May 9, 2011 (No. 1-6571)
*10.5	—	Form of stock option terms for 2012 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.20 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2011 filed February 28, 2012 (No. 1-6571)
*10.6	—	Form of stock option terms for 2013 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.19 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2012 filed February 28, 2013 (No. 1-6571)
*10.7	—	Form of stock option terms for 2014 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.18 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2014 filed February 27, 2015 (No. 1-6571)
*10.8	—	Form of stock option terms for 2015 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.20 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2015 filed February 26, 2016 (No. 1-6571)
*10.9	—	Form of stock option terms for 2018 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by referent to Exhibit 10.12 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2017 filed February 27, 2018 (No. 1-6571)

Exhibit Number		Description
*10.10	—	Form of stock option terms for 2016 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.19 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2016 filed February 28, 2017 (No. 1-6571)
*10.11	—	Form of restricted stock unit terms for 2018 quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.17 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2017 filed on February 28, 2018 (No. 1-6571)
*10.12	—	2018 Performance Share Unit Award Terms under the Merck & Co., Inc. 2010 Stock Incentive Plan — Incorporated by reference to Exhibit 10 to Merck & Co., Inc.'s Current Report on Form 10-Q Quarterly Report for the period ended March 31, 2018 filed May 8, 2018 (No. 1-6571)
*10.13	—	Merck & Co., Inc. 2019 Incentive Stock Plan - Incorporated by reference to Appendix C to Merck & Co., Inc.'s Schedule 14A filed April 8, 2019 (No. 1-6571)
*10.14	—	Merck & Co., Inc. Change in Control Separation Benefits Plan (effective as amended and restated, as of January 1, 2013) — Incorporated by reference to Exhibit 10.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 29, 2012 (No. 1-6571)
*10.15	—	Merck & Co., Inc. U.S. Separation Benefits Plan (amended and restated as of January 1, 2019) - Incorporated by reference to Exhibit 10.19 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2018 filed February 27, 2019 (No. 1-6571)
*10.16	—	Merck & Co., Inc. 2010 Non-Employee Directors Stock Option Plan (amended and restated as of December 1, 2010) — Incorporated by reference to Exhibit 10.17 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2010 filed February 28, 2011 (No. 1-6571)
*10.17	—	Retirement Plan for the Directors of Merck & Co., Inc. (amended and restated June 21, 1996) — Incorporated by reference to Exhibit 10.C to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1996 filed August 13, 1996 (No. 1-3305)
*10.18	—	Merck & Co., Inc. Plan for Deferred Payment of Directors' Compensation (Amended and Restated effective as of January 1, 2020)
10.19	—	Distribution agreement between Schering-Plough and Centocor, Inc., dated April 3, 1998 — Incorporated by reference to Exhibit 10(u) to Schering-Plough's Amended 10-K for the year ended December 31, 2003 filed May 3, 2004 (No. 1-6571)†
10.20	—	Amendment Agreement to the Distribution Agreement between Centocor, Inc., CAN Development, LLC, and Schering-Plough (Ireland) Company — Incorporated by reference to Exhibit 10.1 to Schering-Plough's Current Report on Form 8-K filed December 21, 2007 (No. 1-6571)†
10.21	—	Severance Agreement and General Release between Merck & Co., Inc. and Adam H. Schechter, dated December 1, 2018 - Incorporated by reference to Exhibit 10.27 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2018 filed February 27, 2019 (No. 1-6571)
10.22	—	Offer Letter between Merck & Co., Inc. and Jennifer Zachary, dated March 16, 2018 - Incorporated by reference to Exhibit 10.28 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2018 filed February 27, 2019 (No. 1-6571)
21	—	Subsidiaries of Merck & Co., Inc.
23	—	Consent of Independent Registered Public Accounting Firm
24.1	—	Power of Attorney
24.2	—	Certified Resolution of Board of Directors
31.1	—	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
31.2	—	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer
32.1	—	Section 1350 Certification of Chief Executive Officer
32.2	—	Section 1350 Certification of Chief Financial Officer

Exhibit Number		Description
101.INS	—	XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	—	XBRL Taxonomy Extension Schema Document.
101.CAL	—	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	—	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	—	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	—	XBRL Taxonomy Extension Presentation Linkbase Document.
104	—	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

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* *Management contract or compensatory plan or arrangement.*

† *Certain portions of the exhibit have been omitted pursuant to a request for confidential treatment. The non-public information has been filed separately with the Securities and Exchange Commission pursuant to rule 24b-2 under the Securities Exchange Act of 1934, as amended.*

Long-term debt instruments under which the total amount of securities authorized does not exceed 10% of Merck & Co., Inc.'s total consolidated assets are not filed as exhibits to this report. Merck & Co., Inc. will furnish a copy of these agreements to the Securities and Exchange Commission on request.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: February 26, 2020

MERCK & CO., INC.

By: KENNETH C. FRAZIER
(Chairman, President and Chief Executive Officer)

By: /s/ JENNIFER ZACHARY
Jennifer Zachary
(Attorney-in-Fact)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signatures	Title	Date
KENNETH C. FRAZIER	Chairman, President and Chief Executive Officer; Principal Executive Officer; Director	February 26, 2020
ROBERT M. DAVIS	Executive Vice President, Global Services, and Chief Financial Officer; Principal Financial Officer	February 26, 2020
RITA A. KARACHUN	Senior Vice President Finance-Global Controller; Principal Accounting Officer	February 26, 2020
LESLIE A. BRUN	Director	February 26, 2020
THOMAS R. CECH	Director	February 26, 2020
MARY ELLEN COE	Director	February 26, 2020
PAMELA J. CRAIG	Director	February 26, 2020
THOMAS H. GLOCER	Director	February 26, 2020
ROCHELLE B. LAZARUS	Director	February 26, 2020
PAUL B. ROTHMAN	Director	February 26, 2020
PATRICIA F. RUSSO	Director	February 26, 2020
INGE G. THULIN	Director	February 26, 2020
WENDELL P. WEEKS	Director	February 26, 2020
PETER C. WENDELL	Director	February 26, 2020

Jennifer Zachary, by signing her name hereto, does hereby sign this document pursuant to powers of attorney duly executed by the persons named, filed with the Securities and Exchange Commission as an exhibit to this document, on behalf of such persons, all in the capacities and on the date stated, such persons including a majority of the directors of the Company.

By: /S/ JENNIFER ZACHARY
Jennifer Zachary
(Attorney-in-Fact)