Merck & Co., Inc.
Form 10-K
February 27, 2019
As filed with the Securities and Exchange Commission on February 27, 2019

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

FORM 10-K
(MARK ONE)

Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the Fiscal Year Ended December 31, 2018
or
Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from to

Commission File No. 1-6571

Merck & Co., Inc.
2000 Galloping Hill Road
Kenilworth, N. J. 07033
(908) 740-4000

Incorporated in New Jersey	I.R.S. Employer Identification No. 22-1918501

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

Title of Each Class	Name of Each Exchange on which Registered
Common Stock ($0.50 par value)	New York Stock Exchange
1.125% Notes due 2021	New York Stock Exchange
0.500% Notes due 2024	New York Stock Exchange
1.875% Notes due 2026	New York Stock Exchange
2.500% Notes due 2034	New York Stock Exchange
1.375% Notes due 2036	New York Stock Exchange

Number of shares of Common Stock ($0.50 par value) outstanding as of January 31, 2019: 2,581,220,308.
Aggregate market value of Common Stock ($0.50 par value) held by non-affiliates on June 30, 2018 based on closing price on June 30, 2018: $161,991,000,000.
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of registrant’s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated

filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check One):

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

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

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

Documents Incorporated by Reference:

Document	Part of Form 10-K
Proxy Statement for the Annual Meeting of Shareholders to be held May 28, 2019, to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this report	Part III

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PART I

Item 1. Business.

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

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

The Animal Health segment discovers, develops, manufactures and markets animal health products, including pharmaceutical and vaccine products, for the prevention, treatment and control of disease in all major livestock and companion animal species, which the Company sells to veterinarians, distributors and animal producers.

The Healthcare Services segment provides services and solutions that focus on engagement, health analytics and clinical services to improve the value of care delivered to patients.

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

The Company was incorporated in New Jersey in 1970.

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

Product Sales

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

($ in millions)	2018	2017	2016
Total Sales	$42,294	$40,122	$39,807
Pharmaceutical	37,689	35,390	35,151
Keytruda	7,171	3,809	1,402
Januvia/Janumet	5,914	5,896	6,109
Gardasil/Gardasil 9	3,151	2,308	2,173
ProQuad/M-M-R II/Varivax	1,798	1,676	1,640
Zetia/Vytorin	1,355	2,095	3,701
Isentress/Isentress HD	1,140	1,204	1,387
Bridion	917	704	482
Pneumovax 23	907	821	641
NuvaRing	902	761	777
Simponi	893	819	766
Animal Health	4,212	3,875	3,478
Livestock	2,630	2,484	2,287
Companion Animals	1,582	1,391	1,191
Other Revenues[(1)]	393	857	1,178

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

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Pharmaceutical

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

Oncology

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

Vaccines

Gardasil (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant)/Gardasil 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), vaccines to help prevent certain diseases caused by certain types of human papillomavirus (HPV); ProQuad (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella; M-M-R II (Measles, Mumps and Rubella Virus Vaccine Live), a vaccine to help prevent measles, mumps and rubella; Varivax (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox (varicella); Pneumovax 23 (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease; RotaTeq (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children; and Zostavax (Zoster Vaccine Live), a vaccine to help prevent shingles (herpes zoster).

Hospital Acute Care

Bridion (sugammadex) Injection, a medication for the reversal of two types of neuromuscular blocking agents used during surgery; Noxafil (posaconazole) for the prevention of invasive fungal infections; Invanz (ertapenem sodium) for the treatment of certain infections; Cubicin (daptomycin for injection), an I.V. antibiotic for complicated skin and skin structure infections or bacteremia, when caused by designated susceptible organisms; Cancidas (caspofungin acetate), an anti-fungal product; Primaxin (imipenem and cilastatin sodium), an anti-bacterial product; and Zerbaxa (ceftolozane and tazobactam) is currently approved in the United States for the treatment of adult patients with complicated urinary tract infections caused by certain susceptible Gram-negative microorganisms, and is also indicated, in combination with metronidazole, for the treatment of adult patients with complicated intra-abdominal infections caused by certain susceptible Gram-negative and Gram-positive microorganisms.

Immunology

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

Neuroscience

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

Virology

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

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Cardiovascular

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

Diabetes

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

Women's Health

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

Animal Health

The Animal Health segment discovers, develops, manufactures and markets animal health products, including pharmaceutical and vaccine products, for the prevention, treatment and control of disease in all major livestock and companion animal species. Principal products in this segment include:

Livestock Products

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

Companion Animal Products

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

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

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2018 Product Approvals

Set forth below is a summary of significant product approvals received by the Company in 2018.

Product	Date	Approval
Keytruda	December 2018	The Japanese Ministry of Health, Labor and Welfare (JMHLW) approved Keytruda for three expanded uses in unresectable, advanced or recurrent NSCLC, one in malignant melanoma, as well as a new indication in high microsatellite instability solid tumors.
	December 2018	The U.S. Food and Drug Administration (FDA) approved Keytruda for the treatment of adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma.
	December 2018	The European Commission (EC) approved Keytruda for the adjuvant treatment of adults with stage III melanoma and lymph node involvement who have undergone complete resection.
	November 2018	FDA approved Keytruda for the treatment of patients with hepatocellular carcinoma who have been previously treated with sorafenib.
	October 2018	FDA approved Keytruda, in combination with carboplatin and either paclitaxel or nab-paclitaxel, for the first-line treatment of patients with metastatic squamous non-small cell lung cancer (NSCLC).
	September 2018	EC approved Keytruda in combination with pemetrexed and platinum chemotherapy for the first-line treatment of metastatic nonsquamous NSCLC in adults whose tumors have no EGFR or ALK positive mutations.
	September 2018	EC approved Keytruda for the treatment of recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) in adults whose tumors express PD-L1 with a ≥ 50% TPS and progressing on or after platinum-containing chemotherapy.
	August 2018	FDA approved Keytruda in combination with pemetrexed and platinum chemotherapy for the first-line treatment of metastatic nonsquamous NSCLC patients with no EGFR or ALK genomic tumor aberrations.
	July 2018	The China National Drug Administration (CNDA) approved Keytruda for the treatment of adult patients with unresectable or metastatic melanoma following failure of one prior line of therapy.
	June 2018	FDA approved Keytruda for the treatment of adult and pediatric patients with refractory primary mediastinal large B-cell lymphoma (PMBCL), or who have relapsed after two or more prior lines of therapy.
	June 2018	FDA approved Keytruda for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 as determined by an FDA-approved test.
Lynparza[(1)]	December 2018	FDA approved Lynparza for use as maintenance treatment of certain patients with advanced ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy.
	July 2018	JMHLW approved Lynparza for use in patients with unresectable or recurrent BRCA-mutated, human epidermal growth factor receptor 2 (HER2)-negative breast cancer who have received prior chemotherapy.
	May 2018	EC approved Lynparza for use as a maintenance therapy in patients with platinum-sensitive relapsed high grade epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in response (complete or partial) to platinum based chemotherapy regardless of BRCA mutation status.
	January 2018	FDA approved Lynparza for use in patients with BRCA-mutated, HER2-negative metastatic breast cancer who have been previously treated with chemotherapy.
	January 2018	JMHLW approved Lynparza for use as a maintenance therapy in patients with platinum-sensitive relapsed ovarian cancer, regardless of BRCA mutation status.

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Lenvima[2]	September 2018	CNDA approved Lenvima for the treatment of certain patients with hepatocellular carcinoma.
	August 2018	FDA approved Lenvima for the treatment of certain patients with hepatocellular carcinoma.
	August 2018	EC approved Lenvima for the treatment of certain patients with hepatocellular carcinoma.
	March 2018	JMHLW approved Lenvima for the treatment of certain patients with unresectable hepatocellular carcinoma.
Gardasil 9	October 2018	FDA approved Gardasil 9 for an expanded age indication for use in women and men ages 27 to 45 for the prevention of certain cancers and diseases caused by the nine HPV types covered by the vaccine.
	April 2018	CNDA approved Gardasil 9 for use in girls and women ages 16 to 26.
Delstrigo	November 2018	EC approved Delstrigo (doravirine, lamivudine, and tenofovir disoproxil fumarate) for the treatment of adults infected with human immunodeficiency virus (HIV-1) without past or present evidence of resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, lamivudine, or tenofovir.
	August 2018	FDA approved Delstrigo for the treatment of HIV-1 infection in adult patients with no prior antiretroviral treatment experience.
Pifeltro	November 2018	EC approved Pifeltro (doravirine), in combination with other antiretroviral medicinal products, for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the NNRTI class.
	August 2018	FDA approved Pifeltro for the treatment of HIV-1 infection in adult patients with no prior antiretroviral treatment experience.
Isentress	March 2018	EC approved Isentress for an extension to the existing indication to cover treatment of neonates. Isentress is now indicated in combination with other anti-retroviral medicinal products for the treatment of HIV-1 infection.
Prevymis	January 2018	EC approved Prevymis (letermovir) for the prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant.
Steglatro, Steglujan and Segluromet[3]	March 2018	EC approved Steglatro (ertugliflozin), Steglujan (ertugliflozin and sitagliptin) and Segluromet (ertugliflozin and metformin hydrochloride) for the treatment of adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control (as monotherapy in patients for whom the use of metformin is considered inappropriate due to intolerance or contraindications, and in addition to other medicinal products for the treatment of diabetes).
Vaxelis	December 2018	FDA approved Vaxelis (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus, Haemophilus b Conjugate [Meningococcal Protein Conjugate] and Hepatitis B [Recombinant] Vaccine) for use in children from 6 weeks through 4 years of age (prior to the 5th birthday)

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

(2) In March 2018, Merck and Eisai Co., Ltd. announced a strategic collaboration for the worldwide co-development and co-commercialization of Eisai's Lenvima.

(3) In 2013, Merck and Pfizer Inc. announced that they entered into a worldwide collaboration, except Japan, for the co-development and co-promotion of ertugliflozin.

Competition and the Health Care Environment

Competition

The markets in which the Company conducts its business and the pharmaceutical industry in general are highly competitive and highly regulated. The Company's competitors include other worldwide research-based pharmaceutical

companies, smaller research companies with more limited therapeutic focus, generic drug manufacturers and animal health care companies. The Company's operations may be adversely affected by generic and biosimilar competition as the Company's products mature, as well as technological advances of competitors, industry consolidation,

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patents granted to competitors, competitive combination products, new products of competitors, the generic availability of competitors' branded products, and new information from clinical trials of marketed products or post-marketing surveillance. In addition, patent rights are increasingly being challenged by competitors, and the outcome can be highly uncertain. An adverse result in a patent dispute can preclude commercialization of products or negatively affect sales of existing products and could result in the payment of royalties or in the recognition of an impairment charge with respect to intangible assets associated with certain products. Competitive pressures have intensified as pressures in the industry have grown.

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

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

Health Care Environment and Government Regulation

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

Against this backdrop, the United States enacted major health care reform legislation in 2010 (the Patient Protection and Affordable Care Act (ACA)). Various insurance market reforms have since advanced and state and federal insurance exchanges were launched in 2014. With respect to the effect of the law on the pharmaceutical industry, the law increased the mandated Medicaid rebate from 15.1% to 23.1%, expanded the rebate to Medicaid managed care utilization, and increased the types of entities eligible for the federal 340B drug discount program. The law also requires pharmaceutical manufacturers to pay a 50% point of service discount to Medicare Part D beneficiaries when they are in the Medicare Part D coverage gap (i.e., the so-called "donut hole"). Approximately $365 million, $385 million and $415 million was recorded by Merck as a reduction to revenue in 2018, 2017 and 2016, respectively, related to the donut hole provision. Beginning in 2019, the 50% point of service discount will increase to a 70% point of service discount in the coverage gap, as a result of the Balanced Budget Act of 2018. In addition, the 70% point of service discount will be extended to biosimilar products. Also, pharmaceutical manufacturers are now required to pay an annual non-tax deductible health care reform fee. The total annual industry fee was $4.1 billion in 2018 and will decrease to $2.8 billion in 2019 and is currently planned to remain at that amount thereafter. The fee is assessed on each company in proportion to its share of prior year branded pharmaceutical sales to certain government programs, such as Medicare and Medicaid. The Company recorded $124 million, $210 million and $193 million of costs within Selling, general and administrative expenses in 2018, 2017 and 2016, respectively, for the annual health care reform fee. In February 2016, the Centers for Medicare & Medicaid Services (CMS) issued the Medicaid rebate final rule that implements provisions of the ACA effective April 1, 2016. The rule provides comprehensive guidance on the calculation of Average Manufacturer Price and Best Price; two metrics utilized to determine the rebates drug manufacturers are required to pay to state Medicaid programs. The impact of changes resulting from the issuance of the rule is not material to Merck at this time. However, the Company is still awaiting guidance from CMS on two aspects of the rule that were deferred for later implementation. These include a definition of what constitutes a product 'line extension' and a delay in the participation of the U.S. Territories in the Medicaid Drug Rebate Program until April

1, 2020. The Company will evaluate the financial impact of these two elements when they become effective.

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

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

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

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

In addition, in the effort to contain the U.S. federal deficit, the pharmaceutical industry could be considered a potential source of savings via legislative proposals that have been debated but not enacted. These types of revenue generating or cost saving proposals include additional direct price controls in the Medicare prescription drug program (Part D). In addition, Congress may again consider proposals to allow, under certain conditions, the importation of medicines from other countries. It remains very uncertain as to what proposals, if any, may be included as part of future federal budget deficit reduction proposals that would directly or indirectly affect the Company.

In the U.S. private sector, consolidation and integration among health care providers is a major factor in the competitive marketplace for pharmaceutical products. Health plans and pharmacy benefit managers have been consolidating into fewer, larger entities, thus enhancing their purchasing strength and importance. Private third-party insurers, as well as governments, increasingly employ formularies to control costs by negotiating discounted prices in exchange for formulary inclusion. Failure to obtain timely or adequate pricing or formulary placement for Merck's products or obtaining such placement at unfavorable pricing could adversely impact revenue. In addition to formulary tier co-pay differentials, private health insurance companies and self-insured employers have been raising co-payments required from beneficiaries, particularly for branded pharmaceuticals and biotechnology products.

Private health insurance companies also are increasingly imposing utilization management tools, such as clinical protocols, requiring prior authorization for a branded product if a generic product is available or requiring the patient to first fail on one or more generic products before permitting access to a branded medicine. These same management tools are also used in treatment areas in which the payer has taken the position that multiple branded products are therapeutically comparable. As the U.S. payer market concentrates further and as more drugs become available in generic form, pharmaceutical companies may face greater pricing pressure from private third-party payers.

In order to provide information about the Company's pricing practices, the Company annually posts on its website its Pricing Transparency Report for the United States. The report provides the Company's average annual list price and net price increases across the Company's U.S. portfolio dating back to 2010.

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

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In addition, in Japan, the pharmaceutical industry is subject to government-mandated biennial price reductions of pharmaceutical products and certain vaccines, which occurred in 2018. Furthermore, the government can order repricings for classes of drugs if it determines that it is appropriate under applicable rules.

Certain markets outside of the United States have also implemented other cost management strategies, such as health technology assessments (HTA), which require additional data, reviews and administrative processes, all of which increase the complexity, timing and costs of obtaining product reimbursement and exert downward pressure on available reimbursement. In the United States, HTAs are also being used by government and private payers.

The Company's focus on emerging markets has continued. Governments in many emerging markets are also focused on constraining health care costs and have enacted price controls and related measures, such as compulsory licenses, that aim to put pressure on the price of pharmaceuticals and constrain market access. The Company anticipates that pricing pressures and market access challenges will continue in 2019 to varying degrees in the emerging markets. Beyond pricing and market access challenges, other conditions in emerging market countries can affect the Company's efforts to continue to grow in these markets, including potential political instability, changes in trade sanctions and embargoes, significant currency fluctuation and controls, financial crises, limited or changing availability of funding for health care, and other developments that may adversely impact the business environment for the Company. Further, the Company may engage third-party agents to assist in operating in emerging market countries, which may affect its ability to realize continued growth and may also increase the Company's risk exposure.

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

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

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

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

The European Union (EU) has adopted directives and other legislation concerning the classification, labeling, advertising, wholesale distribution, integrity of the supply chain, enhanced pharmacovigilance monitoring and approval for marketing of medicinal products for human use. These provide mandatory standards throughout the EU, which may be supplemented or implemented with additional regulations by the EU member states. The Company's policies and procedures are already consistent with the substance of these directives; consequently, it is believed that they will not have any material effect on the Company's business.

The Company's business in China has grown rapidly in the past few years, and the importance of China to the Company's overall pharmaceutical and vaccines business has increased accordingly. Continued growth of the Company's business in China is dependent upon ongoing development of a favorable environment for innovative pharmaceutical products and vaccines, sustained access for the Company's current in-line products, and the absence

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of trade impediments or adverse pricing controls. In recent years, the Chinese government has introduced and implemented a number of structural reforms to accelerate the shift to innovative products and reduce costs. Since 2017, there have been multiple new policies introduced by the government to improve access to new innovation, reduce the complexity of regulatory filings, and accelerate the review and approval process. This has led to a significant expansion of the new products being approved each year. Additionally, in 2017, the government updated the National Reimbursement Drug List for the first time in eight years. While the mechanism for drugs being added to the list evolves, it is likely that in the future, inclusion will require a price negotiation which could impact the outlook in the market for selected brands. While pricing pressure has always existed in China, health care reform has led to the acceleration of generic substitution, through a pilot tendering process for mature products that have generic substitutes with a Generic Quality Consistency Evaluation approval.

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

Access to Medicines

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

Privacy and Data Protection

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

Distribution

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

Raw Materials

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

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Patents, Trademarks and Licenses

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

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

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

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Product	Year of Expiration (U.S.)	Year of Expiration (EU)[1]	Year of Expiration (Japan)[3]
Emend	Expired	2019	2019
Emend for Injection	2019	2020[2]	2020
Noxafil	2019	2019	N/A
Vaxelis[4]	2020 (method of making)	2021[5] (SPCs)	Not Marketed
Januvia	2022[2]	2022[2]	2025-2026
Janumet	2022[2]	2023	N/A
Janumet XR	2022[2]	N/A	N/A
Isentress	2024	2022[2]	2022
Simponi	N/A[6]	2025[7]	N/A[6]
Lenvima[8]	2025[2] (with pending PTE)	2021 (patents), 2026[2] (SPCs)	2026
Adempas[9]	2026[2]	2028[2]	2027-2028
Bridion	2026[2] (with pending PTE)	2023	2024
Nexplanon	2027 (device)	2025 (device)	Not Marketed
Bravecto	2027 (with pending PTE)	2025 (patents), 2029 (SPCs)	2029
Gardasil	2028	2021[2]	Expired
Gardasil 9	2028	2025 (patents), 2030[2] (SPCs)	N/A
Keytruda	2028	2028 (patents), 2030[2] (SPCs)	2032
Lynparza[10]	2028[2] (with pending PTE)	2024 (patents), 2029[2] (SPCs)	2028-2029 (with pending PTE)
Zerbaxa	2028[2] (with pending PTE)	2023 (patents), 2028[2] (SPCs)	N/A
Sivextro	2028[2]	2024 (patents), 2029[2] (SPCs)	2029 (with pending PTE)
Belsomra	2029[2]	N/A	2031
Prevymis	2029[2] (with pending PTE)	2024 (patents), 2029[2] (SPCs)	2029 (with pending PTE)
Steglatro[11]	2031[2] (with pending PTE)	2029 (patents), 2034[2] (SPCs)	N/A
Steglujan[11]	2031 (with pending PTE)	2029 (patents), 2034 (SPCs)	N/A
Segluromet[11]	2031 (with pending PTE)	2029 (patents), 2034 (SPCs)	N/A
Delstrigo	2032 (with pending PTE)	2031[12]	N/A
Pifeltro	2032 (with pending PTE)	2031[12]	N/A

N/A: Currently no marketing approval.

Compound patent unless otherwise noted. Certain of the products listed may be the subject of patent litigation.

Note: See Item 8. “Financial Statements and Supplementary Data,” Note 11. “Contingencies and Environmental Liabilities” below.

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

(2) Eligible for 6 months Pediatric Exclusivity.

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

(4) Being commercialized in a U.S.-based joint partnership with Sanofi Pasteur.

(5) SPCs are granted in four Major EU Markets and pending in one, based on a patent that expired in 2016.

(6) The Company has no marketing rights in the U.S. and Japan.

(7) Includes Pediatric Exclusivity, which is granted in four Major EU Markets and pending in one.

(8) Being developed and commercialized in a global strategic oncology collaboration with Eisai.

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

(10) Being developed and commercialized in a global strategic oncology collaboration with AstraZeneca.

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

(12) SPC applications to be filed by May 2019.

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

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increase in the number of incentives for and use of generic products. Additionally, improvements in intellectual property laws are sought in the United States and other countries through reform of patent and other relevant laws and implementation of international treaties.

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

Under Review (in the U.S.)	Currently Anticipated Year of Expiration (in the U.S.)
V920 (ebola vaccine)	2023
MK-7655A (relebactam + imipenem/cilastatin)	2029

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

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

[1] Being developed in a worldwide clinical development collaboration with Bayer AG.

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

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

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

Royalty income in 2018 on patent and know-how licenses and other rights amounted to $135 million. Merck also incurred royalty expenses amounting to $1.3 billion in 2018 under patent and know-how licenses it holds.

Research and Development

The Company's business is characterized by the introduction of new products or new uses for existing products through a strong research and development program. At December 31, 2018, approximately 14,500 people were employed in the Company's research activities. The Company prioritizes its research and development efforts and focuses on candidates that it believes represent breakthrough science that will make a difference for patients and payers.

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

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component of its pipeline strategy, with a focus on supplementing its internal research with a licensing and external alliance strategy focused on the entire spectrum of collaborations from early research to late-stage compounds, as well as access to new technologies.

The Company also reviews its pipeline to examine candidates that may provide more value through out-licensing. The Company continues to evaluate certain late-stage clinical development and platform technology assets to determine their out-licensing or sale potential.

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

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

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

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

In the United States, the FDA review process begins once a complete NDA or BLA is submitted, received and accepted for review by the agency. Within 60 days after receipt, the FDA determines if the application is sufficiently complete to permit a substantive review. The FDA also assesses, at that time, whether the application will be granted a priority review or standard review. Pursuant to the Prescription Drug User Fee Act V (PDUFA), the FDA review period target for NDAs or original BLAs is either six months, for priority review, or ten months, for a standard review, from the time the application is deemed sufficiently complete. Once the review timelines are determined, the FDA will generally act upon the application within those timelines, unless a major amendment has been submitted (either at the Company's own initiative or the FDA's request) to the pending application. If this occurs, the FDA may extend the review period to allow for review of the new information, but by no more than three months. Extensions to

the review period are communicated to the Company. The FDA can act on an application either by issuing an approval letter or by issuing a Complete Response Letter (CRL) stating that the application will not be approved in its present form and describing all deficiencies that the FDA has identified. Should the Company wish to pursue an application after receiving

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a CRL, it can resubmit the application with information that addresses the questions or issues identified by the FDA in order to support approval. Resubmissions are subject to review period targets, which vary depending on the underlying submission type and the content of the resubmission.

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

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

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

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

Research and Development Update

The Company currently has several candidates under regulatory review in the United States and internationally. Keytruda is an approved anti-PD-1 therapy in clinical development for expanded indications in different cancer types. In February 2019, the FDA accepted and granted Priority Review for a supplemental BLA for Keytruda in combination with Inlyta (axitinib), a tyrosine kinase inhibitor, for the first-line treatment of patients with advanced renal cell carcinoma. This supplemental BLA is based on findings from the Phase 3 KEYNOTE-426 trial, which demonstrated that Keytruda in combination with axitinib, as compared to sunitinib, significantly improved overall survival (OS) and progression-free survival (PFS) in the first-line treatment of advanced renal cell carcinoma. These data were presented at the American Society for Clinical Oncology (ASCO) Genitourinary Cancers Symposium in

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February 2019. The supplemental BLA also included supporting data from the Phase 1b KEYNOTE-035 trial. The FDA set a PDUFA date of June 20, 2019. Merck has filed data from KEYNOTE-426 with regulatory authorities worldwide.

In February 2019, the Committee for Medicinal Products for Human Use of the EMA adopted a positive opinion recommending Keytruda, in combination with carboplatin and either paclitaxel or nab-paclitaxel, for the first-line treatment of metastatic squamous NSCLC in adults. This recommendation is based on results from the pivotal Phase 3 KEYNOTE-407 trial, which enrolled patients regardless of PD-L1 tumor expression status. The trial showed a significant improvement in OS and PFS for patients taking Keytruda in combination with chemotherapy (carboplatin and either paclitaxel or nab-paclitaxel) compared with chemotherapy alone. If approved, this would mark the first approval in Europe for an anti-PD-1 therapy in combination with chemotherapy for adults with metastatic squamous NSCLC. In October 2018, the FDA approved Keytruda in combination with carboplatin-paclitaxel or nab-paclitaxel as a first-line treatment for metastatic squamous NSCLC, regardless of PD-L1 expression.

In December 2018, the FDA extended the action date for the supplemental BLA seeking approval for Keytruda as monotherapy for the first-line treatment of locally advanced or metastatic NSCLC in patients whose tumors express PD-L1 (TPS ≥1%) without EGFR or ALK genomic tumor aberrations. The supplemental BLA is based on results of the Phase 3 KEYNOTE-042 trial where Keytruda monotherapy demonstrated a significant improvement in OS compared with chemotherapy in this patient population. The Company submitted additional data and analyses to the FDA, which constituted a major amendment and extended the PDUFA date by three months to April 11, 2019. Merck continues to work closely with the FDA during the review of this supplemental BLA.

In February 2019, the FDA accepted and granted Priority Review for a supplemental BLA for Keytruda as monotherapy for the treatment of patients with advanced small-cell lung cancer (SCLC) whose disease has progressed after two or more lines of prior therapy. This supplemental BLA, which is seeking accelerated approval for this new indication, is based on data from the SCLC cohorts of the Phase 2 KEYNOTE-158 and Phase 1b KEYNOTE-028 trials. The FDA set a PDUFA date of June 17, 2019. Keytruda is also being studied in combination with chemotherapy in the ongoing Phase 3 KEYNOTE-604 study in patients with newly diagnosed extensive stage SCLC.

In February 2019, the FDA accepted a supplemental BLA for Keytruda as monotherapy or in combination with platinum and 5-fluorouracil chemotherapy for the first-line treatment of patients with recurrent or metastatic HNSCC. This supplemental BLA is based in part on data from the pivotal Phase 3 KEYNOTE-048 trial where Keytruda demonstrated a significant improvement in OS compared with the standard of care, as monotherapy in patients whose tumors expressed PD-L1 with Combined Positive Score (CPS)≥20 and CPS≥1 and in combination with chemotherapy in the total patient population. These data were presented at the European Society for Medical Oncology (ESMO) 2018 Congress. The FDA granted Priority Review to the supplemental BLA and set a PDUFA date of June 10, 2019. KEYNOTE-048 also serves as the confirmatory trial for KEYNOTE-012, a Phase 1b study which supported the previous accelerated approval for Keytruda as monotherapy for the treatment of patients with recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy.

In November 2018, Merck announced that the Phase 3 KEYNOTE-181 trial investigating Keytruda as monotherapy in the second-line treatment of advanced or metastatic esophageal or esophagogastric junction carcinoma met a primary endpoint of OS in patients whose tumors expressed PD-L1 (CPS ≥10). In this pivotal study, treatment with Keytruda resulted in a statistically significant improvement in OS compared to chemotherapy (paclitaxel, docetaxel or irinotecan) in patients with CPS ≥10, regardless of histology. The primary endpoint of OS was also evaluated in patients with squamous cell histology and in the entire intention-to-treat study population. While directionally favorable, statistical significance for OS was not met in these two patient groups. Per the statistical analysis plan, the key secondary endpoints of PFS and objective response rate (ORR) were not formally tested, as OS was not reached in the full intention-to-treat study population. These results were presented in January 2019 at the ASCO Gastrointestinal Cancers Symposium and have been submitted for regulatory review.

Additionally, Keytruda has received Breakthrough Therapy designation from the FDA for the treatment of high-risk early-stage triple-negative breast cancer in combination with neoadjuvant chemotherapy. The FDA's Breakthrough Therapy designation is intended to expedite the development and review of a candidate that is planned for use, alone or in combination, to treat a serious or life-threatening disease or condition when preliminary clinical evidence

indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

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In October 2018, Merck announced the first presentation of results from an interim analysis of KEYNOTE-057, a Phase 2 trial evaluating Keytruda for previously treated patients with high-risk non-muscle invasive bladder cancer. An interim analysis of the study's primary endpoint showed a complete response rate of nearly 40% at three months with Keytruda in patients whose disease was unresponsive to Bacillus Calmette-Guérin therapy, the current standard of care for this disease, and who were ineligible for or who refused to undergo radical cystectomy. These results, as well as other study findings, were presented at the ESMO 2018 Congress.

In February 2019, Merck announced that the pivotal Phase 3 KEYNOTE-240 trial evaluating Keytruda, plus best supportive care, for the treatment of patients with advanced hepatocellular carcinoma who were previously treated with systemic therapy, did not meet its co-primary endpoints of OS and PFS compared with placebo plus best supportive care. In the final analysis of the study, there was an improvement in OS for patients treated with Keytruda compared to placebo, however these OS results did not meet statistical significance per the pre-specified statistical plan. Results for PFS were also directionally favorable in the Keytruda arm compared with placebo but did not reach statistical significance. The key secondary endpoint of ORR was not formally tested, since superiority was not reached for OS or PFS. Results will be presented at an upcoming medical meeting and have been shared with the FDA for discussion.

The Keytruda clinical development program consists of more than 900 clinical trials, including more than 600 trials that combine Keytruda with other cancer treatments. These studies encompass more than 30 cancer types including: bladder, cervical, colorectal, esophageal, gastric, head and neck, hepatocellular, Hodgkin lymphoma, non-Hodgkin lymphoma, melanoma, mesothelioma, nasopharyngeal, NSCLC, ovarian, PMBCL, prostate, renal, small-cell lung and triple-negative breast, many of which are currently in Phase 3 clinical development. Further trials are being planned for other cancers.

Lynparza, is an oral PARP inhibitor currently approved for certain types of ovarian and breast cancer. In July 2017, Merck and AstraZeneca entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza for multiple cancer types.

In April 2018, Merck and AstraZeneca announced that the EMA validated for review the MAA for Lynparza for use in patients with deleterious or suspected deleterious BRCA-mutated, HER2-negative metastatic breast cancer who have been previously treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. This was the first regulatory submission for a PARP inhibitor in breast cancer in Europe.

Lynparza tablets are also under review in the EU as a maintenance treatment in patients with newly-diagnosed, BRCA-mutated advanced ovarian cancer who were in complete or partial response following first-line standard platinum-based chemotherapy. This submission was based on positive results from the pivotal Phase 3 SOLO-1 trial. The trial showed a statistically-significant and clinically-meaningful improvement in PFS for Lynparza compared to placebo, reducing the risk of disease progression or death by 70% in patients with newly-diagnosed, BRCA-mutated advanced ovarian cancer who were in complete or partial response to platinum-based chemotherapy.

In December 2018, Merck and AstraZeneca announced positive results from the randomized, open-label, controlled, Phase 3 SOLO-3 trial of Lynparza tablets in patients with relapsed ovarian cancer after two or more lines of treatment. The trial was conducted as a post-approval commitment in agreement with the FDA. Results from the trial showed BRCA-mutated advanced ovarian cancer patients treated with Lynparza following two or more prior lines of chemotherapy demonstrated a statistically significant and clinically meaningful improvement in the primary endpoint of ORR and the key secondary endpoint of PFS compared to chemotherapy. Merck and AstraZeneca plan to discuss these results with the FDA.

MK-7655A is a combination of relebactam, an investigational beta-lactamase inhibitor, and imipenem/cilastatin (an approved carbapenem antibiotic). In February 2019, Merck announced that the FDA accepted for Priority Review an NDA for MK-7655A for the treatment of complicated urinary tract infections and complicated intra-abdominal infections caused by certain susceptible Gram-negative bacteria in adults with limited or no alternative therapies available. The PDUFA date is July 16, 2019. In April 2018, Merck announced that a pivotal Phase 3 study of MK-7655A demonstrated a favorable overall response in the treatment of certain imipenem-non-susceptible bacterial infections, the primary endpoint, with lower treatment-emergent nephrotoxicity (kidney toxicity), a secondary endpoint, compared to a colistin (colistimethate sodium) plus imipenem/cilastatin regimen. The FDA had previously

designated this combination a Qualified Infectious Disease Product with designated Fast Track status for the treatment of hospital-

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acquired bacterial pneumonia, ventilator-associated bacterial pneumonia, complicated intra-abdominal infections and complicated urinary tract infections.

V920 (rVSVΔG-ZEBOV-GP, live attenuated), is an investigational Ebola Zaire disease vaccine candidate being studied in large scale Phase 2/3 clinical trials. In December 2015, Merck announced that the application for Emergency Use Assessment and Listing (EUAL) for V920 was accepted for review by the World Health Organization (WHO). According to the WHO, the EUAL process is designed to expedite the availability of vaccines needed for public health emergencies such as another outbreak of Ebola. The WHO decision to grant V920 EUAL status will be based on data regarding quality, safety, and efficacy/effectiveness; as well as a risk/benefit analysis for emergency use. While EUAL designation allows for emergency use, the vaccine remains investigational and has not yet been licensed for commercial distribution. In July 2016, Merck announced that the FDA granted V920 Breakthrough Therapy designation, and that the EMA granted the vaccine candidate PRIME (PRIority MEdicines) status. In November 2018, Merck announced that it has started the submission of a rolling BLA to the FDA for V920. This rolling submission was made pursuant to the FDA's Breakthrough Therapy designation. Merck expects the rolling submission of the BLA to be completed in 2019. The Company also intends to file V920 with the EMA in 2019.

In February 2019, Merck announced that the FDA accepted for Priority Review a supplemental NDA for Zerbaxa to treat adult patients with nosocomial pneumonia, including ventilator-associated pneumonia, caused by certain susceptible Gram-negative microorganisms. The PDUFA date is June 3, 2019. Zerbaxa is also under review for this indication by the EMA. Zerbaxa is currently approved in the United States for the treatment of adult patients with complicated urinary tract infections caused by certain susceptible Gram-negative microorganisms, and is also indicated, in combination with metronidazole, for the treatment of adult patients with complicated intra-abdominal infections caused by certain susceptible Gram-negative and Gram-positive microorganisms.

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

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

Lenvima, is an orally available tyrosine kinase inhibitor currently approved for certain types of thyroid cancer, hepatocellular carcinoma, and in combination for certain patients with renal cell carcinoma. In March 2018, Merck and Eisai entered into a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima. Under the agreement, Merck and Eisai will develop and commercialize Lenvima jointly, both as monotherapy and in combination with Keytruda. Per the agreement, the companies will jointly initiate clinical studies evaluating the Keytruda/Lenvima combination to support 11 potential indications in six types of cancer (endometrial cancer, NSCLC, hepatocellular carcinoma, head and neck cancer, bladder cancer and melanoma), as well as a basket trial targeting multiple cancer types. The FDA granted Breakthrough Therapy designation for Keytruda in combination with Lenvima for the potential treatment of patients with advanced and/or metastatic renal cell carcinoma and for the potential treatment of certain patients with advanced and/or metastatic non-microsatellite instability high/proficient mismatch repair endometrial carcinoma.

MK-1242, vericiguat, is an investigational treatment for heart failure being studied in patients suffering from chronic heart failure with reduced ejection fracture (Phase 3 clinical trial) and from chronic heart failure with preserved ejection fracture (Phase 2 clinical trial). The development of vericiguat is part of a worldwide strategic collaboration between Merck and Bayer.

V114 is an investigational polyvalent conjugate vaccine for the prevention of pneumococcal disease. In June 2018, Merck initiated the first Phase 3 study in the adult population for the prevention of invasive pneumococcal disease. Currently five Phase 3 adult studies are ongoing, including studies in healthy adults 50 years of age or older, adults with risk factors for pneumococcal disease, those infected with HIV, and those who are recipients of allogeneic hematopoietic stem cell transplant. In October 2018, Merck began the first Phase 3 study in the pediatric population. Currently, three studies are ongoing, including studies in healthy infants and in children afflicted with sickle cell disease. In January 2019, Merck announced that V114 received Breakthrough Therapy designation from the FDA for the prevention of invasive pneumococcal disease caused by the vaccine serotypes in pediatric patients 6 weeks to 18

years of age.

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As a result of changes in the herpes zoster vaccine environment, Merck is ending development of V212, its investigational vaccine for the prevention of shingles in immunocompromised patients.

The chart below reflects the Company's research pipeline as of February 22, 2019. Candidates shown in Phase 3 include specific products and the date such candidate entered into Phase 3 development. Candidates shown in Phase 2 include the most advanced compound with a specific mechanism or, if listed compounds have the same mechanism, they are each currently intended for commercialization in a given therapeutic area. Small molecules and biologics are given MK-number designations and vaccine candidates are given V-number designations. Except as otherwise noted, candidates in Phase 1, additional indications in the same therapeutic area (other than with respect to cancer and certain other indications) and additional claims, line extensions or formulations for in-line products are not shown.

Phase 2

Cancer

MK-3475 Keytruda

Advanced Solid Tumors

Cutaneous Squamous Cell Carcinoma

Prostate

MK-7902 Lenvima[1]

Biliary Tract

Non-Small-Cell Lung

V937 Cavatak

Melanoma

MK-7690

Colorectal[2]

MK-7339 Lynparza[1]

Advanced Solid Tumors

Cytomegalovirus Vaccine

V160

Diabetes Mellitus

MK-8521[3]

HIV-1 Infection

MK-8591

Pediatric Neurofibromatosis Type-1

MK-5618 (selumetinib)[1]

Respiratory Syncytial Virus

MK-1654

Schizophrenia

MK-8189

Phase 3 (Phase 3 Entry Date)

Cancer

MK-3475 Keytruda

Breast (October 2015)

Cervical (October 2018) (EU)

Colorectal (November 2015)

Esophageal (December 2015)

Gastric (May 2015) (EU)

Hepatocellular (May 2016) (EU)

Mesothelioma (May 2018)

Nasopharyngeal (April 2016)

Ovarian (December 2018)

Renal (October 2016) (EU)

Small-Cell Lung (May 2017) (EU)

MK-7902 Lenvima[1,2]

Endometrial (June 2018)

MK-7339 Lynparza[1]

Pancreatic (December 2014)

Prostate (April 2017)

Cough

MK-7264 (gefapixant) (March 2018)

Heart Failure

MK-1242 (vericiguat) (September 2016)[1]

Pneumoconjugate Vaccine

V114 (June 2018)

Under Review

New Molecular Entities/Vaccines

Bacterial Infection

MK-7655A relebactam+imipenem/cilastatin (U.S.)

Ebola Vaccine

V920[4] (U.S.)

Certain Supplemental Filings

Cancer

MK-3475 Keytruda

- First-Line Advanced Renal Cell Carcinoma (KEYNOTE-426) (U.S.)
- First-Line Metastatic Squamous Non-Small-Cell Lung Cancer (KEYNOTE-407) (EU)
- First-Line Metastatic Non-Small-Cell Lung Cancer (KEYNOTE-042) (U.S.) (EU)
- Third-Line Advanced Small-Cell Lung Cancer (KEYNOTE-158) (U.S.)
- First-Line Head and Neck Cancer (KEYNOTE-048) (U.S.)
- Alternative Dosing Regimen (Q6W) (EU)

MK-7339 Lynparza[1]

- Second-Line Metastatic Breast Cancer (EU)
- First-Line Advanced Ovarian Cancer (EU)

HABP/VABP[5]

MK-7625A Zerbaxa (U.S.)

Footnotes:

(1) Being developed in a collaboration.

(2) Being developed in combination with

Keytruda.
(3) Development is currently on hold.
(4) Rolling submission.
(5) HABP - Hospital-Acquired Bacterial Pneumonia / VABP - Ventilator-Associated Bacterial Pneumonia

Employees

As of December 31, 2018, the Company had approximately 69,000 employees worldwide, with approximately 25,400 employed in the United States, including Puerto Rico. Approximately 30% of worldwide employees of the Company are represented by various collective bargaining groups.

Restructuring Activities

In 2010 and 2013, the Company commenced actions under global restructuring programs designed to streamline its cost structure. The actions under these programs include the elimination of positions in sales, administrative and headquarters organizations, as well as the sale or closure of certain manufacturing and research and

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development sites and the consolidation of office facilities. The Company also continues to reduce its global real estate footprint and improve the efficiency of its manufacturing and supply network. Since inception of the programs through December 31, 2018, Merck has eliminated approximately 45,510 positions comprised of employee separations, as well as the elimination of contractors and vacant positions. The Company has substantially completed the actions under these programs.

Environmental Matters

The Company believes that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on the Company. The Company is also remediating environmental contamination resulting from past industrial activity at certain of its sites. Expenditures for remediation and environmental liabilities were $16 million in 2018, and are estimated at $57 million in the aggregate for the years 2019 through 2023. These amounts do not consider potential recoveries from other parties. The Company has taken an active role in identifying and accruing for these costs and, in management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $71 million and $82 million at December 31, 2018 and 2017, respectively. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed $60 million in the aggregate. Management also does not believe that these expenditures should have a material adverse effect on the Company's financial position, results of operations, liquidity or capital resources for any year.

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

Geographic Area Information

The Company's operations outside the United States are conducted primarily through subsidiaries. Sales worldwide by subsidiaries outside the United States as a percentage of total Company sales were 57% of sales in 2018, 57% of sales in 2017 and 54% of sales in 2016.

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

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

Available Information

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

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

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Item 1A. Risk Factors.

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

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

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

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

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

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

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

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

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

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on the Company's business, cash flow, results of operations, financial position and prospects. For example, pursuant to an agreement with a generic manufacturer, that manufacturer launched in the United States a generic version of Zetia in December 2016. In addition, the Company lost U.S. patent protection for Vytorin in April 2017. As a result, the Company experienced a significant and rapid loss of sales of Zetia and Vytorin in the United States in 2017, which continued in 2018. Furthermore, the patents that provide U.S. and EU market exclusivity for Noxafil will expire in July 2019 and December 2019, respectively, and the Company anticipates a significant decline in U.S. and EU Noxafil sales thereafter.

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

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

For example, in 2018, sales of Zepatier were materially unfavorably affected by increasing competition and declining patient volumes. Sales of Zostavax were also materially unfavorably affected due to competition. The Company expects that competition will continue to adversely affect the sales of these products.

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

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

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

The Company cannot state with certainty when or whether any of its products now under development will be approved or launched; whether it will be able to develop, license or otherwise acquire compounds, product candidates or products; or whether any products, once launched, will be commercially successful. The Company must maintain a continuous flow of successful new products and successful new indications or brand extensions for existing products

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sufficient both to cover its substantial research and development costs and to replace sales that are lost as profitable products lose market exclusivity or are displaced by competing products or therapies. Failure to do so in the short term or long term would have a material adverse effect on the Company's business, results of operations, cash flow, financial position and prospects.

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

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

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

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

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

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

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

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

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

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

- results in post-approval Phase 4 trials or other studies;

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- the re-review of products that are already marketed;
- the recall or loss of marketing approval of products that are already marketed;
- changing government standards or public expectations regarding safety, efficacy or labeling changes; and
- greater scrutiny in advertising and promotion.

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

In addition, following in the wake of product withdrawals and other significant safety issues, health authorities such as the FDA, the EMA and Japan's Pharmaceutical and Medical Device Agency have increased their focus on safety when assessing the benefit/risk balance of drugs. Some health authorities appear to have become more cautious when making decisions about approvability of new products or indications and are re-reviewing select products that are already marketed, adding further to the uncertainties in the regulatory processes. There is also greater regulatory scrutiny, especially in the United States, on advertising and promotion and, in particular, direct-to-consumer advertising.

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

The Company faces intense competition from lower cost generic products.

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

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

The Company faces intense competition from competitors' products.

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

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

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

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

In order to provide information about the Company's pricing practices, the Company annually posts on its website its Pricing Transparency Report for the United States. The report provides the Company's average annual list price and net price increases across the Company's U.S. portfolio dating back to 2010.

Outside the United States, numerous major markets, including the EU, Japan and China have pervasive government involvement in funding health care and, in that regard, fix the pricing and reimbursement of pharmaceutical and vaccine products. Consequently, in those markets, the Company is subject to government decision making and budgetary actions with respect to its products.

The Company expects pricing pressures to continue in the future.

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

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

The law also requires pharmaceutical manufacturers to pay a 50% point of service discount to Medicare Part D beneficiaries when they are in the Medicare Part D coverage gap (i.e., the so-called "donut hole"). In 2018, the Company's revenue was reduced by $365 million due to this requirement. Beginning in 2019, the 50% point of service discount will increase to a 70% point of service discount in the coverage gap, as a result of the Balanced Budget Act of 2018. In addition, the 70% point of service discount will be extended to biosimilar products. Also, pharmaceutical manufacturers are now required to pay an annual non-tax deductible health care reform fee. The total annual industry fee was $4.1 billion in 2018 and will be $2.8 billion in 2019. The fee is assessed on each company in proportion to its share of prior year branded pharmaceutical sales to certain government programs, such as Medicare and Medicaid. In 2018, the Company recorded $124 million of costs for this annual fee.

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

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in the participation of the U.S. Territories in the Medicaid Drug Rebate Program until April 1, 2020. The Company will evaluate the financial impact of these two elements when they become effective.

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

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

The Company is increasingly dependent on sophisticated software applications and complex information technology systems and computing infrastructure (collectively, "IT systems") to conduct critical operations. Disruption, degradation, or manipulation of these IT systems through intentional or accidental means could impact key business processes. Cyber-attacks against the Company's IT systems could result in exposure of confidential information, the modification of critical data, and/or the failure of critical operations. Misuse of these IT systems could result in the disclosure of sensitive personal information or the theft of trade secrets, intellectual property, or other confidential business information. The Company continues to leverage new and innovative technologies across the enterprise to improve the efficacy and efficiency of its business processes; the use of which can create new risks.

In 2017, the Company experienced a network cyber-attack that led to a disruption of its worldwide operations, including manufacturing, research and sales operations. Due to the cyber-attack, the Company was unable to fulfill orders for certain products in certain markets, which had an unfavorable effect on sales in 2017 of approximately $260 million. In addition, the Company recorded manufacturing-related expenses, primarily unfavorable manufacturing variances, in Cost of sales, as well as expenses related to remediation efforts in Selling, general and administrative expenses and Research and development expenses, which aggregated $285 million in 2017, net of insurance recoveries of approximately $45 million. Due to a residual backlog of orders, 2018 sales were unfavorably affected in certain markets by approximately $150 million from the cyber-attack.

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

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

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

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

The Company is currently subject to a number of government laws and regulations and, in the future, could become subject to new government laws and regulations. The costs of compliance with such laws and regulations, or the negative results of non-compliance, could adversely affect the business, cash flow, results of operations, financial position and prospects of the Company; these laws and regulations include (i) additional healthcare reform initiatives in the United States or in other countries, including additional mandatory discounts or fees; (ii) the U.S. Foreign Corrupt Practices Act or other anti-bribery and corruption laws; (iii) new laws, regulations and judicial or other governmental

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decisions affecting pricing, drug reimbursement, and access or marketing within or across jurisdictions; (iv) changes in intellectual property laws; (v) changes in accounting standards; (vi) new and increasing data privacy regulations and enforcement, particularly in the EU and the United States; (vii) legislative mandates or preferences for local manufacturing of pharmaceutical or vaccine products; (viii) emerging and new global regulatory requirements for reporting payments and other value transfers to healthcare professionals; (ix) environmental regulations; and (x) the potential impact of importation restrictions, embargoes, trade sanctions and legislative and/or other regulatory changes.

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

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

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access. In the United States, pricing pressures continue on many of the Company's products and, in several international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. The Company anticipates these pricing actions will continue to negatively affect revenue performance in 2019.

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

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

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

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

In addition, there may be changes to the Company's business and political position if there is instability, disruption or destruction in a significant geographic region, regardless of cause, including war, terrorism, riot, civil insurrection or social unrest; and natural or man-made disasters, including famine, flood, fire, earthquake, storm or disease. For example, in 2017, the Company's lone manufacturing plant in Puerto Rico was negatively affected by Hurricane Maria.

In 2016, the United Kingdom (UK) held a referendum in which voters approved an exit from the EU, commonly referred to as "Brexit". As a result of that referendum, the British government has been in the process of negotiating the terms of the UK's future relationship with the EU. While the Company has taken actions and made certain contingency plans for scenarios in which the UK and the EU do not reach a mutually satisfactory understanding as to that relationship, it is not possible at this time to predict whether there will be any such understanding, or if such an understanding is reached, whether its terms will vary in ways that result in greater restrictions on imports and exports between the UK and EU countries, increased regulatory complexities, and/or cross border labor issues that could materially adversely impact the Company's business operations in the UK.

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

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

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

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

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

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

The Company's business in China has grown rapidly in the past few years, and the importance of China to the Company's overall pharmaceutical and vaccines business outside the United States has increased accordingly. Continued growth of the Company's business in China is dependent upon ongoing development of a favorable environment for innovative pharmaceutical products and vaccines, sustained access for the Company's currently marketed products, and the absence of trade impediments or adverse pricing controls. As noted above in Healthcare Environment, pricing pressure in China has increased as the Chinese government has been taking steps to reduce costs, including implementing healthcare reform that has led to the acceleration of generic substitution, where available. In addition, the Company anticipates that the reported inquiries made by various governmental authorities involving multinational pharmaceutical companies in China may continue.

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

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

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

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

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

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

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

Pharmaceutical products can develop unexpected safety or efficacy concerns.

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

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

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

Negative events in the animal health industry could have a negative impact on future results of operations.

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

Biologics and vaccines carry unique risks and uncertainties, which could have a negative impact on future results of operations.

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

- There may be limited access to, and supply of, normal and diseased tissue samples, cell lines, pathogens, bacteria, viral strains and other biological materials. In addition, government regulations in multiple

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jurisdictions, such as the United States and the EU, could result in restricted access to, or transport or use of, such materials. If the Company loses access to sufficient sources of such materials, or if tighter restrictions are imposed on the use of such materials, the Company may not be able to conduct research activities as planned and may incur additional development costs.

- The development, manufacturing and marketing of biologics and vaccines are subject to regulation by the FDA, the EMA and other regulatory bodies. These regulations are often more complex and extensive than the regulations applicable to other pharmaceutical products. For example, in the United States, a BLA, including both preclinical and clinical trial data and extensive data regarding the manufacturing procedures, is required for human vaccine candidates, and FDA approval is generally required for the release of each manufactured commercial lot.
- Manufacturing biologics and vaccines, especially in large quantities, is often complex and may require the use of innovative technologies to handle living micro-organisms. Each lot of an approved biologic and vaccine must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, the Company may be required to provide pre-clinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes.
- Biologics and vaccines are frequently costly to manufacture because production ingredients are derived from living animal or plant material, and most biologics and vaccines cannot be made synthetically. In particular, keeping up with the demand for vaccines may be difficult due to the complexity of producing vaccines.
- The use of biologically derived ingredients can lead to variability in the manufacturing process and could lead to allegations of harm, including infections or allergic reactions, which allegations would be reviewed through a standard investigation process that could lead to closure of product facilities due to possible contamination. Any of these events could result in substantial costs.

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

As a result of a number of factors, product liability insurance has become less available while the cost has increased significantly. The Company is subject to a substantial number of product liability claims. See Item 8. “Financial Statements and Supplementary Data,” Note 11. “Contingencies and Environmental Liabilities” below for more information on the Company’s current product liability litigation. With respect to product liability, the Company self-insures substantially all of its risk, as the availability of commercial insurance has become more restrictive. The Company has evaluated its risks and has determined that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and, as such, has no insurance for certain product liabilities effective August 1, 2004, including liability for legacy Merck products first sold after that date. The Company will continually assess the most efficient means to address its risk; however, there can be no guarantee that insurance coverage will be obtained or, if obtained, will be sufficient to fully cover product liabilities that may arise.

Social media platforms present risks and challenges.

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

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Cautionary Factors that May Affect Future Results
(Cautionary Statements Under the Private Securities Litigation Reform Act of 1995)

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

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

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

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

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

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

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

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

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

•Cyber-attacks on the Company's information technology systems, which could disrupt the Company's operations.

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

•Increased focus on privacy issues in countries around the world, including the United States and the EU. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been

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an increasing amount of focus on privacy and data protection issues with the potential to affect directly the Company's business, including recently enacted laws in a majority of states in the United States requiring security breach notification.

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

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

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

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

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

The Company's corporate headquarters is located in Kenilworth, New Jersey. The Company's U.S. commercial operations are headquartered in Upper Gwynedd, Pennsylvania. The Company's U.S. pharmaceutical business is conducted through divisional headquarters located in Upper Gwynedd, Pennsylvania and Kenilworth, New Jersey. The Company's vaccines business is conducted through divisional headquarters located in Upper Gwynedd, Pennsylvania. Merck's Animal Health headquarters is located in Madison, New Jersey. Principal U.S. research facilities are located in Rahway and Kenilworth, New Jersey, West Point, Pennsylvania, Palo Alto, California, Boston, Massachusetts, South San Francisco, California and Elkhorn, Nebraska (Animal Health). Principal research facilities outside the United States are located in Switzerland and China. Merck's manufacturing operations are headquartered in Whitehouse Station, New Jersey. The Company also has production facilities for human health products at nine locations in the United States and Puerto Rico. Outside the United States, through subsidiaries, the Company owns or has an interest in manufacturing plants or other properties in Japan, Singapore, South Africa, and other countries in Western Europe, Central and South America, and Asia.

Capital expenditures were $2.6 billion in 2018, $1.9 billion in 2017 and $1.6 billion in 2016. In the United States, these amounted to $1.5 billion in 2018, $1.2 billion in 2017 and $1.0 billion in 2016. Abroad, such expenditures amounted to $1.1 billion in 2018, $728 million in 2017 and $594 million in 2016.

The Company and its subsidiaries own their principal facilities and manufacturing plants under titles that they consider to be satisfactory. The Company believes that its properties are in good operating condition and that its machinery and equipment have been well maintained. Plants for the manufacture of products are suitable for their intended purposes and have capacities and projected capacities adequate for current and projected needs for existing Company products. Some capacity of the plants is being converted, with any needed modification, to the requirements of newly introduced and future products. In addition, in October 2018, the Company announced it plans to invest approximately $16 billion on new capital projects from 2018-2022. The focus of this investment will primarily be on increasing manufacturing capacity across Merck's key businesses.

Item 3. Legal Proceedings.

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

Item 4. Mine Safety Disclosures.

Not Applicable.

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Executive Officers of the Registrant (ages as of February 1, 2019)

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

Name	Age	Offices and Business Experience
Kenneth C. Frazier	64	Chairman, President and Chief Executive Officer (since December 2011)
Sanat Chattopadhyay	59	Executive Vice President and President, Merck Manufacturing Division (since March 2016); Senior Vice President, Operations, Merck Manufacturing Division (November 2009-March 2016)
Frank Clyburn	54	Executive Vice President, Chief Commercial Officer (since January 2019); President, Global Oncology Business Unit (October 2013-December 2018); President, Primary Care and Women's Health Business Line (September 2011-October 2013)
Robert M. Davis	52	Executive Vice President, Global Services, and Chief Financial Officer (since April 2016); Executive Vice President and Chief Financial Officer (April 2014-April 2016); Corporate Vice President and President, Medical Products, Baxter International, Inc. (October 2010-March 2014)
Richard R. DeLuca, Jr.	56	Executive Vice President and President, Merck Animal Health (since September 2011)
Julie L. Gerberding	62	Executive Vice President and Chief Patient Officer, Strategic Communications, Global Public Policy and Population Health (since July 2016); Executive Vice President for Strategic Communications, Global Public Policy and Population Health (January 2015-July 2016); President, Merck Vaccines (January 2010-January 2015)
Rita A. Karachun	55	Senior Vice President Finance - Global Controller (since March 2014); Assistant Controller (November 2009-March 2014)
Steven C. Mizell	58	Executive Vice President, Chief Human Resources Officer, Human Resources (since October 2018); Executive Vice President, Chief Human Resources Officer (December 2016-October 2018) and Executive Vice President, Human Resources, Monsanto Company (August 2011-December 2016)
Michael T. Nally	43	Executive Vice President, Chief Marketing Officer (since January 2019); President, Global Vaccines, Global Human Health (September 2016-January 2019); Managing Director, United Kingdom and Ireland, Global Human Health (January 2014-September 2016); Managing Director, Sweden, Global Human Health (November 2011-January 2014)
Roger M. Perlmutter, M.D., Ph.D.	66	Executive Vice President and President, Merck Research Laboratories (since April 2013)
Jim Scholefield	56	Executive Vice President, Chief Information and Digital Officer (since October 2018); Chief Information Officer, Nike, Inc (July 2015-October 2018); Chief Technology Officer, The Coca-Cola Company, (November 2010-June 2015)
Jennifer Zachary	41	Executive Vice President and General Counsel (since April 2018); Partner, Covington & Burling LLP (January 2013-March 2018)

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PART II

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

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

As of January 31, 2019, there were approximately 115,320 shareholders of record of the Company's Common Stock.

Issuer purchases of equity securities for the three months ended December 31, 2018 were as follows:

Issuer Purchases of Equity Securities

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	59,154,075	$70.56	$12,709[2]
November 1 — November 30	5,279,715	$74.64	$12,315
December 1 — December 31	4,788,526	$76.30	$11,949
Total	69,222,316	$71.27	$11,949

(1) All shares purchased during the period were made as part of a plan approved by the Board of Directors in November 2017 to purchase up to $10 billion in Merck shares. In October 2018, the Board of Directors authorized additional purchases of up to $10 billion of Merck's common stock for its treasury. Shares are approximated.

(2) Amount includes $1.0 billion being held back pending final settlement under the accelerated share repurchase agreements discussed below.

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Performance Graph

The following graph assumes a $100 investment on December 31, 2013, and reinvestment of all dividends, in each of the Company's Common Shares, the S&P 500 Index, and a composite peer group of major pharmaceutical companies, which are: AbbVie Inc., Amgen Inc., AstraZeneca plc, Bristol-Myers Squibb Company, Johnson & Johnson, Eli Lilly and Company, GlaxoSmithKline plc, Novartis AG, Pfizer Inc., Roche Holding AG, and Sanofi SA.

Comparison of Five-Year Cumulative Total Return*

Merck & Co., Inc., Composite Peer Group and S&P 500 Index

	End of Period Value	2018/2013 CAGR**
MERCK	$179	12%
PEER GRP.**	142	7%
S&P 500	150	8%

	2013	2014	2015	2016	2017	2018
MERCK	100.00	117.10	112.40	129.40	127.40	178.70
PEER GRP.	100.00	111.40	114.80	111.20	133.00	142.20
S&P 500	100.00	113.70	115.20	129.00	157.20	150.30

*Compound Annual Growth Rate

**Peer group average was calculated on a market cap weighted basis.

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

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Item 6. Selected Financial Data.

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

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

	2018 [1]	2017 [2][3]	2016 [2][4]	2015 [2][5]	2014 [2][6]
Results for Year:					
Sales	$42,294	$40,122	$39,807	$39,498	$42,237
Cost of sales	13,509	12,912	14,030	15,043	16,903
Selling, general and administrative	10,102	10,074	10,017	10,508	11,816
Research and development	9,752	10,339	10,261	6,796	7,290
Restructuring costs	632	776	651	619	1,013
Other (income) expense, net	(402)	(500)	189	1,131	(12,068)
Income before taxes	8,701	6,521	4,659	5,401	17,283
Taxes on income	2,508	4,103	718	942	5,349
Net income	6,193	2,418	3,941	4,459	11,934
Less: Net (loss) income attributable to noncontrolling interests	(27)	24	21	17	14
Net income attributable to Merck & Co., Inc.	6,220	2,394	3,920	4,442	11,920
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	$2.34	$0.88	$1.42	$1.58	$4.12
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	$2.32	$0.87	$1.41	$1.56	$4.07
Cash dividends declared	5,313	5,177	5,135	5,115	5,156
Cash dividends declared per common share	$1.99	$1.89	$1.85	$1.81	$1.77
Capital expenditures	2,615	1,888	1,614	1,283	1,317
Depreciation	1,416	1,455	1,611	1,593	2,471
Average common shares outstanding (millions)	2,664	2,730	2,766	2,816	2,894
Average common shares outstanding assuming dilution (millions)	2,679	2,748	2,787	2,841	2,928
Year-End Position:					
Working capital	$3,669	$6,152	$13,410	$10,550	$14,198
Property, plant and equipment, net	13,291	12,439	12,026	12,507	13,136
Total assets	82,637	87,872	95,377	101,677	98,096
Long-term debt	19,806	21,353	24,274	23,829	18,629
Total equity	26,882	34,569	40,308	44,767	48,791
Year-End Statistics:					
Number of stockholders of record	115,800	121,700	129,500	135,500	142,000
Number of employees	69,000	69,000	68,000	68,000	70,000

(1) Amounts for 2018 include a charge related to the formation of a collaboration with Eisai Co., Ltd.

(2) Amounts have been recast as a result of the adoption, on January 1, 2018, of a new accounting standard related to the classification of certain defined benefit plan costs. There was no impact to net income as a result of adopting the new accounting standard.

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

(4) Amounts for 2016 include a charge related to the settlement of worldwide patent litigation related to Keytruda.

(5) Amounts for 2015 include a net charge related to the settlement of Vioxx shareholder class action litigation, foreign exchange losses related to Venezuela, gains on the dispositions of businesses and other assets, and the

favorable benefit of certain tax items.

(6) Amounts for 2014 reflect the divestiture of Merck's Consumer Care business on October 1, 2014, including a gain on the sale, as well as a gain recognized on an option exercise by AstraZeneca, gains on the dispositions of other businesses and assets, and a loss on extinguishment of debt.

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

Description of Merck's Business

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

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. On December 31, 2016, Merck and Sanofi Pasteur S.A. (Sanofi) terminated their equally-owned joint venture, Sanofi Pasteur MSD (SPMSD), which developed and marketed vaccines in Europe. In 2017, Merck began recording vaccine sales and incurring costs as a result of operating its vaccines business in the European markets that were previously part of the SPMSD joint venture, which was accounted for as an equity method affiliate.

The Animal Health segment discovers, develops, manufactures and markets animal health products, including pharmaceutical and vaccine products, for the prevention, treatment and control of disease in all major livestock and companion animal species, which the Company sells to veterinarians, distributors and animal producers.

The Healthcare Services segment provides services and solutions that focus on engagement, health analytics and clinical services to improve the value of care delivered to patients.

The Alliances segment primarily includes activity from the Company's relationship with AstraZeneca LP related to sales of Nexium and Prilosec, which concluded in 2018 (see Note 9 to the consolidated financial statements).

Overview

The Company's performance during 2018 demonstrates execution of its innovation strategy, with revenue growth in oncology, vaccines, hospital acute care and animal health, focused investment in the research and development pipeline, and disciplined allocation of resources. Additionally, Merck completed several business development transactions, expanded its capital expenditures program primarily to increase future manufacturing capacity, and returned capital to shareholders.

Worldwide sales were $42.3 billion in 2018, an increase of 5% compared with 2017. Strong growth in the oncology franchise reflects the performance of Keytruda, as well as alliance revenue related to Lynparza and Lenvima resulting from Merck's business development activities. Also contributing to revenue growth were higher sales of vaccines, driven primarily by Gardasil/Gardasil 9, and growth in the hospital acute care franchise, largely attributable to Bridion and Noxafil. Higher sales of animal health products, reflecting increases in companion animal and livestock products both from in-line and recently launched products, also contributed to revenue growth. Growth in these areas was partially offset by competitive pressures on Zepatier and Zostavax, as well as the ongoing effects of generic and biosimilar competition that resulted in sales declines for products including Zetia, Vytorin, and Remicade.

Augmenting Merck's portfolio and pipeline with external innovation remains an important component of the Company's overall strategy. In 2018, Merck continued executing on this strategy by entering into a strategic collaboration with Eisai Co., Ltd. (Eisai) for the worldwide co-development and co-commercialization of Lenvima. Lenvima is an orally available tyrosine kinase inhibitor discovered by Eisai, which is approved for certain types of thyroid cancer, hepatocellular carcinoma, and in combination for certain patients with renal cell carcinoma. Under the agreement, Merck and Eisai will develop and commercialize Lenvima jointly, both as monotherapy and in combination with Keytruda. In addition, Merck acquired Viralytics Limited (Viralytics), a company focused on oncolytic immunotherapy treatments for a range of cancers. Also, the Company announced an agreement to acquire Antelliq Group (Antelliq), a leader in digital animal identification, traceability and monitoring solutions.

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During 2018, the Company advanced its leadership in oncology through focused commercial execution, the achievement of important regulatory milestones and the presentation of clinical data. Keytruda continues its global launch with multiple new indications across several tumor types, including approval from the U.S. Food and Drug Administration (FDA) for the treatment of certain patients with cervical cancer, primary mediastinal large B-cell lymphoma (PMBCL), a type of non-Hodgkin lymphoma, hepatocellular carcinoma, Merkel cell carcinoma, and in combination with chemotherapy for the treatment of certain patients with squamous non-small-cell lung cancer (NSCLC). Also during 2018, the European Commission (EC) approved Keytruda for the treatment of certain patients with head and neck squamous cell carcinoma (HNSCC), for the adjuvant treatment of melanoma, and in combination with chemotherapy for the first-line treatment of certain patients with nonsquamous NSCLC. This was the first approval in Europe for an anti-PD-1 therapy in combination with chemotherapy. Also in 2018, Keytruda was approved in China for the treatment of certain patients with melanoma. Additionally, Merck recently announced the receipt of five new approvals for Keytruda in Japan, including three expanded uses in advanced NSCLC, one in adjuvant melanoma, as well as a new indication in advanced microsatellite instability-high (MSI-H) tumors. Keytruda also continues to launch in many other international markets.

In 2018, Lynparza, which is being developed in a collaboration with AstraZeneca PLC (AstraZeneca), received FDA approval for use in certain patients with metastatic breast cancer who have been previously treated with chemotherapy, and for use as maintenance treatment of adult patients with certain types of advanced ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to chemotherapy. Additionally, Lenvima was approved in the United States, European Union (EU), Japan and China for the treatment of certain patients with hepatocellular carcinoma. The FDA and EC also approved two new HIV-1 medicines: Delstrigo, a once-daily fixed-dose combination tablet of doravirine, lamivudine and tenofovir disoproxil fumarate; and Pifeltro (doravirine), a new non-nucleoside reverse transcriptase inhibitor to be administered in combination with other antiretroviral medicines.

Merck continues to invest in its pipeline, with an emphasis on being a leader in immuno-oncology and expanding in other areas such as vaccines and hospital acute care. In addition to the recent regulatory approvals discussed above, the Company has continued to advance its late-stage pipeline with several regulatory submissions. Keytruda is under review in the United States in combination with axitinib, a tyrosine kinase inhibitor, for the first-line treatment of patients with advanced renal cell carcinoma for which it has been granted Priority Review by the FDA; in the EU for the first-line treatment of certain patients with metastatic squamous NSCLC; in the United States and in the EU as monotherapy for the first-line treatment of certain patients with locally advanced or metastatic NSCLC; in the United States as monotherapy for the treatment of certain patients with advanced small-cell lung cancer (SCLC); and in the United States as monotherapy or in combination with chemotherapy for the first-line treatment of certain patients with recurrent or metastatic HNSCC for which it has been granted Priority Review by the FDA. Additionally, MK-7655A, the combination of relebactam and imipenem/cilastatin, has been accepted for Priority Review by the FDA for the treatment of complicated urinary tract infections and complicated intra-abdominal infections caused by certain susceptible Gram-negative bacteria in adults with limited or no alternative therapies available. Merck has also started the submission of a rolling Biologics License Application (BLA) to the FDA for V920, an investigational Ebola Zaire disease vaccine candidate.

The Company’s Phase 3 oncology programs include Keytruda in the therapeutic areas of breast, cervical, colorectal, esophageal, gastric, hepatocellular, mesothelioma, nasopharyngeal, ovarian, renal and small-cell lung cancers; Lynparza for pancreatic and prostate cancer; and Lenvima in combination with Keytruda for endometrial cancer. Additionally, the Company has candidates in Phase 3 clinical development in several other therapeutic areas, including V114, an investigational polyvalent conjugate vaccine for the prevention of pneumococcal disease that received Breakthrough Therapy designation from the FDA for the prevention of invasive pneumococcal disease caused by the vaccine serotypes in pediatric patients 6 weeks to 18 years of age; MK-7264, gefapixant, a selective, non-narcotic, orally-administered P2X3-receptor agonist being developed for the treatment of refractory, chronic cough; and MK-1242, vericiguat, an investigational treatment for heart failure being developed in a collaboration (see “Research and Development” below).

The Company is allocating resources to effectively support its commercial opportunities in the near term while making the necessary investments to support long-term growth. Research and development expenses in 2018 reflect higher clinical development spending and investment in discovery and early drug development.

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In October 2018, Merck's Board of Directors approved a 15% increase to the Company's quarterly dividend, raising it to $0.55 per share from $0.48 per share on the Company's outstanding common stock. Also in October 2018, Merck's Board of Directors approved a $10 billion share repurchase program and the Company entered into $5 billion of accelerated share repurchase (ASR) agreements. During 2018, the Company returned $14.3 billion to shareholders through dividends and share repurchases.

Earnings per common share assuming dilution attributable to common shareholders (EPS) for 2018 were $2.32 compared with $0.87 in 2017. EPS in both years reflect the impact of acquisition and divestiture-related costs, as well as restructuring costs and certain other items. Certain other items in 2018 include a charge related to the formation of the collaboration with Eisai and in 2017 include a provisional net tax charge related to the enactment of U.S. tax legislation and a charge related to the formation of a collaboration with AstraZeneca. Non-GAAP EPS, which exclude these items, were $4.34 in 2018 and $3.98 in 2017 (see "Non-GAAP Income and Non-GAAP EPS" below).

Pricing

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. In the United States, pricing pressure continues on many of the Company's products. Changes to the U.S. health care system as part of health care reform, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, have contributed to pricing pressure. In several international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. In addition, the Company's revenue performance in 2018 was negatively affected by other cost-reduction measures taken by governments and other third-parties to lower health care costs. The Company anticipates all of these actions will continue to negatively affect revenue performance in 2019.

Cyber-attack

On June 27, 2017, the Company experienced a network cyber-attack that led to a disruption of its worldwide operations, including manufacturing, research and sales operations. Due to a backlog of orders for certain products as a result of the cyber-attack, the Company was unable to fulfill orders for certain products in certain markets, which had an unfavorable effect on sales in 2018 and 2017 of approximately $150 million and $260 million, respectively. In addition, the Company recorded manufacturing-related expenses, primarily unfavorable manufacturing variances, in Cost of sales, as well as expenses related to remediation efforts in Selling, general and administrative expenses and Research and development expenses, which aggregated approximately $285 million in 2017, net of insurance recoveries of approximately $45 million. Costs in 2018 were immaterial.

As referenced above, the Company has insurance coverage insuring against costs resulting from cyber-attacks and has received insurance proceeds. However, there are disputes with certain of the insurers about the availability of some of the insurance coverage for claims related to this incident.

Operating Results

Sales

Worldwide sales were $42.3 billion in 2018, an increase of 5% compared with 2017. Sales growth was driven primarily by higher sales in the oncology franchise reflecting strong growth of Keytruda, as well as alliance revenue related to Lynparza and Lenvima. Also contributing to revenue growth were higher sales of vaccines, driven primarily by human papillomavirus (HPV) vaccine Gardasil/Gardasil 9, as well as higher sales in the hospital acute care franchise, largely attributable to Bridion and Noxafil. Higher sales of animal health products also drove revenue growth in 2018.

Sales growth in 2018 was partially offset by declines in the virology franchise driven primarily by lower sales of hepatitis C virus (HCV) treatment Zepatier, as well as lower sales of shingles (herpes zoster) vaccine Zostavax. The ongoing effects of generic and biosimilar competition for cardiovascular products Zetia and Vytorin, and immunology product Remicade, as well as lower sales of products within the diversified brands franchise also partially offset revenue growth in 2018. The diversified brands franchise includes certain products that are approaching the expiration of their marketing exclusivity or that are no longer protected by patents in developed markets.

Sales in the United States were $18.2 billion in 2018, growth of 5% compared with 2017. The increase was driven primarily by higher sales of Keytruda, Gardasil/Gardasil 9, NuvaRing, and Bridion, as well as alliance revenue

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from Lynparza and Lenvima, and higher sales of animal health products. Growth was partially offset by lower sales of Zepatier, Zetia, Vytorin, Zostavax, Januvia, Janumet, Invanz, and products within the diversified brands franchise.
International sales were $24.1 billion in 2018, an increase of 6% compared with 2017. The increase primarily reflects growth in Keytruda, Gardasil/Gardasil 9, Januvia, Janumet and Atozet, as well as higher sales of animal health products. Sales growth was partially offset by lower sales of Zepatier, Remicade, Zetia, Vytorin, and products within the diversified brands franchise. International sales represented 57% of total sales in both 2018 and 2017.
Worldwide sales were $40.1 billion in 2017, an increase of 1% compared with 2016. Sales growth in 2017 was driven primarily by higher sales of Keytruda, Zepatier and Bridion. Additionally, sales in 2017 benefited from the December 31, 2016 termination of SPMSD, which marketed vaccines in most major European markets. In 2017, Merck began recording vaccine sales in the markets that were previously part of the SPMSD joint venture resulting in incremental vaccine sales of approximately $400 million during 2017. Higher sales of Pneumovax 23, Adempas, and animal health products also contributed to revenue growth in 2017. These increases were largely offset by the effects of generic competition for certain products including Zetia, which lost U.S. market exclusivity in December 2016, Vytorin, which lost U.S. market exclusivity in April 2017, Cubicin due to U.S. patent expiration in June 2016, and Cancidas, which lost EU patent protection in April 2017. Revenue growth was also offset by continued biosimilar competition for Remicade and ongoing generic erosion for products including Singulair and Nasonex. Collectively, the sales decline attributable to the above products affected by generic and biosimilar competition was $3.3 billion in 2017.
Lower sales of other products within the diversified brands franchise, as well as lower combined sales of the diabetes franchise of Januvia and Janumet, and declines in sales of Isentress/Isentress HD also partially offset revenue growth.
Additionally, sales in 2017 were reduced by $125 million due to a borrowing the Company made from the U.S. Centers for Disease Control and Prevention (CDC) Pediatric Vaccine Stockpile of doses of Gardasil 9 as discussed below. Also, the Company was unable to fulfill orders for certain products in certain markets due to the cyber-attack, which had an unfavorable effect on sales in 2017 of approximately $260 million.
See Note 19 to the consolidated financial statements for details on sales of the Company’s products.

Pharmaceutical Segment

Oncology

Keytruda is approved in the United States and in the EU as monotherapy for the treatment of certain patients with NSCLC, melanoma, classical Hodgkin lymphoma (cHL), HNSCC and urothelial carcinoma, a type of bladder cancer, and in combination with chemotherapy for certain patients with nonsquamous NSCLC. Keytruda is also approved in the United States as monotherapy for the treatment of certain patients with gastric or gastroesophageal junction adenocarcinoma and MSI-H or mismatch repair deficient cancer. In addition, the FDA recently approved Keytruda for the treatment of certain patients with cervical cancer, PMBCL, hepatocellular carcinoma, Merkel cell carcinoma, and in combination with chemotherapy for patients with squamous NSCLC (see below). Keytruda is approved in Japan for the treatment of certain patients with NSCLC, both as monotherapy and in combination with chemotherapy, melanoma, cHL, MSI-H tumors, and urothelial carcinoma. Additionally, Keytruda has been approved in China for the treatment of certain patients with melanoma. Keytruda is also approved in many other international markets. The Keytruda clinical development program includes studies across a broad range of cancer types (see “Research and Development” below).
In August 2018, the FDA approved an expanded label for Keytruda in combination with pemetrexed and platinum chemotherapy for the first-line treatment of patients with metastatic nonsquamous NSCLC, with no EGFR or ALK genomic tumor aberrations, based on results of the KEYNOTE-189 trial. Keytruda in combination with pemetrexed and carboplatin was first approved in 2017 under the FDA’s accelerated approval process for the first-line treatment of patients with metastatic nonsquamous NSCLC, based on tumor response rates and progression-free survival (PFS) data from a Phase 2 study (KEYNOTE-021, Cohort G1). In accordance with the accelerated approval process, continued approval was contingent upon verification and description of clinical benefit, which was demonstrated in KEYNOTE-189 and resulted in the FDA converting the accelerated approval to full (regular) approval. Also, in September 2018, the EC approved Keytruda in combination with pemetrexed and platinum chemotherapy for the first-line treatment of metastatic nonsquamous NSCLC in adults whose tumors have no EGFR or ALK positive mutations.

In June 2018, the FDA approved Keytruda for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 as determined by an FDA-

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approved test. Also in June 2018, the FDA approved Keytruda for the treatment of adult and pediatric patients with refractory PMBCL, or who have relapsed after two or more prior lines of therapy.

In September 2018, the EC approved Keytruda as monotherapy for the treatment of recurrent or metastatic HNSCC in adults whose tumors express PD-L1 with a tumor proportion score (TPS) of ≥50%, and who progressed on or after platinum-containing chemotherapy, based on data from the Phase 3 KEYNOTE-040 trial.

In October 2018, the FDA approved Keytruda, in combination with carboplatin and either paclitaxel or nab-paclitaxel, for the first-line treatment of patients with metastatic squamous NSCLC based on results from the KEYNOTE-407 trial. This approval marks the first time an anti-PD-1 regimen has been approved for the first-line treatment of squamous NSCLC regardless of tumor PD-L1 expression status.

In November 2018, the FDA approved Keytruda for the treatment of patients with hepatocellular carcinoma who have been previously treated with sorafenib based on data from the KEYNOTE-224 trial.

In December 2018, the FDA approved Keytruda for the treatment of adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma, based on the results of the Cancer Immunotherapy Trials Network's CITN-09/KEYNOTE-017 trial.

Also in December 2018, the EC approved Keytruda for the adjuvant treatment of adults with stage III melanoma and lymph node involvement who have undergone complete resection. Keytruda was approved for this indication by the FDA in February 2019. These approvals were based on data from the pivotal Phase 3 EORTC1325/KEYNOTE-054 trial, conducted in collaboration with the European Organisation for Research and Treatment of Cancer.

Global sales of Keytruda were $7.2 billion in 2018, $3.8 billion in 2017 and $1.4 billion in 2016. The year-over-year increases were driven by volume growth as the Company continues to launch Keytruda with multiple new indications globally. Sales in the United States continue to build across the multiple approved indications, in particular for the treatment of NSCLC reflecting both the continued adoption of Keytruda in the first-line setting as monotherapy for patients with metastatic NSCLC whose tumors have high PD-L1 expression, as well as the uptake of Keytruda in combination with pemetrexed and carboplatin, a commonly used chemotherapy regimen, for the first-line treatment of metastatic nonsquamous NSCLC with or without PD-L1 expression. Other indications contributing to sales growth include HNSCC, bladder, and melanoma. Recently approved indications, including squamous NSCLC and MSI-H cancer, also contributed to growth in 2018. Sales growth in international markets reflects continued uptake for the treatment of NSCLC as the Company has secured reimbursement in most major markets. Sales growth in international markets in 2018 also includes contributions from the more recently approved indications as described above, including for the treatment of HNSCC, bladder cancer and in combination with chemotherapy for the treatment of NSCLC in the EU, multiple new indications in Japan, and for the treatment of melanoma in China.

In January 2017, Merck entered into a settlement and license agreement to resolve worldwide patent infringement litigation related to Keytruda. Pursuant to the settlement, the Company will pay royalties of 6.5% on net sales of Keytruda in 2017 through 2023; and 2.5% on net sales of Keytruda in 2024 through 2026.

Global sales of Emend, for the prevention of chemotherapy-induced and post-operative nausea and vomiting, were $522 million in 2018, a decline of 6% compared with 2017 including a 1% favorable effect from foreign exchange. The decline primarily reflects lower demand in the United States due to competition. Worldwide sales of Emend were $556 million in 2017, an increase of 1% compared with 2016. The patent that provided U.S. market exclusivity for Emend expired in 2015 and the patent that provides market exclusivity in most major European markets will expire in May 2019. The patent that provides U.S. market exclusivity for Emend for Injection expires in September 2019 and the patent that provides market exclusivity in major European markets expires in February 2020 (although six-month pediatric exclusivity may extend this date). The Company anticipates that sales of Emend in these markets will decline significantly after these patent expiries.

Lynparza, an oral poly (ADP-ribose) polymerase (PARP) inhibitor being developed as part of a collaboration with AstraZeneca entered into in July 2017 (see Note 4 to the consolidated financial statements), is currently approved for certain types of ovarian and breast cancer. Merck recorded alliance revenue of $187 million in 2018 and $20 million in 2017 related to Lynparza. The revenue increase reflects the approval of new indications, as well as a full year of activity in 2018. In January 2018, the FDA approved Lynparza for use in patients with BRCA-mutated, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have been previously treated with

chemotherapy,

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triggering a $70 million capitalized milestone payment from Merck to AstraZeneca. Lynparza was also approved in Japan in July 2018 for use in patients with unresectable or recurrent BRCA-mutated, HER2-negative breast cancer who have received prior chemotherapy. Additionally, Lynparza was approved for use as a maintenance therapy in patients with platinum-sensitive relapsed ovarian cancer, regardless of BRCA mutation status in Japan in January 2018 and in the EU in May 2018. In December 2018, the FDA approved Lynparza for use as maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy based on the results of the SOLO-1 clinical trial, triggering a $70 million capitalized milestone payment from Merck to AstraZeneca.

Lenvima, an oral receptor tyrosine kinase inhibitor being developed as part of a collaboration with Eisai entered into in March 2018 (see Note 4 to the consolidated financial statements), is approved for certain types of thyroid cancer, hepatocellular carcinoma, and in combination for certain patients with renal cell carcinoma. Merck recorded alliance revenue of $149 million in 2018 related to Lenvima. In 2018, Lenvima was approved for the treatment of certain patients with hepatocellular carcinoma in the United States, the EU, Japan and China, triggering capitalized milestone payments of $250 million in the aggregate from Merck to Eisai.

Vaccines

On December 31, 2016, Merck and Sanofi terminated their equally-owned joint venture, SPMSD, which developed and marketed vaccines in Europe. Accordingly, vaccine sales in 2018 and 2017 include sales of Merck vaccines in the European markets that were previously part of the SPMSD joint venture, whereas sales in periods prior to 2017 do not. Prior to 2017, vaccine sales in these European markets were sold through the SPMSD joint venture, the results of which were reflected in equity income from affiliates included in Other (income) expense, net. Supply sales to SPMSD, however, are included in vaccine sales in periods prior to 2017. Incremental vaccine sales resulting from the termination of the SPMSD joint venture were approximately $400 million in 2017, of which approximately $215 million relate to Gardasil/Gardasil 9.

Worldwide sales of Gardasil/Gardasil 9, vaccines to help prevent certain cancers and other diseases caused by certain types of HPV, were $3.2 billion in 2018, growth of 37% compared with 2017 including a 1% favorable effect from foreign exchange. Sales growth was driven primarily by higher sales in the Asia Pacific region, particularly in China reflecting continued uptake since launch, as well as higher demand in certain European markets. The sales increase was also attributable to the replenishment in 2018 of doses borrowed from the CDC Pediatric Vaccine Stockpile in 2017 as discussed below. In April 2018, China’s Food and Drug Administration approved Gardasil 9 for use in girls and women ages 16 to 26. In October 2018, the FDA approved an expanded age indication for use in women and men ages 27 to 45 for the prevention of certain cancers and diseases caused by the nine HPV types covered by the vaccine.

During 2017, the Company made a request to borrow doses of Gardasil 9 from the CDC Pediatric Vaccine Stockpile, which the CDC granted. The Company’s decision to borrow the doses from the CDC was driven in part by the temporary shutdown resulting from the cyber-attack that occurred in June 2017, as well as by overall higher demand than expected. As a result of the borrowing, the Company reversed the sales related to the borrowed doses and recognized a corresponding liability. The Company subsequently replenished a portion of the doses borrowed from the stockpile. The net effect of the borrowing and subsequent partial replenishment was a reduction in sales of $125 million in 2017. The Company replenished the remaining borrowed doses in 2018 resulting in the recognition of sales of $125 million in 2018 and a reversal of the related liability.

Global sales of Gardasil/Gardasil 9 were $2.3 billion in 2017, growth of 6% compared with 2016. Sales growth was driven primarily by higher sales in Europe resulting from the termination of the SPMSD joint venture noted above, as well as higher demand in the Asia Pacific region due in part to the launch in China, partially offset by lower sales in the United States. Lower sales in the United States reflect the timing of public sector purchases and the CDC stockpile borrowing as described above.

The Company is a party to certain third-party license agreements with respect to Gardasil/Gardasil 9 pursuant to which the Company pays royalties on worldwide Gardasil/Gardasil 9 sales. The royalties, which vary by country and range from 7% to 13%, are included in Cost of sales.

Global sales of ProQuad, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, were $593 million in 2018, an increase of 12% compared with 2017, driven primarily by higher volumes

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and pricing in the United States and volume growth in certain European markets. Worldwide sales of ProQuad were $528 million in 2017, an increase of 7% compared with $495 million in 2016. Sales growth in 2017 was driven primarily by higher pricing and volumes in the United States, as well as volume growth in international markets, particularly in Europe. Foreign exchange favorably affected global sales performance by 1% in 2017.

Worldwide sales of M-M-R II, a vaccine to help protect against measles, mumps and rubella, were $430 million in 2018, an increase of 13% compared with 2017, driven primarily by volume growth in Latin America. Global sales of M-M-R II were $382 million in 2017, an increase of 8% compared with $353 million in 2016. Sales growth in 2017 was largely attributable to higher sales in Europe resulting from the termination of the SPMSD joint venture. Foreign exchange favorably affected global sales performance by 1% in 2018 and unfavorably affected global sales performance by 1% in 2017.

Global sales of Varivax, a vaccine to help prevent chickenpox (varicella), were $774 million in 2018, an increase of 1% compared with 2017, reflecting volume growth in Latin America and the Asia Pacific region, along with higher pricing in the United States, largely offset by volume declines in Turkey from the loss of a government tender due to competition. Worldwide sales of Varivax were $767 million in 2017, a decline of 3% compared with $792 million in 2016. The sales decline in 2017 was driven primarily by lower volumes in Brazil due to the loss of a government tender, as well as lower sales in the United States reflecting lower demand that was partially offset by higher pricing. Higher sales in Europe resulting from the termination of the SPMSD joint venture partially offset the sales decline in 2017.

Worldwide sales of Pneumovax 23, a vaccine to help prevent pneumococcal disease, were $907 million in 2018, an increase of 10% compared with 2017. Sales growth was driven primarily by higher pricing in the United States and volume growth in Europe. Global sales of Pneumovax 23 were $821 million in 2017, an increase of 28% compared with 2016, driven primarily by higher demand and pricing in the United States, as well as higher sales in Europe resulting from the termination of the SPMSD joint venture. Foreign exchange unfavorably affected sales performance by 1% in 2017.

Global sales of RotaTeq, a vaccine to help protect against rotavirus gastroenteritis in infants and children, were $728 million in 2018, an increase of 6% compared with 2017, driven primarily by the launch in China. Worldwide sales of RotaTeq were $686 million in 2017, an increase of 5% compared with 2016, driven primarily by higher sales in Europe resulting from the termination of the SPMSD joint venture.

Worldwide sales of Zostavax, a vaccine to help prevent shingles (herpes zoster) in adults 50 years of age and older, were $217 million in 2018, a decline of 68% compared with 2017, driven by lower volumes in most markets, particularly in the United States. Lower demand in the United States reflects the launch of a competing vaccine that received a preferential recommendation from the CDC’s Advisory Committee on Immunization Practices in October 2017 for the prevention of shingles over Zostavax. The declines were partially offset by higher demand in certain European markets. The Company anticipates competition will continue to have an adverse effect on sales of Zostavax in future periods. Global sales of Zostavax were $668 million in 2017, a decline of 2% compared with 2016 including a 1% favorable effect from foreign exchange. The sales decline was driven primarily by lower demand in the United States reflecting the approval of a competing vaccine as noted above, partially offset by growth in Europe resulting from the termination of the SPMSD joint venture and volume growth in the Asia Pacific region.

In 2018, the FDA approved Vaxelis (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus, Haemophilus b Conjugate [Meningococcal Protein Conjugate] and Hepatitis B [Recombinant] Vaccine) for use in children from 6 weeks through 4 years of age (prior to the 5th birthday). Vaxelis, which is currently being marketed in Europe, was developed as part of a joint-partnership between Merck and Sanofi. Merck and Sanofi are working to maximize production of Vaxelis to allow for a sustainable supply to meet anticipated U.S. demand. Commercial supply will not be available prior to 2020.

Hospital Acute Care

Global sales of Bridion, for the reversal of two types of neuromuscular blocking agents used during surgery, were $917 million in 2018, growth of 30% compared with 2017, driven primarily by volume growth in the United States and certain European markets. Worldwide sales of Bridion were $704 million in 2017, growth of 46% compared with 2016, driven by strong global demand, particularly in the United States.

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Worldwide sales of Noxafil, for the prevention of invasive fungal infections, were $742 million in 2018, an increase of 17% compared with 2017 including a 2% favorable effect from foreign exchange. Sales growth primarily reflects higher demand in the United States, certain European markets and China. Global sales of Noxafil were $636 million in 2017, an increase of 7% compared with 2016, primarily reflecting higher demand and pricing in the United States, as well as volume growth in Europe. The patent that provides U.S. market exclusivity for Noxafil expires in July 2019. Additionally, the patent for Noxafil will expire in a number of major European markets in December 2019. The Company anticipates sales of Noxafil in these markets will decline significantly thereafter.

Global sales of Invanz, for the treatment of certain infections, were $496 million in 2018, a decline of 18% compared with 2017 including a 1% unfavorable effect from foreign exchange. The sales decline was driven by lower volumes in the United States. The patent that provided U.S. market exclusivity for Invanz expired in November 2017 and generic competition began in the second half of 2018. The Company is experiencing a significant decline in U.S. Invanz sales as a result of this generic competition and expects the decline to continue. Worldwide sales of Invanz were $602 million in 2017, an increase of 7% compared with 2016, driven primarily by higher sales in the United States, reflecting higher pricing that was partially offset by lower demand, as well as higher demand in Brazil.

Global sales of Cubicin, an I.V. antibiotic for complicated skin and skin structure infections or bacteremia when caused by designated susceptible organisms, were $367 million in 2018, a decline of 4% compared with 2017 including a 1% favorable effect from foreign exchange. Worldwide sales of Cubicin were $382 million in 2017, a decline of 65% compared with 2016, resulting from generic competition in the United States following expiration of the U.S. composition patent for Cubicin in June 2016.

Global sales of Cancidas, an anti-fungal product sold primarily outside of the United States, were $326 million in 2018, a decline of 23% compared with 2017, and were $422 million in 2017, a decline of 24% compared with 2016. Foreign exchange favorably affected global sales performance by 2% in 2018. The sales declines were driven primarily by generic competition in certain European markets. The EU compound patent for Cancidas expired in April 2017. Accordingly, the Company is experiencing a significant decline in Cancidas sales in these European markets and expects the decline to continue.

Immunology

Sales of Simponi, a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were $893 million in 2018, growth of 9% compared with 2017 including a 4% favorable effect from foreign exchange. Sales of Simponi were $819 million in 2017, growth of 7% compared with 2016 including a 1% favorable effect from foreign exchange. Sales growth in both years was driven by higher demand in Europe. The Company anticipates sales of Simponi will be unfavorably affected in future periods by the recent launch of biosimilars for a competing product.

Sales of Remicade, a treatment for inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were $582 million in 2018, a decline of 31% compared with 2017, and were $837 million in 2017, a decline of 34% compared with 2016. Foreign exchange favorably affected sales performance by 2% in 2018. The Company lost market exclusivity for Remicade in major European markets in 2015 and no longer has market exclusivity in any of its marketing territories. The Company is experiencing pricing and volume declines in these markets as a result of biosimilar competition and expects the declines to continue.

Virology

Worldwide sales of Isentress/Isentress HD, an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, were $1.1 billion in 2018, a decline of 5% compared with 2017, and were $1.2 billion in 2017, a decline of 13% compared with 2016. Foreign exchange favorably affected global sales performance by 1% in 2017. The sales declines primarily reflect competitive pressure in the United States and Europe. In August 2018, the FDA approved two new HIV-1 medicines: Delstrigo, a once-daily fixed-dose combination tablet of doravirine, lamivudine and tenofovir disoproxil fumarate; and Pifeltro (doravirine), a new non-nucleoside reverse transcriptase inhibitor to be administered in combination with other antiretroviral medicines. Both Delstrigo and Pifeltro are indicated for the treatment of HIV-1 infection in adult patients with no prior antiretroviral treatment experience. Delstrigo and Pifeltro were also approved by the EC in November 2018. In January 2019, the FDA accepted for review supplemental New Drug Applications (NDA) for Pifeltro and Delstrigo seeking approval for

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use in patients living with HIV-1 who are switching from a stable antiretroviral regimen and whose virus is suppressed. The Prescription Drug User Fee Act (PDUFA) date for the supplemental NDAs is September 20, 2019. Global sales of Zepatier, a treatment for adult patients with certain types of chronic hepatitis C virus (HCV) infection, were $455 million in 2018, a decline of 73% compared with 2017. The sales decline was driven primarily by the unfavorable effects of increasing competition and declining patient volumes, particularly in the United States, Europe and Japan. The Company anticipates that sales of Zepatier in the future will continue to be adversely affected by competition and lower patient volumes. Worldwide sales of Zepatier were $1.7 billion in 2017 compared with $555 million in 2016. Sales growth in 2017 was driven primarily by higher sales in Europe, the United States and Japan following product launch in 2016.

Cardiovascular

Combined global sales of Zetia (marketed in most countries outside the United States as Ezetrol), Vytorin (marketed outside the United States as Inegy), as well as Atozet and Rosuzet (both marketed in certain countries outside of the United States), medicines for lowering LDL cholesterol, were $1.8 billion in 2018, a decline of 26% compared with 2017 including a 3% favorable effect from foreign exchange. The sales decline was driven primarily by lower demand in the United States and Europe. Zetia and Vytorin lost market exclusivity in the United States in December 2016 and April 2017, respectively. Accordingly, the Company experienced a rapid and substantial decline in U.S. Zetia and Vytorin sales as a result of generic competition and has lost nearly all U.S. sales of these products. In addition, the Company lost market exclusivity in major European markets for Ezetrol in April 2018 and has also lost market exclusivity in certain European markets for Inegy (see Note 11 to the consolidated financial statements). Accordingly, the Company is experiencing significant sales declines in these markets as a result of generic competition and expects the declines to continue. These declines were partially offset by higher sales in Japan due in part to the launch of Atozet. Combined worldwide sales of the ezetimibe family were $2.4 billion in 2017, a decline of 39% compared with 2016. The sales decline was driven by lower volumes and pricing of Zetia and Vytorin in the United States as a result of generic competition due to the loss of U.S. market exclusivity as described above.

Pursuant to a collaboration with Bayer AG (Bayer) (see Note 4 to the consolidated financial statements), Merck has lead commercial rights for Adempas, a cardiovascular drug for the treatment of pulmonary arterial hypertension, in countries outside the Americas while Bayer has lead rights in the Americas, including the United States. The companies share profits equally under the collaboration. In 2016, Merck began promoting and distributing Adempas in Europe. Transition from Bayer in other Merck territories, including Japan, continued in 2017. Revenue from Adempas includes sales in Merck’s marketing territories, as well as Merck’s share of profits from the sale of Adempas in Bayer’s marketing territories. Merck recorded revenue related to Adempas of $329 million in 2018, an increase of 10% compared with 2017, reflecting higher sales in Merck’s marketing territories, partially offset by lower profit sharing from Bayer due in part to lower pricing in the United States. Revenue related to Adempas was $300 million in 2017, an increase of 78% compared with 2016, reflecting both higher sales in Merck’s marketing territories, as well as the recognition of higher profit sharing from Bayer. Foreign exchange favorably affected global sales performance by 3% in 2018 and by 1% in 2017.

Diabetes

Worldwide combined sales of Januvia and Janumet, medicines that help lower blood sugar levels in adults with type 2 diabetes, were $5.9 billion in 2018, essentially flat compared with 2017. Global combined sales of Januvia and Janumet were $5.9 billion in 2017, a decline of 3% compared with 2016. Foreign exchange favorably affected sales performance by 1% in both 2018 and 2017. Sales performance in both periods was driven primarily by ongoing pricing pressure, particularly in the United States, partially offset by higher demand in most international markets. The Company expects pricing pressure to continue.

Women’s Health

Worldwide sales of NuvaRing, a vaginal contraceptive product, were $902 million in 2018, an increase of 19% compared with 2017 including a 1% favorable effect from foreign exchange. Sales growth was driven primarily by higher pricing in the United States. The patent that provided U.S. market exclusivity for NuvaRing expired in April 2018 and the Company anticipates a significant decline in U.S. NuvaRing sales in future periods as a result of generic competition. Global sales of NuvaRing were $761 million in 2017, a decline of 2% compared with 2016 including a

1% favorable effect from foreign exchange. The sales decline was driven primarily by lower sales in the United States reflecting lower volumes that were partially offset by higher pricing, and lower demand in Europe.

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Animal Health Segment

Global sales of Animal Health products were $4.2 billion in 2018, an increase of 9% compared with 2017, reflecting growth from both in-line and recently launched companion animal and livestock products. Higher sales of companion animal products reflect growth in the Bravecto line of products that kill fleas and ticks in dogs and cats for up to 12 weeks, as well as higher sales of companion animal vaccines. Growth in livestock products reflects higher sales of ruminant, poultry and swine products. Worldwide sales of Animal Health products were $3.9 billion in 2017, an increase of 11% compared with 2016, primarily reflecting higher sales of companion animal products, largely driven by growth in Bravecto, reflecting both growth in the oral formulation and continued uptake in the topical formulation, which was launched in 2016. Animal Health sales growth in 2017 was also driven by higher sales of ruminant, poultry and swine products.

In December 2018, the Company signed an agreement to acquire Antelliq, a leader in digital animal identification, traceability and monitoring solutions (see Note 3 to the consolidated financial statements).

Costs, Expenses and Other

($ in millions)	2018	Change	2017	Change	2016
Cost of sales	$13,509	5 %	$12,912	-8 %	$14,030
Selling, general and administrative	10,102	— %	10,074	1 %	10,017
Research and development	9,752	-6 %	10,339	1 %	10,261
Restructuring costs	632	-19 %	776	19 %	651
Other (income) expense, net	(402)	-20 %	(500)	*	189
	$33,593	— %	$33,601	-4 %	$35,148

* Greater than 100%.

Cost of Sales

Cost of sales was $13.5 billion in 2018, $12.9 billion in 2017 and $14.0 billion in 2016. Costs in 2018 include a $423 million charge related to the termination of a collaboration agreement with Samsung Bioepis Co., Ltd. (Samsung) for insulin glargine (see Note 3 to the consolidated financial statements). Also in 2018, the Company recorded $188 million of cumulative amortization expense for amounts capitalized in connection with the recognition of liabilities for potential future milestone payments related to collaborations (see Note 4 to the consolidated financial statements). Cost of sales includes expenses for the amortization of intangible assets recorded in connection with business acquisitions which totaled $2.7 billion in 2018, $3.1 billion in 2017 and $3.7 billion in 2016. Costs in 2017 and 2016 also include intangible asset impairment charges of $58 million and $347 million, respectively, related to marketed products and other intangibles recorded in connection with business acquisitions (see Note 8 to the consolidated financial statements). Costs in 2017 also include a $76 million intangible asset impairment charge related to a licensing agreement. The Company may recognize additional non-cash impairment charges in the future related to intangible assets that were measured at fair value and capitalized in connection with business acquisitions and such charges could be material. Also included in cost of sales are expenses associated with restructuring activities which amounted to $21 million, $138 million and $181 million in 2018, 2017 and 2016, respectively, primarily reflecting accelerated depreciation and asset write-offs related to the planned sale or closure of manufacturing facilities. Separation costs associated with manufacturing-related headcount reductions have been incurred and are reflected in Restructuring costs as discussed below.

Gross margin was 68.1% in 2018 compared with 67.8% in 2017 and 64.5% in 2016. The year-over-year improvements in gross margin reflect a lower net impact from the amortization of intangible assets and intangible asset impairment charges related to business acquisitions, as well as restructuring costs as noted above, which reduced gross margin by 6.3 percentage points in 2018, 8.3 percentage points in 2017 and 10.6 percentage points in 2016. The gross margin improvement in 2018 compared with 2017 also reflects the favorable effects of product mix and amortization of unfavorable manufacturing variances recorded in 2017, resulting in part from the June 2017 cyber-attack. The gross margin improvement in 2018 was partially offset by a charge associated with the termination of a collaboration agreement

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with Samsung, as well as the unfavorable effects of pricing pressure and cumulative amortization expense for potential future milestone payments related to collaborations as noted above. The gross margin improvement in 2017 compared with 2016 also reflects the favorable effects of product mix. Manufacturing-related costs associated with the cyber-attack partially offset the gross margin improvement in 2017.

Selling, General and Administrative

Selling, general and administrative (SG&A) expenses were $10.1 billion in 2018, essentially flat compared with 2017, reflecting higher administrative costs and the unfavorable effect of foreign exchange, offset by lower selling and promotional expenses. SG&A expenses were $10.1 billion in 2017, an increase of 1% compared with 2016. Higher administrative costs, including costs associated with the Company operating its vaccines business in the European markets that were previously part of the SPMSD joint venture, remediation costs related to the cyber-attack, and higher promotional expenses related to product launches, were partially offset by lower restructuring and acquisition and divestiture-related costs, lower selling expenses and the favorable effect of foreign exchange. SG&A expenses in 2016 include restructuring costs of $95 million related primarily to accelerated depreciation for facilities to be closed or divested. Separation costs associated with sales force reductions have been incurred and are reflected in Restructuring costs as discussed below. SG&A expenses also include acquisition and divestiture-related costs of $32 million, $44 million and $78 million in 2018, 2017 and 2016, respectively, consisting of integration, transaction, and certain other costs related to business acquisitions and divestitures.

Research and Development

Research and development (R&D) expenses were $9.8 billion in 2018, a decline of 6% compared with 2017. The decrease primarily reflects lower expenses in 2018 for upfront and license option payments related to the formation of oncology collaborations, lower in-process research and development (IPR&D) impairment charges, and a reduction in expenses associated with a decrease in the estimated fair value measurement of liabilities for contingent consideration, partially offset by higher clinical development spending and investment in discovery and early drug development, as well as higher expenses related to other business development activities, including a charge in 2018 for the acquisition of Viralytics. R&D expenses were $10.3 billion in 2017, an increase of 1% compared with 2016. The increase was driven primarily by a charge in 2017 related to the formation of a collaboration with AstraZeneca, an unfavorable effect from changes in the estimated fair value measurement of liabilities for contingent consideration, and higher clinical development spending, largely offset by lower IPR&D impairment charges and lower restructuring costs. R&D expenses are comprised of the costs directly incurred by Merck Research Laboratories (MRL), the Company’s research and development division that focuses on human health-related activities, which were $5.1 billion in 2018, $4.6 billion in 2017 and $4.4 billion in 2016. Also included in R&D expenses are costs incurred by other divisions in support of R&D activities, including depreciation, production and general and administrative, as well as licensing activity, and certain costs from operating segments, including the Pharmaceutical and Animal Health segments, which in the aggregate were $2.8 billion, $2.9 billion and $2.6 billion for 2018, 2017 and 2016, respectively. Additionally, R&D expenses in 2018 include a $1.4 billion charge related to the formation of a collaboration with Eisai (see Note 4 to the consolidated financial statements), as well as a $344 million charge for the acquisition of Viralytics (see Note 3 to the consolidated financial statements). R&D expenses in 2017 include a $2.35 billion charge related to the formation of a collaboration with AstraZeneca (see Note 4 to the consolidated financial statements). R&D expenses also include IPR&D impairment charges of $152 million, $483 million and $3.6 billion in 2018, 2017 and 2016, respectively (see Note 8 to the consolidated financial statements). The Company may recognize additional non-cash impairment charges in the future related to the cancellation or delay of other pipeline programs that were measured at fair value and capitalized in connection with business acquisitions and such charges could be material. In addition, R&D expenses include expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration recorded in connection with acquisitions. During 2018 and 2016, the Company recorded a net reduction in expenses of $54 million and $402 million, respectively, to decrease the estimated fair value of liabilities for contingent consideration related to the discontinuation or delay of certain programs (see Note 6 to the consolidated financial statements). During 2017, the Company recorded charges of $27 million to increase the estimated fair value of liabilities for contingent consideration. R&D expenses in 2016 also reflect $142 million of accelerated depreciation and asset abandonment costs associated with restructuring activities.

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Restructuring Costs

In 2010 and 2013, the Company commenced actions under global restructuring programs designed to streamline its cost structure. The actions under these programs include the elimination of positions in sales, administrative and headquarters organizations, as well as the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities. The Company also continues to reduce its global real estate footprint and improve the efficiency of its manufacturing and supply network.

Restructuring costs, primarily representing separation and other related costs associated with these restructuring activities, were $632 million, $776 million and $651 million in 2018, 2017 and 2016, respectively. In 2018, 2017 and 2016, separation costs of $473 million, $552 million and $216 million, respectively, were incurred associated with actual headcount reductions, as well as estimated expenses under existing severance programs for headcount reductions that were probable and could be reasonably estimated. Merck eliminated approximately 2,160 positions in 2018, 2,450 positions in 2017 and 2,625 positions in 2016 related to these restructuring activities. Also included in restructuring costs are asset abandonment, shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation plan costs. For segment reporting, restructuring costs are unallocated expenses.

Additional costs associated with the Company's restructuring activities are included in Cost of sales, Selling, general and administrative and Research and development as discussed above. The Company recorded aggregate pretax costs of $658 million in 2018, $927 million in 2017 and $1.1 billion in 2016 related to restructuring program activities (see Note 5 to the consolidated financial statements). The Company has substantially completed the actions under these programs.

Other (Income) Expense, Net

Other (income) expense, net, was $402 million of income in 2018, $500 million of income in 2017 and $189 million of expense in 2016. For details on the components of Other (income) expense, net, see Note 15 to the consolidated financial statements.

Segment Profits

($ in millions)	2018	2017	2016
Pharmaceutical segment profits	$24,292	$22,495	$22,141
Animal Health segment profits	1,659	1,552	1,357
Other non-reportable segment profits	103	275	146
Other	(17,353)	(17,801)	(18,985)
Income before taxes	$8,701	$6,521	$4,659

Pharmaceutical segment profits are comprised of segment sales less standard costs, as well as SG&A and R&D expenses directly incurred by the segment. Animal Health segment profits are comprised of segment sales, less all cost of sales, as well as SG&A and R&D expenses directly incurred by the segment. For internal management reporting presented to the chief operating decision maker, Merck does not allocate the remaining cost of sales not included in segment profits as described above, research and development expenses incurred in MRL, or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. Also excluded from the determination of segment profits are acquisition and divestiture-related costs (amortization of purchase accounting adjustments, intangible asset impairment charges and expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration), restructuring costs, and a portion of equity income. Additionally, segment profits do not reflect other expenses from corporate and manufacturing cost centers and other miscellaneous income or expense. These unallocated items, including a charge related to the termination of a collaboration agreement with Samsung for insulin glargine in 2018, a loss on the extinguishment of debt in 2017, and a charge related to the settlement of worldwide Keytruda patent litigation and gains on divestitures in 2016, are reflected in "Other" in the above table. Also included in "Other" are miscellaneous corporate profits (losses), as well as operating profits (losses) related to third-party manufacturing sales. In the first quarter of 2018, the Company adopted a new accounting standard related to the classification of certain defined benefit plan costs, which resulted in a change to the measurement of segment

profits (see Note 19 to the consolidated financial statements). Prior period amounts have been recast to conform to the new presentation.

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Pharmaceutical segment profits grew 8% in 2018 compared with 2017 primarily reflecting higher sales and lower selling and promotional costs. Pharmaceutical segment profits grew 2% in 2017 compared with 2016 primarily reflecting higher sales and the favorable effects of product mix. Animal Health segment profits grew 7% in 2018 and 14% in 2017 driven primarily by higher sales, partially offset by increased selling and promotional costs.

Taxes on Income

The effective income tax rates of 28.8% in 2018, 62.9% in 2017 and 15.4% in 2016 reflect the impacts of acquisition and divestiture-related costs, restructuring costs and the beneficial impact of foreign earnings. The effective income tax rate in 2018 includes measurement-period adjustments to the provisional amounts recorded in 2017 associated with the enactment of U.S. tax legislation known as the Tax Cuts and Jobs Act (TCJA), including $124 million related to the transition tax (see Note 16 to the consolidated financial statements). In addition, the effective income tax rate for 2018 reflects the unfavorable impacts of a $1.4 billion pretax charge recorded in connection with the formation of a collaboration with Eisai and a $423 million pretax charge related to the termination of a collaboration agreement with Samsung for which no tax benefits were recognized. The effective income tax rate for 2017 includes a provisional net charge of $2.6 billion related to the enactment of the TCJA. The effective income tax rate for 2017 also reflects the unfavorable impact of a $2.35 billion pretax charge recorded in connection with the formation of a collaboration with AstraZeneca for which no tax benefit was recognized, partially offset by the favorable impact of a net tax benefit of $234 million related to the settlement of certain federal income tax issues (see Note 16 to the consolidated financial statements), and a benefit of $88 million related to the settlement of a state income tax issue.

Net (Loss) Income Attributable to Noncontrolling Interests

Net (loss) income attributable to noncontrolling interests was $(27) million in 2018 compared with $24 million in 2017 and $21 million in 2016. The loss in 2018 primarily reflects the portion of goodwill impairment charges related to certain business in the Healthcare Services segment that are attributable to noncontrolling interests.

Net Income and Earnings per Common Share

Net income attributable to Merck & Co., Inc. was $6.2 billion in 2018, $2.4 billion in 2017 and $3.9 billion in 2016. EPS was $2.32 in 2018, $0.87 in 2017 and $1.41 in 2016.

Non-GAAP Income and Non-GAAP EPS

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

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

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

($ in millions except per share amounts)	2018	2017	2016
Income before taxes as reported under GAAP	$8,701	$6,521	$4,659
Increase (decrease) for excluded items:			
Acquisition and divestiture-related costs	3,066	3,760	7,312
Restructuring costs	658	927	1,069
Other items:			
Charge related to the formation of an oncology collaboration with Eisai	1,400	—	—
Charge related to the termination of a collaboration with Samsung	423	—	—
Charge for the acquisition of Viralytics	344	—	—
Charge related to the formation of an oncology collaboration with AstraZeneca	—	2,350	—
Charge related to the settlement of worldwide Keytruda patent litigation	—	—	625
Other	(57)	(16)	(67)
Non-GAAP income before taxes	14,535	13,542	13,598
Taxes on income as reported under GAAP	2,508	4,103	718
Estimated tax benefit on excluded items [1]	535	785	2,321
Net tax charge related to the enactment of the TCJA [2]	(160)	(2,625)	—
Net tax benefit from the settlement of certain federal income tax issues	—	234	—
Tax benefit related to the settlement of a state income tax issue	—	88	—
Non-GAAP taxes on income	2,883	2,585	3,039
Non-GAAP net income	11,652	10,957	10,559
Less: Net (loss) income attributable to noncontrolling interests as reported under GAAP	(27)	24	21
Acquisition and divestiture-related costs attributable to noncontrolling interests	(58)	—	—
Non-GAAP net income attributable to noncontrolling interests	31	24	21
Non-GAAP net income attributable to Merck & Co., Inc.	$11,621	$10,933	$10,538
EPS assuming dilution as reported under GAAP	$2.32	$0.87	$1.41
EPS difference [3]	2.02	3.11	2.37
Non-GAAP EPS assuming dilution	$4.34	$3.98	$3.78

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

(2) Amount in 2017 was provisional (see Note 16 to the consolidated financial statements).

(3) Represents the difference between calculated GAAP EPS and calculated non-GAAP EPS, which may be different than the amount calculated by dividing the impact of the excluded items by the weighted-average shares for the applicable year.

Acquisition and Divestiture-Related Costs

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

Restructuring Costs

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

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life prior to the restructuring actions. Restructuring costs also include asset abandonment, shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation costs.

Certain Other Items

Non-GAAP income and non-GAAP EPS exclude certain other items. These items are adjusted for after evaluating them on an individual basis, considering their quantitative and qualitative aspects, and typically consist of items that are unusual in nature, significant to the results of a particular period or not indicative of future operating results.

Excluded from non-GAAP income and non-GAAP EPS in 2018 is a charge related to the formation of a collaboration with Eisai (see Note 4 to the consolidated financial statements), a charge related to the termination of a collaboration agreement with Samsung for insulin glargine (see Note 3 to the consolidated financial statements), a charge for the acquisition of Viralytics (see Note 3 to the consolidated financial statements), and measurement-period adjustments related to the provisional amounts recorded for the TCJA (see Note 16 to the consolidated financial statements).

Excluded from non-GAAP income and non-GAAP EPS in 2017 is a charge related to the formation of a collaboration with AstraZeneca (see Note 4 to the consolidated financial statements), as well as a provisional net tax charge related to the enactment of the TCJA, a net tax benefit related to the settlement of certain federal income tax issues and a tax benefit related to the settlement of a state income tax issue (see Note 16 to the consolidated financial statements).

Excluded from non-GAAP income and non-GAAP EPS in 2016 is a charge to settle worldwide patent litigation related to Keytruda.

Research and Development

A chart reflecting the Company's current research pipeline as of February 22, 2019 is set forth in Item 1. "Business — Research and Development" above.

Research and Development Update

The Company currently has several candidates under regulatory review in the United States and internationally. Keytruda is an approved anti-PD-1 therapy in clinical development for expanded indications in different cancer types.

In February 2019, the FDA accepted and granted Priority Review for a supplemental BLA for Keytruda in combination with Inlyta (axitinib), a tyrosine kinase inhibitor, for the first-line treatment of patients with advanced renal cell carcinoma. This supplemental BLA is based on findings from the Phase 3 KEYNOTE-426 trial, which demonstrated that Keytruda in combination with axitinib, as compared to sunitinib, significantly improved overall survival (OS) and PFS in the first-line treatment of advanced renal cell carcinoma. These data were presented at the American Society for Clinical Oncology (ASCO) Genitourinary Cancers Symposium in February 2019. The supplemental BLA also included supporting data from the Phase 1b KEYNOTE-035 trial. The FDA set a PDUFA date of June 20, 2019. Merck has filed data from KEYNOTE-426 with regulatory authorities worldwide.

In February 2019, the Committee for Medicinal Products for Human Use of the European Medicines Agency (EMA) adopted a positive opinion recommending Keytruda, in combination with carboplatin and either paclitaxel or nab-paclitaxel, for the first-line treatment of metastatic squamous NSCLC in adults. This recommendation is based on results from the pivotal Phase 3 KEYNOTE-407 trial, which enrolled patients regardless of PD-L1 tumor expression status. The trial showed a significant improvement in OS and PFS for patients taking Keytruda in combination with chemotherapy (carboplatin and either paclitaxel or nab-paclitaxel) compared with chemotherapy alone. If approved, this would mark the first approval in Europe for an anti-PD-1 therapy in combination with chemotherapy for adults with metastatic squamous NSCLC. In October 2018, the FDA approved Keytruda in combination with carboplatin-paclitaxel or nab-paclitaxel as a first-line treatment for metastatic squamous NSCLC, regardless of PD-L1 expression.

In December 2018, the FDA extended the action date for the supplemental BLA seeking approval for Keytruda as monotherapy for the first-line treatment of locally advanced or metastatic NSCLC in patients whose tumors express PD-L1 (TPS ≥1%) without EGFR or ALK genomic tumor aberrations. The supplemental BLA is based on results of the Phase 3 KEYNOTE-042 trial where Keytruda monotherapy demonstrated a significant improvement in OS compared with chemotherapy in this patient population. The Company submitted additional data and analyses to

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the FDA, which constituted a major amendment and extended the PDUFA date by three months to April 11, 2019. Merck continues to work closely with the FDA during the review of this supplemental BLA.

In February 2019, the FDA accepted and granted Priority Review for a supplemental BLA for Keytruda as monotherapy for the treatment of patients with advanced SCLC whose disease has progressed after two or more lines of prior therapy. This supplemental BLA, which is seeking accelerated approval for this new indication, is based on data from the SCLC cohorts of the Phase 2 KEYNOTE-158 and Phase 1b KEYNOTE-028 trials. The FDA set a PDUFA date of June 17, 2019. Keytruda is also being studied in combination with chemotherapy in the ongoing Phase 3 KEYNOTE-604 study in patients with newly diagnosed extensive stage SCLC.

In February 2019, the FDA accepted a supplemental BLA for Keytruda as monotherapy or in combination with platinum and 5-fluorouracil chemotherapy for the first-line treatment of patients with recurrent or metastatic HNSCC. This supplemental BLA is based in part on data from the pivotal Phase 3 KEYNOTE-048 trial where Keytruda demonstrated a significant improvement in OS compared with the standard of care, as monotherapy in patients whose tumors expressed PD-L1 with Combined Positive Score (CPS)≥20 and CPS≥1 and in combination with chemotherapy in the total patient population. These data were presented at the European Society for Medical Oncology (ESMO) 2018 Congress. The FDA granted Priority Review to the supplemental BLA and set a PDUFA date of June 10, 2019. KEYNOTE-048 also serves as the confirmatory trial for KEYNOTE-012, a Phase 1b study which supported the previous accelerated approval for Keytruda as monotherapy for the treatment of patients with recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy.

In November 2018, Merck announced that the Phase 3 KEYNOTE-181 trial investigating Keytruda as monotherapy in the second-line treatment of advanced or metastatic esophageal or esophagogastric junction carcinoma met a primary endpoint of OS in patients whose tumors expressed PD-L1 (CPS ≥10). In this pivotal study, treatment with Keytruda resulted in a statistically significant improvement in OS compared to chemotherapy (paclitaxel, docetaxel or irinotecan) in patients with CPS ≥10, regardless of histology. The primary endpoint of OS was also evaluated in patients with squamous cell histology and in the entire intention-to-treat study population. While directionally favorable, statistical significance for OS was not met in these two patient groups. Per the statistical analysis plan, the key secondary endpoints of PFS and objective response rate (ORR) were not formally tested, as OS was not reached in the full intention-to-treat study population. These results were presented in January 2019 at the ASCO Gastrointestinal Cancers Symposium and have been submitted for regulatory review.

Additionally, Keytruda has received Breakthrough Therapy designation from the FDA for the treatment of high-risk early-stage triple-negative breast cancer in combination with neoadjuvant chemotherapy. The FDA’s Breakthrough Therapy designation is intended to expedite the development and review of a candidate that is planned for use, alone or in combination, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

In October 2018, Merck announced the first presentation of results from an interim analysis of KEYNOTE-057, a Phase 2 trial evaluating Keytruda for previously treated patients with high-risk non-muscle invasive bladder cancer. An interim analysis of the study’s primary endpoint showed a complete response rate of nearly 40% at three months with Keytruda in patients whose disease was unresponsive to Bacillus Calmette-Guérin therapy, the current standard of care for this disease, and who were ineligible for or who refused to undergo radical cystectomy. These results, as well as other study findings, were presented at the ESMO 2018 Congress.

In February 2019, Merck announced that the pivotal Phase 3 KEYNOTE-240 trial evaluating Keytruda, plus best supportive care, for the treatment of patients with advanced hepatocellular carcinoma who were previously treated with systemic therapy, did not meet its co-primary endpoints of OS and PFS compared with placebo plus best supportive care. In the final analysis of the study, there was an improvement in OS for patients treated with Keytruda compared to placebo, however these OS results did not meet statistical significance per the pre-specified statistical plan. Results for PFS were also directionally favorable in the Keytruda arm compared with placebo but did not reach statistical significance. The key secondary endpoint of ORR was not formally tested, since superiority was not reached for OS or PFS. Results will be presented at an upcoming medical meeting and have been shared with the FDA for discussion.

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The Keytruda clinical development program consists of more than 900 clinical trials, including more than 600 trials that combine Keytruda with other cancer treatments. These studies encompass more than 30 cancer types including: bladder, cervical, colorectal, esophageal, gastric, head and neck, hepatocellular, Hodgkin lymphoma, non-Hodgkin lymphoma, melanoma, mesothelioma, nasopharyngeal, NSCLC, ovarian, PMBCL, prostate, renal, small-cell lung and triple-negative breast, many of which are currently in Phase 3 clinical development. Further trials are being planned for other cancers.

Lynparza, is an oral PARP inhibitor currently approved for certain types of ovarian and breast cancer. In July 2017, Merck and AstraZeneca entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza for multiple cancer types (see Note 4 to the consolidated financial statements).

In April 2018, Merck and AstraZeneca announced that the EMA validated for review the Marketing Authorization Application for Lynparza for use in patients with deleterious or suspected deleterious BRCA-mutated, HER2-negative metastatic breast cancer who have been previously treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. This was the first regulatory submission for a PARP inhibitor in breast cancer in Europe.

Lynparza tablets are also under review in the EU as a maintenance treatment in patients with newly-diagnosed, BRCA-mutated advanced ovarian cancer who were in complete or partial response following first-line standard platinum-based chemotherapy. This submission was based on positive results from the pivotal Phase 3 SOLO-1 trial. The trial showed a statistically-significant and clinically-meaningful improvement in PFS for Lynparza compared to placebo, reducing the risk of disease progression or death by 70% in patients with newly-diagnosed, BRCA-mutated advanced ovarian cancer who were in complete or partial response to platinum-based chemotherapy.

In December 2018, Merck and AstraZeneca announced positive results from the randomized, open-label, controlled, Phase 3 SOLO-3 trial of Lynparza tablets in patients with relapsed ovarian cancer after two or more lines of treatment. The trial was conducted as a post-approval commitment in agreement with the FDA. Results from the trial showed BRCA-mutated advanced ovarian cancer patients treated with Lynparza following two or more prior lines of chemotherapy demonstrated a statistically significant and clinically meaningful improvement in the primary endpoint of ORR and the key secondary endpoint of PFS compared to chemotherapy. Merck and AstraZeneca plan to discuss these results with the FDA.

MK-7655A is a combination of relebactam, an investigational beta-lactamase inhibitor, and imipenem/cilastatin (an approved carbapenem antibiotic). In February 2019, Merck announced that the FDA accepted for Priority Review an NDA for MK-7655A for the treatment of complicated urinary tract infections and complicated intra-abdominal infections caused by certain susceptible Gram-negative bacteria in adults with limited or no alternative therapies available. The PDUFA date is July 16, 2019. In April 2018, Merck announced that a pivotal Phase 3 study of MK-7655A demonstrated a favorable overall response in the treatment of certain imipenem-non-susceptible bacterial infections, the primary endpoint, with lower treatment-emergent nephrotoxicity (kidney toxicity), a secondary endpoint, compared to a colistin (colistimethate sodium) plus imipenem/cilastatin regimen. The FDA had previously designated this combination a Qualified Infectious Disease Product with designated Fast Track status for the treatment of hospital-acquired bacterial pneumonia, ventilator-associated bacterial pneumonia, complicated intra-abdominal infections and complicated urinary tract infections.

V920 (rVSVΔG-ZEBOV-GP, live attenuated), is an investigational Ebola Zaire disease vaccine candidate being studied in large scale Phase 2/3 clinical trials. In December 2015, Merck announced that the application for Emergency Use Assessment and Listing (EUAL) for V920 was accepted for review by the World Health Organization (WHO). According to the WHO, the EUAL process is designed to expedite the availability of vaccines needed for public health emergencies such as another outbreak of Ebola. The WHO decision to grant V920 EUAL status will be based on data regarding quality, safety, and efficacy/effectiveness; as well as a risk/benefit analysis for emergency use. While EUAL designation allows for emergency use, the vaccine remains investigational and has not yet been licensed for commercial distribution. In July 2016, Merck announced that the FDA granted V920 Breakthrough Therapy designation, and that the EMA granted the vaccine candidate PRIME (PRIority MEdicines) status. In November 2018, Merck announced that it has started the submission of a rolling BLA to the FDA for V920. This rolling submission was made pursuant to the FDA's Breakthrough Therapy designation. Merck expects the rolling submission of the BLA to be completed in 2019. The Company also intends to file V920 with the EMA in 2019.

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In February 2019, Merck announced that the FDA accepted for Priority Review a supplemental NDA for Zerbaxa to treat adult patients with nosocomial pneumonia, including ventilator-associated pneumonia, caused by certain susceptible Gram-negative microorganisms. The PDUFA date is June 3, 2019. Zerbaxa is also under review for this indication by the EMA. Zerbaxa is currently approved in the United States for the treatment of adult patients with complicated urinary tract infections caused by certain susceptible Gram-negative microorganisms, and is also indicated, in combination with metronidazole, for the treatment of adult patients with complicated intra-abdominal infections caused by certain susceptible Gram-negative and Gram-positive microorganisms.

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

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

Lenvima, is an orally available tyrosine kinase inhibitor currently approved for certain types of thyroid cancer, hepatocellular carcinoma, and in combination for certain patients with renal cell carcinoma. In March 2018, Merck and Eisai entered into a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima (see Note 4 to the consolidated financial statements). Under the agreement, Merck and Eisai will develop and commercialize Lenvima jointly, both as monotherapy and in combination with Keytruda. Per the agreement, the companies will jointly initiate clinical studies evaluating the Keytruda/Lenvima combination to support 11 potential indications in six types of cancer (endometrial cancer, NSCLC, hepatocellular carcinoma, head and neck cancer, bladder cancer and melanoma), as well as a basket trial targeting multiple cancer types. The FDA granted Breakthrough Therapy designation for Keytruda in combination with Lenvima for the potential treatment of patients with advanced and/or metastatic renal cell carcinoma and for the potential treatment of certain patients with advanced and/or metastatic non-microsatellite instability high/proficient mismatch repair endometrial carcinoma.

MK-1242, vericiguat, is an investigational treatment for heart failure being studied in patients suffering from chronic heart failure with reduced ejection fracture (Phase 3 clinical trial) and from chronic heart failure with preserved ejection fracture (Phase 2 clinical trial). The development of vericiguat is part of a worldwide strategic collaboration between Merck and Bayer (see Note 4 to the consolidated financial statements).

V114 is an investigational polyvalent conjugate vaccine for the prevention of pneumococcal disease. In June 2018, Merck initiated the first Phase 3 study in the adult population for the prevention of invasive pneumococcal disease. Currently five Phase 3 adult studies are ongoing, including studies in healthy adults 50 years of age or older, adults with risk factors for pneumococcal disease, those infected with HIV, and those who are recipients of allogeneic hematopoietic stem cell transplant. In October 2018, Merck began the first Phase 3 study in the pediatric population. Currently, three studies are ongoing, including studies in healthy infants and in children afflicted with sickle cell disease. In January 2019, Merck announced that V114 received Breakthrough Therapy designation from the FDA for the prevention of invasive pneumococcal disease caused by the vaccine serotypes in pediatric patients 6 weeks to 18 years of age.

As a result of changes in the herpes zoster vaccine environment, Merck is ending development of V212, its investigational vaccine for the prevention of shingles in immunocompromised patients.

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

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The Company also reviews its pipeline to examine candidates that may provide more value through out-licensing. The Company continues to evaluate certain late-stage clinical development and platform technology assets to determine their out-licensing or sale potential.
The Company's clinical pipeline includes candidates in multiple disease areas, including cancer, cardiovascular diseases, diabetes, infectious diseases, neurosciences, obesity, pain, respiratory diseases, and vaccines.

Acquired In-Process Research and Development
In connection with business acquisitions, the Company has recorded the fair value of in-process research projects which, at the time of acquisition, had not yet reached technological feasibility. At December 31, 2018, the balance of IPR&D was $1.1 billion.
The IPR&D projects that remain in development are subject to the inherent risks and uncertainties in drug development and it is possible that the Company will not be able to successfully develop and complete the IPR&D programs and profitably commercialize the underlying product candidates. The time periods to receive approvals from the FDA and other regulatory agencies are subject to uncertainty. Significant delays in the approval process, or the Company's failure to obtain approval at all, would delay or prevent the Company from realizing revenues from these products. Additionally, if certain of the IPR&D programs fail or are abandoned during development, then the Company will not realize the future cash flows it has estimated and recorded as IPR&D as of the acquisition date, and the Company may also not recover the research and development expenditures made since the acquisition to further develop such programs. If such circumstances were to occur, the Company's future operating results could be adversely affected and the Company may recognize impairment charges and such charges could be material.
In 2018, 2017, and 2016 the Company recorded IPR&D impairment charges within Research and development expenses of $152 million, $483 million and $3.6 billion, respectively (see Note 8 to the consolidated financial statements).
Additional research and development will be required before any of the remaining programs reach technological feasibility. The costs to complete the research projects will depend on whether the projects are brought to their final stages of development and are ultimately submitted to the FDA or other regulatory agencies for approval.

Acquisitions, Research Collaborations and License Agreements
Merck continues to remain focused on pursuing opportunities that have the potential to drive both near- and long-term growth. Certain of the more recent transactions are described below. Merck is actively monitoring the landscape for growth opportunities that meet the Company's strategic criteria.
In March 2018, Merck and Eisai announced a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima, an orally available tyrosine kinase inhibitor discovered by Eisai. Under the agreement, Merck and Eisai will develop and commercialize Lenvima jointly, both as monotherapy and in combination with Merck's anti-PD-1 therapy, Keytruda. Under the agreement, Merck made an upfront payment to Eisai of $750 million and will make payments of up to $650 million for certain option rights through 2021 (of which $325 million will be paid in March 2019, $200 million is expected to be paid in 2020 and $125 million is expected to be paid in 2021). The Company recorded a charge of $1.4 billion in Research and development expenses in 2018 related to the upfront payment and future option payments. In addition, the agreement provides for Eisai to receive up to $385 million associated with the achievement of certain clinical and regulatory milestones and up to $3.97 billion for the achievement of milestones associated with sales of Lenvima (see Note 4 to the consolidated financial statements).
In June 2018, Merck acquired Viralytics Limited (Viralytics), an Australian publicly traded company focused on oncolytic immunotherapy treatments for a range of cancers, for AUD 502 million ($378 million). The transaction provided Merck with full rights to Cavatak (V937, formerly CVA21), Viralytics's investigational oncolytic immunotherapy. Cavatak is based on Viralytics's proprietary formulation of an oncolytic virus (Coxsackievirus Type A21) that has been shown to preferentially infect and kill cancer cells. Cavatak is currently being evaluated in multiple Phase 1 and Phase 2 clinical trials, both as an intratumoral and intravenous agent, including in combination with Keytruda. Under a previous agreement between Merck and Viralytics, a study is investigating the use of the Keytruda

and Cavatak combination in melanoma, prostate, lung and bladder cancers. The transaction was accounted for as an acquisition of an asset. Merck recorded net assets of $34 million (primarily cash) at the acquisition date and Research

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and development expenses of $344 million in 2018 related to the transaction. There are no future contingent payments associated with the acquisition.

In February 2019, Merck and Immune Design entered into a definitive agreement under which Merck will acquire Immune Design for $5.85 per share in cash for an approximate value of $300 million. Immune Design is a late-stage immunotherapy company employing next-generation in vivo approaches to enable the body's immune system to fight disease. Immune Design's proprietary technologies, GLAAS and ZVex, are engineered to activate the immune system's natural ability to generate and/or expand antigen-specific cytotoxic immune cells to fight cancer and other chronic diseases. Under the terms of the acquisition agreement, Merck, through a subsidiary, will initiate a tender offer to acquire all outstanding shares of Immune Design. The closing of the tender offer will be subject to certain conditions, including the tender of shares representing at least a majority of the total number of Immune Design's outstanding shares, the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and other customary conditions. The transaction is expected to close early in the second quarter of 2019.

Capital Expenditures

Capital expenditures were $2.6 billion in 2018, $1.9 billion in 2017 and $1.6 billion in 2016. Expenditures in the United States were $1.5 billion in 2018, $1.2 billion in 2017 and $1.0 billion in 2016. In October 2018, the Company announced it plans to invest approximately $16 billion on new capital projects from 2018-2022. The focus of this investment will primarily be on increasing manufacturing capacity across Merck's key businesses.

Depreciation expense was $1.4 billion in 2018, $1.5 billion in 2017 and $1.6 billion in 2016. In each of these years, $1.0 billion of the depreciation expense applied to locations in the United States. Total depreciation expense in 2017 and 2016 included accelerated depreciation of $60 million and $227 million, respectively, associated with restructuring activities (see Note 5 to the consolidated financial statements).

Analysis of Liquidity and Capital Resources

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

Selected Data

($ in millions)	2018	2017	2016
Working capital	$3,669	$6,152	$13,410
Total debt to total liabilities and equity	30.4 %	27.8 %	26.0 %
Cash provided by operations to total debt	0.4:1	0.3:1	0.4:1

The decline in working capital in 2018 compared with 2017 reflects the utilization of cash and short-term borrowings to fund $5.0 billion of ASR agreements, a $1.25 billion payment to redeem debt in connection with the exercise of a make-whole provision as discussed below, as well as a $750 million upfront payment related to the formation of a collaboration with Eisai discussed above. The decline in working capital in 2017 compared with 2016 primarily reflects the reclassification of $3.0 billion of notes due in the first half of 2018 from long-term debt to short-term debt, $1.85 billion of upfront and option payments related to the formation of the AstraZeneca collaboration discussed above, as well as $810 million paid to redeem debt in connection with tender offers discussed below.

Cash provided by operating activities was $10.9 billion in 2018, $6.5 billion in 2017 and $10.4 billion in 2016. The lower cash provided by operating activities in 2017 reflects a $2.8 billion payment related to the settlement of certain federal income tax issues (see Note 16 to the consolidated financial statements), payments of $1.85 billion related to the formation of a collaboration with AstraZeneca (see Note 4 to the consolidated financial statements), and a $625 million payment made by the Company related to the previously disclosed settlement of worldwide Keytruda patent litigation. Cash provided by operating activities continues to be the Company's primary source of funds to finance operating needs, capital expenditures, treasury stock purchases and dividends paid to shareholders.

Cash provided by investing activities was $4.3 billion in 2018 compared with $2.7 billion in 2017. The increase in cash provided by investing activities was driven primarily by lower purchases of securities and other investments, partially offset by higher capital expenditures, lower proceeds from the sales of securities and other investments, and a $350 million milestone payment in 2018 related to a collaboration with Bayer (see Note 4 to the consolidated financial statements). Cash provided by investing activities was $2.7 billion in 2017 compared with a use

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of cash in investing activities of $3.2 billion in 2016. The change was driven primarily by lower purchases of securities and other investments, higher proceeds from the sales of securities and other investments and a lower use of cash for the acquisitions of businesses.

Cash used in financing activities was $13.2 billion in 2018 compared with $10.0 billion in 2017. The increase in cash used in financing activities was driven primarily by higher purchases of treasury stock (largely under ASR agreements as discussed below), higher payments on debt and payment of contingent consideration related to a prior year business acquisition, partially offset by an increase in short-term borrowings. Cash used in financing activities was $10.0 billion in 2017 compared with $9.0 billion in 2016. The increase in cash used in financing activities was driven primarily by proceeds from the issuance of debt in 2016, as well as higher purchases of treasury stock and lower proceeds from the exercise of stock options in 2017, partially offset by lower payments on debt in 2017.

The Company's contractual obligations as of December 31, 2018 are as follows:

Payments Due by Period					
($ in millions)	Total	2019	2020—2021	2022—2023	Thereafter
Purchase obligations [1]	$2,349	$886	$ 1,011	$ 407	$ 45
Loans payable and current portion of long-term debt	5,309	5,309	—	—	—
Long-term debt	19,882	—	4,237	4,000	11,645
Interest related to debt obligations	7,680	662	1,163	932	4,923
Unrecognized tax benefits [2]	44	44	—	—	—
Transition tax related to the enactment of the TCJA [3]	4,899	275	873	1,217	2,534
Leases	997	188	348	218	243
	$41,160	$7,364	$ 7,632	$ 6,774	$ 19,390

(1) Includes future inventory purchases the Company has committed to in connection with certain divestitures.

(2) As of December 31, 2018, the Company's Consolidated Balance Sheet reflects liabilities for unrecognized tax benefits, interest and penalties of $2.3 billion, including $44 million reflected as a current liability. Due to the high degree of uncertainty regarding the timing of future cash outflows of liabilities for unrecognized tax benefits beyond one year, a reasonable estimate of the period of cash settlement for years beyond 2019 cannot be made.

(3) In connection with the enactment of the TCJA, the Company is required to pay a one-time transition tax, which the Company has elected to pay over a period of eight years as permitted under the TCJA (see Note 16 to the consolidated financial statements).

Purchase obligations are enforceable and legally binding obligations for purchases of goods and services including minimum inventory contracts, research and development and advertising. Amounts reflected for research and development obligations do not include contingent milestone payments related to collaborative arrangements and acquisitions. Contingent milestone payments are not considered contractual obligations as they are contingent upon the successful achievement of developmental, regulatory approval and commercial milestones. At December 31, 2018, the Company has liabilities for milestone payments related to collaborations with AstraZeneca, Eisai and Bayer (see Note 4 to the consolidated financial statements). Also excluded from research and development obligations are potential future funding commitments of up to approximately $40 million for investments in research venture capital funds. Loans payable and current portion of long-term debt reflects $149 million of long-dated notes that are subject to repayment at the option of the holders. Required funding obligations for 2019 relating to the Company's pension and other postretirement benefit plans are not expected to be material. However, the Company currently anticipates contributing approximately $50 million to its U.S. pension plans, $150 million to its international pension plans and $15 million to its other postretirement benefit plans during 2019.

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

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

In November 2016, the Company issued €1.0 billion principal amount of senior unsecured notes consisting of €500 million principal amount of 0.50% notes due 2024 and €500 million principal amount of 1.375% notes due 2036. The

Company used the net proceeds of the offering of $1.1 billion for general corporate purposes.

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The Company has a $6.0 billion credit facility that matures in June 2023. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

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

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

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

In October 2018, Merck announced that its Board of Directors approved a 15% increase to the Company's quarterly dividend, raising it to $0.55 per share from $0.48 per share on the Company's outstanding common stock. Payment was made in January 2019. In January 2019, the Board of Directors declared a quarterly dividend of $0.55 per share on the Company's common stock for the second quarter of 2019 payable in April 2019.

In November 2017, Merck's Board of Directors authorized purchases of up to $10 billion of Merck's common stock for its treasury. The treasury stock purchase authorization has no time limit and will be made over time in open-market transactions, block transactions, on or off an exchange, or in privately negotiated transactions. In October 2018, Merck's Board of Directors authorized an additional $10 billion of treasury stock purchases with no time limit for completion and the Company entered into ASR agreements of $5 billion as discussed below. The Company spent $9.1 billion to purchase shares of its common stock for its treasury during 2018. As of December 31, 2018, the Company's remaining share repurchase authorization was $11.9 billion. The Company purchased $4.0 billion and $3.4 billion of its common stock during 2017 and 2016, respectively, under authorized share repurchase programs.

On October 25, 2018, the Company entered into ASR agreements with two third-party financial institutions (Dealers). Under the ASR agreements, Merck agreed to purchase $5 billion of Merck's common stock, in total, with an initial delivery of 56.7 million shares of Merck's common stock, based on the then-current market price, made by the Dealers to Merck, and payments of $5 billion made by Merck to the Dealers on October 29, 2018, which were funded with existing cash and investments, as well as short-term borrowings. The number of shares of Merck's common stock that Merck may receive, or may be required to remit, upon final settlement under the ASR agreements will be based upon the average daily volume weighted-average price of Merck's common stock during the term of the ASR program, less a negotiated discount. Final settlement of the transaction under the ASR agreements is expected to occur in the first half of 2019, but may occur earlier at the option of the Dealers, or later under certain circumstances. If Merck is obligated to make adjustment payments to the Dealers under the ASR agreements, Merck may elect to satisfy such obligations in cash or in shares of Merck's common stock.

Financial Instruments Market Risk Disclosures

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

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

Foreign Currency Risk Management

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

foreign exchange rates.

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

Because Merck principally sells foreign currency in its revenue hedging program, a uniform weakening of the U.S. dollar would yield the largest overall potential loss in the market value of these hedge instruments. The market value of Merck's hedges would have declined by an estimated $441 million and $400 million at December 31, 2018 and 2017, respectively, from a uniform 10% weakening of the U.S. dollar. The market value was determined using a foreign exchange option pricing model and holding all factors except exchange rates constant. Although not predictive in nature, the Company believes that a 10% threshold reflects reasonably possible near-term changes in Merck's major foreign currency exposures relative to the U.S. dollar. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

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

A sensitivity analysis to changes in the value of the U.S. dollar on foreign currency denominated derivatives, investments and monetary assets and liabilities indicated that if the U.S. dollar uniformly weakened by 10% against all currency exposures of the Company at December 31, 2018 and 2017, Income before taxes would have declined by approximately $134 million and $92 million in 2018 and 2017, respectively. Because the Company was in a net short (payable) position relative to its major foreign currencies after consideration of forward contracts, a uniform weakening of the U.S. dollar will yield the largest overall potential net loss in earnings due to exchange. This measurement assumes that a change in one foreign currency relative to the U.S. dollar would not affect other foreign currencies relative to the U.S. dollar. Although not predictive in nature, the Company believes that a 10% threshold reflects reasonably possible near-term changes in Merck's major foreign currency exposures relative to the U.S. dollar. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

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

The Company also uses forward exchange contracts to hedge its net investment in foreign operations against movements in exchange rates. The forward contracts are designated as hedges of the net investment in a foreign operation. The Company hedges a portion of the net investment in certain of its foreign operations. The unrealized gains or losses on these contracts are recorded in foreign currency translation adjustment within Other Comprehensive Income (Loss) (OCI), and remain in Accumulated Other Comprehensive Income (Loss) (AOCI) until either the sale or complete or substantially complete liquidation of the subsidiary. The Company excludes certain portions of the change in fair value of its derivative instruments from the assessment of hedge effectiveness (excluded component). Changes in fair value of the excluded components are recognized in OCI. In accordance with the new guidance

adopted on January 1, 2018 (see Note 2 to the consolidated financial statements), the Company has elected to recognize in earnings the initial value of the excluded component on a straight-line basis over the life of the derivative instrument, rather

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than using the mark-to-market approach. The cash flows from these contracts are reported as investing activities in the Consolidated Statement of Cash Flows.

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

Interest Rate Risk Management

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

In May 2018, four interest rate swaps with notional amounts aggregating $1.0 billion matured. These swaps effectively converted the Company's $1.0 billion, 1.30% fixed-rate notes due 2018 to variable rate debt. In December 2018, in connection with the early repayment of debt, the Company settled three interest rate swaps with notional amounts aggregating $550 million. These swaps effectively converted a portion of the Company's $1.25 billion, 5.00% notes due 2019 to variable rate debt. At December 31, 2018, the Company was a party to 19 pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes as detailed in the table below.

($ in millions)	2018		
Debt Instrument	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
1.85% notes due 2020	$1,250	5	$ 1,250
3.875% notes due 2021	1,150	5	1,150
2.40% notes due 2022	1,000	4	1,000
2.35% notes due 2022	1,250	5	1,250

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

The Company's investment portfolio includes cash equivalents and short-term investments, the market values of which are not significantly affected by changes in interest rates. The market value of the Company's medium- to long-term fixed-rate investments is modestly affected by changes in U.S. interest rates. Changes in medium- to long-term U.S. interest rates have a more significant impact on the market value of the Company's fixed-rate borrowings, which generally have longer maturities. A sensitivity analysis to measure potential changes in the market value of Merck's investments and debt from a change in interest rates indicated that a one percentage point increase in interest rates at December 31, 2018 and 2017 would have positively affected the net aggregate market value of these instruments by $1.2 billion and $1.3 billion, respectively. A one percentage point decrease at December 31, 2018 and 2017 would have negatively affected the net aggregate market value by $1.4 billion and $1.5 billion, respectively. The fair value of Merck's debt was determined using pricing models reflecting one percentage point shifts in the appropriate yield curves. The fair values of Merck's investments were determined using a combination of pricing and duration models.

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Critical Accounting Policies

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

Acquisitions and Dispositions

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

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

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

The fair values of identifiable intangible assets related to currently marketed products and product rights are primarily determined by using an income approach through which fair value is estimated based on each asset's

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

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

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

Revenue Recognition

On January 1, 2018, the Company adopted a new standard on revenue recognition (see Note 2 to the consolidated financial statements). Changes to the Company's revenue recognition policy as a result of adopting the new guidance are described below.

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

The vast majority of revenues from sales of products are recognized at a point in time when control of the goods is transferred to the customer, which the Company has determined is when title and risks and rewards of ownership transfer to the customer and the Company is entitled to payment. Certain Merck entities, including U.S. entities, have contract terms under which control of the goods passes to the customer upon shipment; however, either pursuant to the terms of the contract or as a business practice, Merck retains responsibility for goods lost or damaged in transit. Prior to the adoption of the new standard, Merck would recognize revenue for these entities upon delivery of the goods. Under the new guidance, the Company is now recognizing revenue at time of shipment for these entities.

For businesses within the Company's Healthcare Services segment and certain services in the Animal Health segment, revenue is recognized over time, generally ratably over the contract term as services are provided. These service revenues are not material.

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

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

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

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

The Company continually monitors its provision for aggregate customer discounts. There were no material adjustments to estimates associated with the aggregate customer discount provision in 2018, 2017 or 2016.

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

($ in millions)	2018	2017
Balance January 1	$2,551	$2,945
Current provision	10,837	11,001
Adjustments to prior years	(117)	(286)
Payments	(10,641)	(11,109)
Balance December 31	$2,630	$2,551

Accruals for chargebacks are reflected as a direct reduction to accounts receivable and accruals for rebates as current liabilities. The accrued balances relative to these provisions included in Accounts receivable and Accrued and other current liabilities were $245 million and $2.4 billion, respectively, at December 31, 2018 and were $198 million and $2.4 billion, respectively, at December 31, 2017.

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

The Company maintains a returns policy that allows its U.S. pharmaceutical customers to return product within a specified period prior to and subsequent to the expiration date (generally, three to six months before and 12 months after product expiration). The estimate of the provision for returns is based upon historical experience with actual returns. Additionally, the Company considers factors such as levels of inventory in the distribution channel, product dating and expiration period, whether products have been discontinued, entrance in the market of generic competition, changes in formularies or launch of over-the-counter products, among others. The product returns provision for U.S. pharmaceutical sales as a percentage of U.S. net pharmaceutical sales was 1.6% in 2018, 2.1% in 2017 and 1.4% in 2016. Outside of the United States, returns are only allowed in certain countries on a limited basis.

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

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

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

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

Inventories Produced in Preparation for Product Launches

The Company capitalizes inventories produced in preparation for product launches sufficient to support estimated initial market demand. Typically, capitalization of such inventory does not begin until the related product candidates are in Phase 3 clinical trials and are considered to have a high probability of regulatory approval. The Company monitors the status of each respective product within the regulatory approval process; however, the Company generally does not disclose specific timing for regulatory approval. If the Company is aware of any specific risks or contingencies other than the normal regulatory approval process or if there are any specific issues identified during the research process relating to safety, efficacy, manufacturing, marketing or labeling, the related inventory would generally not be capitalized. Expiry dates of the inventory are affected by the stage of completion. The Company manages the levels of inventory at each stage to optimize the shelf life of the inventory in relation to anticipated market demand in order to avoid product expiry issues. For inventories that are capitalized, anticipated future sales and shelf lives support the realization of the inventory value as the inventory shelf life is sufficient to meet initial product launch requirements. Inventories produced in preparation for product launches capitalized at December 31, 2018 and 2017 were $7 million and $80 million, respectively.

Contingencies and Environmental Liabilities

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

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company’s legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of December 31, 2018 and 2017 of approximately $245 million and $160 million, respectively, represents the Company’s best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

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

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

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

The Company believes that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on the Company. Expenditures for remediation and environmental liabilities were $16 million in 2018, and are estimated at $57 million in the aggregate for the years 2019 through 2023. In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $71 million and $82 million at December 31, 2018 and 2017, respectively. These liabilities are undiscounted, do not consider potential recoveries from other parties and will be paid out over the periods of remediation for the applicable sites, which are expected to occur primarily over the next 15 years. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed $60 million in the aggregate. Management also does not believe that these expenditures should result in a material adverse effect on the Company's financial position, results of operations, liquidity or capital resources for any year.

Share-Based Compensation

The Company expenses all share-based payment awards to employees, including grants of stock options, over the requisite service period based on the grant date fair value of the awards. The Company determines the fair value of certain share-based awards using the Black-Scholes option-pricing model which uses both historical and current market data to estimate the fair value. This method incorporates various assumptions such as the risk-free interest rate, expected volatility, expected dividend yield and expected life of the options. Total pretax share-based compensation expense was $348 million in 2018, $312 million in 2017 and $300 million in 2016. At December 31, 2018, there was $560 million of total pretax unrecognized compensation expense related to nonvested stock option, restricted stock unit and performance share unit awards which will be recognized over a weighted average period of 1.9 years. For segment reporting, share-based compensation costs are unallocated expenses.

Pensions and Other Postretirement Benefit Plans

Net periodic benefit cost for pension plans totaled $195 million in 2018, $201 million in 2017 and $144 million in 2016. Net periodic benefit (credit) for other postretirement benefit plans was $(45) million in 2018, $(60) million in 2017 and $(88) million in 2016. Pension and other postretirement benefit plan information for financial reporting purposes is calculated using actuarial assumptions including a discount rate for plan benefit obligations and an expected rate of return on plan assets. The changes in net periodic benefit cost year over year for pension plans are largely attributable to changes in the discount rate affecting net loss amortization.

The Company reassesses its benefit plan assumptions on a regular basis. For both the pension and other postretirement benefit plans, the discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due. The discount rates for the Company's U.S. pension and other postretirement benefit plans ranged from 4.00% to 4.40% at December 31, 2018, compared with a range of 3.20% to 3.80% at December 31, 2017.

The expected rate of return for both the pension and other postretirement benefit plans represents the average rate of return to be earned on plan assets over the period the benefits included in the benefit obligation are to be paid. In developing the expected rate of return, the Company considers long-term compound annualized returns of historical market data, current market conditions and actual returns on the Company's plan assets. Using this reference information, the Company develops forward-looking return expectations for each asset category and a weighted-average expected long-term rate of return for a target portfolio allocated across these investment categories. The expected portfolio performance reflects the contribution of active management as appropriate. For 2019, the expected rate of return for the Company's U.S. pension and other postretirement benefit plans will range from 7.70% to 8.10%, compared to a range of 7.70% to 8.30% in 2018. The decrease is primarily due to a modest shift in asset

allocation.

The Company has established investment guidelines for its U.S. pension and other postretirement plans to create an asset allocation that is expected to deliver a rate of return sufficient to meet the long-term obligation of each

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plan, given an acceptable level of risk. The target investment portfolio of the Company's U.S. pension and other postretirement benefit plans is allocated 30% to 50% in U.S. equities, 15% to 30% in international equities, 30% to 45% in fixed-income investments, and up to 5% in cash and other investments. The portfolio's equity weighting is consistent with the long-term nature of the plans' benefit obligations. The expected annual standard deviation of returns of the target portfolio, which approximates 11%, reflects both the equity allocation and the diversification benefits among the asset classes in which the portfolio invests. For non-U.S. pension plans, the targeted investment portfolio varies based on the duration of pension liabilities and local government rules and regulations. Although a significant percentage of plan assets are invested in U.S. equities, concentration risk is mitigated through the use of strategies that are diversified within management guidelines.

Actuarial assumptions are based upon management's best estimates and judgment. A reasonably possible change of plus (minus) 25 basis points in the discount rate assumption, with other assumptions held constant, would have had an estimated $80 million favorable (unfavorable) impact on the Company's net periodic benefit cost in 2018. A reasonably possible change of plus (minus) 25 basis points in the expected rate of return assumption, with other assumptions held constant, would have had an estimated $50 million favorable (unfavorable) impact on Merck's net periodic benefit cost in 2018. Required funding obligations for 2019 relating to the Company's pension and other postretirement benefit plans are not expected to be material. The preceding hypothetical changes in the discount rate and expected rate of return assumptions would not impact the Company's funding requirements.

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

Restructuring Costs

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

Impairments of Long-Lived Assets

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

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

Goodwill represents the excess of the consideration transferred over the fair value of net assets of businesses acquired. Goodwill is assigned to reporting units and evaluated for impairment on at least an annual basis, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. Some of the factors considered in the assessment include general macroeconomic conditions, conditions specific to the industry and market, cost factors which could

have a significant effect on earnings or cash flows, the overall financial performance of the reporting unit,

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and whether there have been sustained declines in the Company's share price. If the Company concludes it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a quantitative fair value test is performed. If the carrying value of a reporting unit is greater than its fair value, a goodwill impairment charge will be recorded for the difference (up to the carrying value of goodwill).

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

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

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

Impairments of Investments

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

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

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

Taxes on Income

The Company's effective tax rate is based on pretax income, statutory tax rates and tax planning opportunities available in the various jurisdictions in which the Company operates. An estimated effective tax rate for a year is applied to the Company's quarterly operating results. In the event that there is a significant unusual or one-time item recognized, or expected to be recognized, in the Company's quarterly operating results, the tax attributable to that item would be separately calculated and recorded at the same time as the unusual or one-time item. The Company considers the resolution of prior year tax matters to be such items. Significant judgment is required in determining the

Company’s tax provision and in evaluating its tax positions. The recognition and measurement of a tax position is based on

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management's best judgment given the facts, circumstances and information available at the reporting date. The Company evaluates tax positions to determine whether the benefits of tax positions are more likely than not of being sustained upon audit based on the technical merits of the tax position. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely of being realized upon ultimate settlement in the financial statements. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit in the financial statements. If the more likely than not threshold is not met in the period for which a tax position is taken, the Company may subsequently recognize the benefit of that tax position if the tax matter is effectively settled, the statute of limitations expires, or if the more likely than not threshold is met in a subsequent period (see Note 16 to the consolidated financial statements).

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

Recently Issued Accounting Standards

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

Cautionary Factors That May Affect Future Results

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

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

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

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

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Item 8. Financial Statements and Supplementary Data.

(a) Financial Statements

The consolidated balance sheet of Merck & Co., Inc. and subsidiaries as of December 31, 2018 and 2017, and the related consolidated statements of income, of comprehensive income, of equity and of cash flows for each of the three years in the period ended December 31, 2018, the notes to consolidated financial statements, and the report dated February 27, 2019 of PricewaterhouseCoopers LLP, independent registered public accounting firm, are as follows:

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

	2018	2017	2016
Sales	$42,294	$40,122	$39,807
Costs, Expenses and Other			
Cost of sales	13,509	12,912	14,030
Selling, general and administrative	10,102	10,074	10,017
Research and development	9,752	10,339	10,261
Restructuring costs	632	776	651
Other (income) expense, net	(402)	(500)	189
	33,593	33,601	35,148
Income Before Taxes	8,701	6,521	4,659
Taxes on Income	2,508	4,103	718
Net Income	6,193	2,418	3,941
Less: Net (Loss) Income Attributable to Noncontrolling Interests	(27)	24	21
Net Income Attributable to Merck & Co., Inc.	$6,220	$2,394	$3,920
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	$2.34	$0.88	$1.42
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	$2.32	$0.87	$1.41

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

	2018	2017	2016
Net Income Attributable to Merck & Co., Inc.	$6,220	$2,394	$3,920
Other Comprehensive (Loss) Income Net of Taxes:			
Net unrealized gain (loss) on derivatives, net of reclassifications	297	(446)	(66)
Net unrealized loss on investments, net of reclassifications	(10)	(58)	(44)
Benefit plan net (loss) gain and prior service (cost) credit, net of amortization	(425)	419	(799)
Cumulative translation adjustment	(223)	401	(169)
	(361)	316	(1,078)
Comprehensive Income Attributable to Merck & Co., Inc.	$5,859	$2,710	$2,842

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

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

	2018	2017
Assets		
Current Assets		
Cash and cash equivalents	$7,965	$6,092
Short-term investments	899	2,406
Accounts receivable (net of allowance for doubtful accounts of $119 in 2018 and $159 in 2017)	7,071	6,873
Inventories (excludes inventories of $1,417 in 2018 and $1,187 in 2017 classified in Other assets - see Note 7)	5,440	5,096
Other current assets	4,500	4,299
Total current assets	25,875	24,766
Investments	6,233	12,125
Property, Plant and Equipment (at cost)		
Land	333	365
Buildings	11,486	11,726
Machinery, equipment and office furnishings	14,441	14,649
Construction in progress	3,355	2,301
	29,615	29,041
Less: accumulated depreciation	16,324	16,602
	13,291	12,439
Goodwill	18,253	18,284
Other Intangibles, Net	11,431	14,183
Other Assets	7,554	6,075
	$82,637	$87,872
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	$5,308	$3,057
Trade accounts payable	3,318	3,102
Accrued and other current liabilities	10,151	10,427
Income taxes payable	1,971	708
Dividends payable	1,458	1,320
Total current liabilities	22,206	18,614
Long-Term Debt	19,806	21,353
Deferred Income Taxes	1,702	2,219
Other Noncurrent Liabilities	12,041	11,117
Merck & Co., Inc. Stockholders' Equity		
Common stock, $0.50 par value		
Authorized - 6,500,000,000 shares	1,788	1,788
Issued - 3,577,103,522 shares in 2018 and 2017		
Other paid-in capital	38,808	39,902
Retained earnings	42,579	41,350
Accumulated other comprehensive loss	(5,545)	(4,910)
	77,630	78,130
Less treasury stock, at cost: 984,543,979 shares in 2018 and 880,491,914 shares in 2017	50,929	43,794

Total Merck & Co., Inc. stockholders' equity	26,701	34,336
Noncontrolling Interests	181	233
Total equity	26,882	34,569
	$82,637	$87,872

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

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

	Common Stock	Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock	Non-controlling Interests	Total
Balance January 1, 2016	$1,788	$40,222	$45,348	$ (4,148)	$(38,534)	$ 91	$44,767
Net income attributable to Merck & Co., Inc.	—	—	3,920	—	—	—	3,920
Other comprehensive loss, net of taxes	—	—	—	(1,078)	—	—	(1,078)
Cash dividends declared on common stock ($1.85 per share)	—	—	(5,135)	—	—	—	(5,135)
Treasury stock shares purchased	—	—	—	—	(3,434)	—	(3,434)
Acquisition of The StayWell Company LLC	—	—	—	—	—	124	124
Net income attributable to noncontrolling interests	—	—	—	—	—	21	21
Distributions attributable to noncontrolling interests	—	—	—	—	—	(16)	(16)
Share-based compensation plans and other	—	(283)	—	—	1,422	—	1,139
Balance December 31, 2016	1,788	39,939	44,133	(5,226)	(40,546)	220	40,308
Net income attributable to Merck & Co., Inc.	—	—	2,394	—	—	—	2,394
Other comprehensive income, net of taxes	—	—	—	316	—	—	316
Cash dividends declared on common stock ($1.89 per share)	—	—	(5,177)	—	—	—	(5,177)
Treasury stock shares purchased	—	—	—	—	(4,014)	—	(4,014)
Acquisition of Vallée S.A.	—	—	—	—	—	7	7
Net income attributable to noncontrolling interests	—	—	—	—	—	24	24
Distributions attributable to noncontrolling interests	—	—	—	—	—	(18)	(18)
Share-based compensation plans and other	—	(37)	—	—	766	—	729
Balance December 31, 2017	1,788	39,902	41,350	(4,910)	(43,794)	233	34,569
Net income attributable to Merck & Co., Inc.	—	—	6,220	—	—	—	6,220
Adoption of new accounting standards (see Note 2)	—	—	322	(274)	—	—	48
Other comprehensive loss, net of taxes	—	—	—	(361)	—	—	(361)
Cash dividends declared on common stock ($1.99 per share)	—	—	(5,313)	—	—	—	(5,313)
Treasury stock shares purchased	—	(1,000)	—	—	(8,091)	—	(9,091)
Net loss attributable to noncontrolling interests	—	—	—	—	—	(27)	(27)

Distributions attributable to noncontrolling interests	—	—	—	—	—	(25)	(25)
Share-based compensation plans and other	—	(94)	—	—	956	—	862
Balance December 31, 2018	$1,788	$38,808	$42,579	$ (5,545)	$(50,929)	$ 181	$26,882

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

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

	2018	2017	2016
Cash Flows from Operating Activities			
Net income	$6,193	$2,418	$3,941
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	4,519	4,676	5,471
Intangible asset impairment charges	296	646	3,948
Charge for future payments related to collaboration license options	650	500	—
Provisional charge for one-time transition tax related to the enactment of U.S. tax legislation	—	5,347	—
Charge related to the settlement of worldwide Keytruda patent litigation	—	—	625
Deferred income taxes	(509)	(2,621)	(1,521)
Share-based compensation	348	312	300
Other	978	190	213
Net changes in assets and liabilities:			
Accounts receivable	(418)	297	(619)
Inventories	(911)	(145)	206
Trade accounts payable	230	254	278
Accrued and other current liabilities	(341)	(922)	(2,018)
Income taxes payable	827	(3,291)	124
Noncurrent liabilities	(266)	(123)	(809)
Other	(674)	(1,087)	237
Net Cash Provided by Operating Activities	10,922	6,451	10,376
Cash Flows from Investing Activities			
Capital expenditures	(2,615)	(1,888)	(1,614)
Purchases of securities and other investments	(7,994)	(10,739)	(15,651)
Proceeds from sales of securities and other investments	15,252	15,664	14,353
Acquisitions, net of cash acquired	(431)	(396)	(780)
Other	102	38	482
Net Cash Provided by (Used in) Investing Activities	4,314	2,679	(3,210)
Cash Flows from Financing Activities			
Net change in short-term borrowings	5,124	(26)	—
Payments on debt	(4,287)	(1,103)	(2,386)
Proceeds from issuance of debt	—	—	1,079
Purchases of treasury stock	(9,091)	(4,014)	(3,434)
Dividends paid to stockholders	(5,172)	(5,167)	(5,124)
Proceeds from exercise of stock options	591	499	939
Other	(325)	(195)	(118)
Net Cash Used in Financing Activities	(13,160)	(10,006)	(9,044)
Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash	(205)	457	(131)
Net Increase (Decrease) in Cash, Cash Equivalents and Restricted Cash	1,871	(419)	(2,009)
Cash, Cash Equivalents and Restricted Cash at Beginning of Year (includes $4 million of restricted cash at January 1, 2018 included in Other Assets)	6,096	6,515	8,524
Cash, Cash Equivalents and Restricted Cash at End of Year (includes $2 million of restricted cash at December 31, 2018 included in Other Assets)	$7,967	$6,096	$6,515

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

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

1. Nature of Operations

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

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. On December 31, 2016, Merck and Sanofi Pasteur S.A. (Sanofi) terminated their equally-owned joint venture, Sanofi Pasteur MSD (SPMSD), which developed and marketed vaccines in Europe. In 2017, Merck began recording vaccine sales and incurring costs as a result of operating its vaccines business in the European markets that were previously part of the SPMSD joint venture, which was accounted for as an equity method affiliate.

The Animal Health segment discovers, develops, manufactures and markets animal health products, including pharmaceutical and vaccine products, for the prevention, treatment and control of disease in all major livestock and companion animal species, which the Company sells to veterinarians, distributors and animal producers.

The Healthcare Services segment provides services and solutions that focus on engagement, health analytics and clinical services to improve the value of care delivered to patients.

The Alliances segment primarily includes activity from the Company's relationship with AstraZeneca LP related to sales of Nexium and Prilosec, which concluded in 2018 (see Note 9).

2. Summary of Accounting Policies

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

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

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definition of a business under the acquisition method of accounting, the transaction will be accounted for as an acquisition of assets rather than a business combination and, therefore, no goodwill will be recorded. In an asset acquisition, acquired in-process research and development (IPR&D) with no alternative future use is charged to expense and contingent consideration is not recognized at the acquisition date.

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

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

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

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

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

Revenue Recognition — On January 1, 2018, the Company adopted ASU 2014-09, Revenue from Contracts with Customers, and subsequent amendments (ASC 606 or new guidance), using the modified retrospective method. Merck applied the new guidance to all contracts with customers within the scope of the standard that were in effect on January 1, 2018 and recognized the cumulative effect of initially applying the new guidance as an adjustment to the opening balance of retained earnings (see “Recently Adopted Accounting Standards” below). Comparative information for prior periods has not been restated and continues to be reported under the accounting standards in effect for those periods.

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The new guidance requires an entity to recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration that it expects to be entitled to in exchange for those goods or services. The new guidance introduces a 5-step model to recognize revenue when or as control is transferred: identify the contract with a customer, identify the performance obligations in the contract, determine the transaction price, allocate the transaction price to the performance obligations in the contract, and recognize revenue when or as the performance obligations are satisfied. Changes to the Company's revenue recognition policy as a result of adopting ASC 606 are described below. See Note 19 for disaggregated revenue disclosures.

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

The vast majority of revenues from sales of products are recognized at a point in time when control of the goods is transferred to the customer, which the Company has determined is when title and risks and rewards of ownership transfer to the customer and the Company is entitled to payment. Certain Merck entities, including U.S. entities, have contract terms under which control of the goods passes to the customer upon shipment; however, either pursuant to the terms of the contract or as a business practice, Merck retains responsibility for goods lost or damaged in transit. Prior to the adoption of the new standard, Merck would recognize revenue for these entities upon delivery of the goods. Under the new guidance, the Company is now recognizing revenue at time of shipment for these entities.

The Company recognizes revenue from the sales of vaccines to the Federal government for placement into vaccine stockpiles in accordance with Securities and Exchange Commission (SEC) Interpretation, Commission Guidance Regarding Accounting for Sales of Vaccines and BioTerror Countermeasures to the Federal Government for Placement into the Pediatric Vaccine Stockpile or the Strategic National Stockpile. This interpretation allows companies to recognize revenue for sales of vaccines into U.S. government stockpiles even though these sales might not meet the criteria for revenue recognition under other accounting guidance.

For businesses within the Company's Healthcare Services segment and certain services in the Animal Health segment, revenue is recognized over time, generally ratably over the contract term as services are provided. These service revenues are not material.

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

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

The U.S. provision for aggregate customer discounts covering chargebacks and rebates was $10.7 billion in 2018, $10.7 billion in 2017 and $9.7 billion in 2016. Chargebacks are discounts that occur when a contracted customer purchases through an intermediary wholesaler. The contracted customer generally purchases product from the wholesaler at its contracted price plus a mark-up. The wholesaler, in turn, charges the Company back for the difference between the price initially paid by the wholesaler and the contract price paid to the wholesaler by the customer. The provision for chargebacks is based on expected sell-through levels by the Company's wholesale customers to contracted customers, as well as estimated wholesaler inventory levels. Rebates are amounts owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. The Company uses historical customer segment utilization mix, sales forecasts, changes to product mix and price, inventory levels in the distribution channel,

government pricing calculations and prior payment history in order to estimate the expected provision. Amounts accrued for aggregate customer discounts

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are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal and state agencies, and other customers to the amounts accrued. The accrued balances relative to the provisions for chargebacks and rebates included in Accounts receivable and Accrued and other current liabilities were $245 million and $2.4 billion, respectively, at December 31, 2018 and were $198 million and $2.4 billion, respectively, at December 31, 2017.

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

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

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

The following table provides the effects of adopting ASC 606 on the Consolidated Statement of Income:

Year Ended December 31, 2018	As Reported	Effects of Adopting ASC 606	Amounts Without Adoption of ASC 606
Sales	$ 42,294	$ (2)	$ 42,292
Cost of sales	13,509	(6)	13,503
Income before taxes	8,701	4	8,705
Taxes on income	2,508	1	2,509
Net income attributable to Merck & Co., Inc.	6,220	3	6,223

The following table provides the effects of adopting ASC 606 on the Consolidated Balance Sheet:

December 31, 2018	As Reported	Effects of Adopting ASC 606	Amounts Without Adoption of ASC 606
Assets			
Accounts receivable	$ 7,071	$ (13)	$ 7,058
Inventories	5,440	7	5,447
Liabilities			
Accrued and other current liabilities	10,151	(3)	10,148
Income taxes payable	1,971	(1)	1,970
Equity			
Retained earnings	42,579	(2)	42,577

Depreciation — Depreciation is provided over the estimated useful lives of the assets, principally using the straight-line method. For tax purposes, accelerated tax methods are used. The estimated useful lives primarily range from 25 to 45 years for Buildings, and from 3 to 15 years for Machinery, equipment and office furnishings. Depreciation expense was $1.4 billion in 2018, $1.5 billion in 2017 and $1.6 billion in 2016.

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Advertising and Promotion Costs — Advertising and promotion costs are expensed as incurred. The Company recorded advertising and promotion expenses of $2.1 billion, $2.2 billion and $2.1 billion in 2018, 2017 and 2016, respectively.
Software Capitalization — The Company capitalizes certain costs incurred in connection with obtaining or developing internal-use software including external direct costs of material and services, and payroll costs for employees directly involved with the software development. Capitalized software costs are included in Property, plant and equipment and amortized beginning when the software project is substantially complete and the asset is ready for its intended use. Capitalized software costs associated with projects that are being amortized over 6 to 10 years (including the Company's on-going multi-year implementation of an enterprise-wide resource planning system) were $439 million and $449 million, net of accumulated amortization at December 31, 2018 and 2017, respectively. All other capitalized software costs are being amortized over periods ranging from 3 to 5 years. Costs incurred during the preliminary project stage and post-implementation stage, as well as maintenance and training costs, are expensed as incurred.
Goodwill — Goodwill represents the excess of the consideration transferred over the fair value of net assets of businesses acquired. Goodwill is assigned to reporting units and evaluated for impairment on at least an annual basis, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If the Company concludes it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a quantitative fair value test is performed. If the carrying value of a reporting unit is greater than its fair value, a goodwill impairment charge will be recorded for the difference (up to the carrying value of goodwill).
Acquired Intangibles — Acquired intangibles include products and product rights, tradenames and patents, which are initially recorded at fair value, assigned an estimated useful life, and amortized primarily on a straight-line basis over their estimated useful lives ranging from 2 to 20 years (see Note 8). The Company periodically evaluates whether current facts or circumstances indicate that the carrying values of its acquired intangibles may not be recoverable. If such circumstances are determined to exist, an estimate of the undiscounted future cash flows of these assets, or appropriate asset groupings, is compared to the carrying value to determine whether an impairment exists. If the asset is determined to be impaired, the loss is measured based on the difference between the carrying value of the intangible asset and its fair value, which is determined based on the net present value of estimated future cash flows.
Acquired In-Process Research and Development — Acquired IPR&D that the Company acquires through business combinations represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. The amounts are capitalized and are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, Merck will make a determination as to the then-useful life of the intangible asset, generally determined by the period in which the substantial majority of the cash flows are expected to be generated, and begin amortization. The Company tests IPR&D for impairment at least annually, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the IPR&D intangible asset is less than its carrying amount. If the Company concludes it is more likely than not that the fair value is less than the carrying amount, a quantitative test that compares the fair value of the IPR&D intangible asset with its carrying value is performed. If the fair value is less than the carrying amount, an impairment loss is recognized in operating results.
Contingent Consideration — Certain of the Company's business acquisitions involve the potential for future payment of consideration that is contingent upon the achievement of performance milestones, including product development milestones and royalty payments on future product sales. The fair value of contingent consideration liabilities is determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date, at each reporting period, the contingent consideration liability is remeasured at current fair value with changes (either expense or income) recorded in earnings.
Research and Development — Research and development is expensed as incurred. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the

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

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

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

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

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

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

Taxes on Income — Deferred taxes are recognized for the future tax effects of temporary differences between financial and income tax reporting based on enacted tax laws and rates. The Company evaluates tax positions to determine whether the benefits of tax positions are more likely than not of being sustained upon audit based on the technical merits of the tax position. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely of being realized upon ultimate settlement in the financial statements. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit in the financial statements. The Company recognizes interest

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and penalties associated with uncertain tax positions as a component of Taxes on income in the Consolidated Statement of Income.

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

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

Recently Adopted Accounting Standards — In May 2014, the Financial Accounting Standards Board (FASB) issued amended accounting guidance on revenue recognition (ASU 2014-09) that applies to all contracts with customers. The objective of the new guidance is to improve comparability of revenue recognition practices across entities and to provide more useful information to users of financial statements through improved disclosure requirements. The new standard permits two methods of adoption: retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of adopting the guidance being recognized at the date of initial application (modified retrospective method). The new standard was effective as of January 1, 2018 and was adopted using the modified retrospective method. The Company recorded a cumulative-effect adjustment upon adoption increasing Retained earnings by $5 million.

In January 2016, the FASB issued revised guidance for the accounting and reporting of financial instruments (ASU 2016-01) and in 2018 issued related technical corrections (ASU 2018-03). The new guidance requires that equity investments with readily determinable fair values currently classified as available for sale be measured at fair value with changes in fair value recognized in net income. The Company has elected to measure equity investments without readily determinable fair values at cost, adjusted for subsequent observable price changes and less impairments, which will be recognized in net income. The new guidance also changed certain disclosure requirements. ASU 2016-01 was effective as of January 1, 2018 and was adopted using a modified retrospective approach. The Company recorded a cumulative-effect adjustment upon adoption increasing Retained earnings by $8 million. ASU 2018-03 was also adopted as of January 1, 2018 on a prospective basis and did not result in any additional impacts upon adoption.

In October 2016, the FASB issued guidance on the accounting for the income tax consequences of intra-entity transfers of assets other than inventory (ASU 2016-16). The new guidance requires the recognition of the income tax consequences of an intra-entity transfer of an asset (with the exception of inventory) when the intra-entity transfer occurs, replacing the prohibition against doing so. The current exception to defer the recognition of any tax impact on the transfer of inventory within the consolidated entity until it is sold to a third party remains unaffected. The new standard was effective as of January 1, 2018 and was adopted using a modified retrospective approach. The Company recorded a cumulative-effect adjustment upon adoption increasing Retained earnings by $54 million with a corresponding decrease to Deferred Income Taxes.

In August 2017, the FASB issued new guidance on hedge accounting (ASU 2017-12) that is intended to more closely align hedge accounting with companies' risk management strategies, simplify the application of hedge accounting, and increase transparency as to the scope and results of hedging programs. The new guidance makes more financial and nonfinancial hedging strategies eligible for hedge accounting, amends the presentation and disclosure requirements, and changes how companies assess effectiveness. The Company elected to early adopt this guidance as of January 1, 2018 on a modified retrospective basis. The new guidance was applied to all existing hedges as of the adoption date. For fair value hedges of interest rate risk outstanding as of the date of adoption, the Company recorded a cumulative-effect adjustment upon adoption to the basis adjustment on the hedged item resulting from applying the

benchmark component of the coupon guidance. This adjustment decreased Retained earnings by $11 million. Also, in

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accordance with the transition provisions of ASU 2017-12, the Company was required to eliminate the separate measurement of ineffectiveness for its cash flow hedging instruments existing as of the adoption date through a cumulative-effect adjustment to retained earnings; however, all such amounts were de minimis.

In February 2018, the FASB issued new guidance to address a narrow-scope financial reporting issue that arose as a consequence of the Tax Cuts and Jobs Act of 2017 (TCJA) (ASU 2018-02). Existing guidance requires that deferred tax liabilities and assets be adjusted for a change in tax laws or rates with the effect included in income from continuing operations in the reporting period that includes the enactment date. That guidance is applicable even in situations in which the related income tax effects of items in accumulated other comprehensive income were originally recognized in other comprehensive income (rather than in net income), such as amounts related to benefit plans and hedging activity. As a result, the tax effects of items within accumulated other comprehensive income do not reflect the appropriate tax rate (the difference is referred to as stranded tax effects). The new guidance allows for a reclassification of the stranded tax effects resulting from the TCJA from accumulated other comprehensive income to retained earnings thereby eliminating these stranded tax effects. The Company elected to early adopt the new guidance in the first quarter of 2018 and reclassified the stranded income tax effects of the TCJA, increasing Accumulated other comprehensive loss in the amount of $266 million with a corresponding increase to Retained earnings (see Note 18). The Company's policy for releasing disproportionate income tax effects from Accumulated other comprehensive loss is to utilize the item-by-item approach.

The impact of adopting the above standards is as follows:

($ in millions)	ASU 2014-09 (Revenue)	ASU 2016-01 (Financial Instruments)	ASU 2016-16 (Intra-Entity Transfers of Assets Other than Inventory)	ASU 2017-12 (Derivatives and Hedging)	ASU 2018-02 (Reclassification of Certain Tax Effects)	Total
Assets - Increase (Decrease)						
Accounts receivable	$ 5					$ 5
Liabilities - Increase (Decrease)						
Income Taxes Payable				(3)		(3)
Debt				14		14
Deferred Income Taxes			(54)			(54)
Equity - Increase (Decrease)						
Retained earnings	5	8	54	(11)	266	322
Accumulated other comprehensive loss		(8)			(266)	(274)

In March 2017, the FASB issued amended guidance on retirement benefits (ASU 2017-07) related to net periodic benefit cost for defined benefit plans that requires entities to (1) disaggregate the current service cost component from the other components of net benefit cost and present it with other employee compensation costs in the income statement within operations if such a subtotal is presented; (2) present the other components of net benefit cost separately in the income statement and outside of income from operations; and (3) only capitalize the service cost component when applicable. The Company adopted the new standard as of January 1, 2018 using a retrospective transition method as to the requirement for separate presentation in the income statement of service costs and other components, and a prospective transition method as to the requirement to limit the capitalization of benefit costs to the service cost component. The Company utilized a practical expedient that permits it to use the amounts disclosed in its pension and other postretirement benefit plan note for the prior comparative periods as the estimation basis for applying the retrospective presentation requirements. Upon adoption, net periodic benefit cost (credit) other than service cost of $(512) million and $(531) million for the years ended December 31, 2017 and 2016, respectively, was reclassified to Other (income) expense, net from the previous classification within Cost of sales, Selling, general and administrative expenses and Research and development expenses (see Note 15).

In August 2016, the FASB issued guidance on the classification of certain cash receipts and payments in the statement of cash flows intended to reduce diversity in practice. The Company adopted the new standard effective as of January 1, 2018 using a retrospective application. There were no changes to the presentation of the Consolidated Statement of Cash Flows in the previous years presented as a result of adopting the new standard.

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In November 2016, the FASB issued guidance requiring that amounts generally described as restricted cash and restricted cash equivalents be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The new standard was effective as of January 1, 2018 and was adopted using a retrospective application. The adoption of the new guidance did not have a material effect on the Company's Consolidated Statement of Cash Flows.

In May 2017, the FASB issued guidance clarifying when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The Company adopted the new standard effective as of January 1, 2018 and will apply the new guidance to future share-based payment award modifications should they occur.

In January 2017, the FASB issued guidance that provides for the elimination of Step 2 from the goodwill impairment test. Under the new guidance, impairment charges are recognized to the extent the carrying amount of a reporting unit exceeds its fair value with certain limitations. The Company adopted the new standard in the fourth quarter of 2018 and applied the new guidance for purposes of its fourth quarter goodwill impairment assessment. The adoption of the new guidance had an immaterial effect on its consolidated financial statements.

Recently Issued Accounting Standards Not Yet Adopted —In February 2016, the FASB issued new accounting guidance for the accounting and reporting of leases and subsequently issued several updates to the new guidance. The new guidance requires that lessees recognize a right-of-use asset and a lease liability recorded on the balance sheet for each of its leases (other than leases that meet the definition of a short-term lease). Leases will be classified as either operating or finance. Operating leases will result in straight-line expense in the income statement (similar to current operating leases) while finance leases will result in more expense being recognized in the earlier years of the lease term (similar to current capital leases). The new standard is effective as of January 1, 2019 and will be adopted using a modified retrospective approach. Merck will elect the transition method that allows for application of the standard at the adoption date rather than at the beginning of the earliest comparative period presented in the financial statements. The Company intends to elect available practical expedients. Merck has implemented a lease accounting software application and has completed data validation of the Company's portfolio of leases, including its assessment of potential embedded leases. Upon adoption, the Company anticipates it will recognize approximately $1 billion of additional assets and corresponding liabilities on its consolidated balance sheet, subject to finalization.

In June 2016, the FASB issued amended guidance on the accounting for credit losses on financial instruments. The guidance introduces an expected loss model for estimating credit losses, replacing the incurred loss model. The new guidance also changes the impairment model for available-for-sale debt securities, requiring the use of an allowance to record estimated credit losses (and subsequent recoveries). The new guidance is effective for interim and annual periods beginning in 2020, with earlier application permitted in 2019. The new guidance is to be applied on a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings in the beginning of the period of adoption. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In April 2018, the FASB issued new guidance on the accounting for costs incurred to implement a cloud computing arrangement that is considered a service arrangement. The new guidance requires the capitalization of such costs, aligning it with the accounting for costs associated with developing or obtaining internal-use software. The new guidance is effective for interim and annual periods beginning in 2020. Early adoption is permitted, including adoption in any interim period. Prospective adoption for eligible costs incurred on or after the date of adoption or retrospective adoption is permitted. The Company is currently evaluating the impact of adoption on its consolidated financial statements and may elect to early adopt this guidance.

In November 2018, the FASB issued new guidance for collaborative arrangements intended to reduce diversity in practice by clarifying whether certain transactions between collaborative arrangement participants should be accounted for under the recently issued guidance on revenue recognition (ASC 606). The new guidance is effective for interim and annual periods beginning in 2020. Early adoption is permitted, including adoption in any interim period. The new guidance is to be applied on a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings. The Company is currently evaluating the impact of adoption on its consolidated financial

statements.

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3. Acquisitions, Divestitures, Research Collaborations and License Agreements

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

Recently Announced Transaction

In December 2018, Merck and privately held Antelliq Group (Antelliq) signed a definitive agreement under which Merck will acquire Antelliq from funds advised by BC Partners. Antelliq is a leader in digital animal identification, traceability and monitoring solutions. These solutions help veterinarians, farmers and pet owners gather critical data to improve management, health and well-being of livestock and pets. Merck will make a cash payment of approximately €2.1 billion (approximately $2.4 billion based on exchange rates at the time of the announcement) to acquire all outstanding shares of Antelliq and will assume Antelliq's debt of €1.1 billion (approximately $1.3 billion), which it intends to repay shortly after the closing of the acquisition. The transaction is subject to clearance by antitrust and competition law authorities and other customary closing conditions, and is expected to close in the second quarter of 2019.

2018 Transactions

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

In June 2018, Merck acquired Viralytics Limited (Viralytics), an Australian publicly traded company focused on oncolytic immunotherapy treatments for a range of cancers, for AUD 502 million ($378 million). The transaction provided Merck with full rights to Cavatak (V937, formerly CVA21), Viralytics's investigational oncolytic immunotherapy. Cavatak is based on Viralytics's proprietary formulation of an oncolytic virus (Coxsackievirus Type A21) that has been shown to preferentially infect and kill cancer cells. Cavatak is currently being evaluated in multiple Phase 1 and Phase 2 clinical trials, both as an intratumoral and intravenous agent, including in combination with Keytruda. Under a previous agreement between Merck and Viralytics, a study is investigating the use of the Keytruda and Cavatak combination in melanoma, prostate, lung and bladder cancers. The transaction was accounted for as an acquisition of an asset. Merck recorded net assets of $34 million (primarily cash) at the acquisition date and Research and development expenses of $344 million in 2018 related to the transaction. There are no future contingent payments associated with the acquisition.

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

2017 Transactions

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

transaction was accounted for as an acquisition of an asset and the upfront payment is reflected within Research and development expenses in 2017.

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

In March 2017, Merck acquired a controlling interest in Vallée S.A. (Vallée), a leading privately held producer of animal health products in Brazil. Vallée has an extensive portfolio of products spanning parasiticides, anti-infectives and vaccines that include products for livestock, horses, and companion animals. Under the terms of the agreement, Merck acquired 93.5% of the shares of Vallée for $358 million. Of the total purchase price, $176 million was placed into escrow pending resolution of certain contingent items. The transaction was accounted for as an acquisition of a business. Merck recognized intangible assets of $297 million related to currently marketed products, net deferred tax liabilities of $102 million, other net assets of $32 million and noncontrolling interest of $25 million. In addition, the Company recorded liabilities of $37 million for contingencies identified at the acquisition date and corresponding indemnification assets of $37 million, representing the amounts to be reimbursed to Merck if and when the contingent liabilities are paid. The excess of the consideration transferred over the fair value of net assets acquired of $156 million was recorded as goodwill. The goodwill was allocated to the Animal Health segment and is not deductible for tax purposes. The estimated fair values of identifiable intangible assets related to currently marketed products were determined using an income approach. The probability-adjusted future net cash flows of each product were discounted to present value utilizing a discount rate of 15.5%. Actual cash flows are likely to be different than those assumed. The intangible assets related to currently marketed products are being amortized over their estimated useful lives of 15 years. In the fourth quarter of 2017, Merck acquired an additional 4.5% interest in Vallée for $18 million, which reduced the noncontrolling interest related to Vallée.

2016 Transactions

In July 2016, Merck acquired Afferent Pharmaceuticals (Afferent), a privately held pharmaceutical company focused on the development of therapeutic candidates targeting the P2X3 receptor for the treatment of common, poorly-managed, neurogenic conditions. Afferent's lead investigational candidate, MK-7264 (formerly AF-219), gefapixant, is a selective, non-narcotic, orally-administered P2X3 antagonist being evaluated for the treatment of refractory, chronic cough and for the treatment of endometriosis-related pain. Total consideration transferred of $510 million included cash paid for outstanding Afferent shares of $487 million, as well as share-based compensation payments to settle equity awards attributable to precombination service and cash paid for transaction costs on behalf of Afferent. In addition, former Afferent shareholders are eligible to receive a total of up to an additional $750 million contingent upon the attainment of certain clinical development and commercial milestones for multiple indications and candidates, including MK-7264. This transaction was accounted for as an acquisition of a business. The Company determined the fair value of the contingent consideration was $223 million at the acquisition date utilizing a probability-weighted estimated cash flow stream using an appropriate discount rate dependent on the nature and timing of the milestone payment. Merck recognized an intangible asset for IPR&D of $832 million, net deferred tax liabilities of $258 million, and other net assets of $29 million (primarily consisting of cash acquired). The excess of the consideration transferred over the fair value of net assets acquired of $130 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair value of the identifiable intangible asset related to IPR&D was determined using an income approach. The asset's probability-adjusted future net cash flows were discounted to present value using a discount rate of 11.5%. Actual cash flows are likely to be different than those assumed. In 2018, as a result of the achievement of a clinical development milestone, Merck made a $175 million payment, which was accrued for at estimated fair value at the time of acquisition as noted above. The contingent consideration liability was then remeasured at current fair value at each subsequent reporting period until payment was made (see Note 6).

In June 2016, Merck and Moderna Therapeutics (Moderna) entered into a strategic collaboration and license agreement to develop and commercialize novel messenger RNA (mRNA)-based personalized cancer vaccines. The development program will entail multiple studies in several types of cancer and include the evaluation of mRNA-based personalized cancer vaccines in combination with Merck's Keytruda. Pursuant to the terms of the agreement, Merck made an upfront cash payment to Moderna of $200 million, which was recorded in Research and development expenses. Following human proof of concept studies, Merck has the right to elect to make an additional payment to Moderna. If Merck exercises this right, the two companies will then equally share costs and profits under a

worldwide collaboration for the development of personalized cancer vaccines. Moderna will have the right to elect to co-promote the personalized cancer vaccines in the United States. The agreement entails exclusivity around combinations with Keytruda. Moderna and Merck each have the ability to combine mRNA-based personalized cancer vaccines with other (non-PD-1) agents.

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In January 2016, Merck acquired IOmet Pharma Ltd (IOmet), a privately held UK-based drug discovery company focused on the development of innovative medicines for the treatment of cancer, with a particular emphasis on the fields of cancer immunotherapy and cancer metabolism. The acquisition provided Merck with IOmet's preclinical pipeline of IDO (indoleamine-2,3-dioxygenase 1), TDO (tryptophan-2,3-dioxygenase), and dual-acting IDO/TDO inhibitors. The transaction was accounted for as an acquisition of a business. Total purchase consideration in the transaction included a cash payment of $150 million and future additional milestone payments of up to $250 million contingent upon certain clinical and regulatory milestones being achieved. The Company determined the fair value of the contingent consideration was $94 million at the acquisition date utilizing a probability-weighted estimated cash flow stream adjusted for the expected timing of each payment utilizing a discount rate of 10.5%. Merck recognized intangible assets for IPR&D of $155 million and net deferred tax assets of $32 million. The excess of the consideration transferred over the fair value of net assets acquired of $57 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair values of the identifiable intangible assets related to IPR&D were determined using an income approach. The assets' probability-adjusted future net cash flows were discounted to present value also using a discount rate of 10.5%. Actual cash flows are likely to be different than those assumed. In 2017, as a result of the achievement of a clinical development milestone, Merck made a $100 million payment, which was accrued for at estimated fair value at the time of acquisition as noted above. The contingent consideration liability was then remeasured at current fair value at each subsequent reporting period until payment was made (see Note 6).

Remicade/Simponi

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

4. Collaborative Arrangements

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

AstraZeneca

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

Gross profits from Lynparza and selumetinib product sales generated through monotherapies or combination therapies are shared equally. Merck will fund all development and commercialization costs of Keytruda in combination with Lynparza or selumetinib. AstraZeneca will fund all development and commercialization costs of Imfinzi in combination with Lynparza or selumetinib. AstraZeneca is currently the principal on Lynparza sales transactions. Merck records its share of Lynparza product sales, net of cost of sales and commercialization costs, as alliance

revenue within the Pharmaceutical segment and its share of development costs associated with the collaboration as part of Research

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and development expenses. Reimbursements received from AstraZeneca for research and development expenses are recognized as reductions to Research and development costs.

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

In 2018, Merck determined it was probable that annual sales of Lynparza in the future would trigger three sales-based milestone payments from Merck to AstraZeneca aggregating $600 million. Accordingly, in 2018, Merck recorded $600 million of liabilities and a corresponding increase to the intangible asset related to Lynparza, and recognized $58 million of cumulative amortization expense within Cost of sales. During 2018, one of the sales-based milestones was triggered, resulting in a $150 million payment to AstraZeneca. In 2018, Merck made an additional $100 million sales-based milestone payment, which was accrued for in 2017 when the Company deemed to the payment to be probable. The remaining $3.4 billion of potential future sales-based milestone payments have not yet been accrued as they are not deemed by the Company to be probable at this time.

In 2018, Lynparza received approval in the United States for the treatment of certain patients with metastatic breast cancer and for use in the first-line maintenance setting for advanced ovarian cancer, triggering capitalized milestone payments of $140 million in the aggregate from Merck to AstraZeneca. Potential future regulatory milestone payments of $1.76 billion remain under the agreement.

The asset balance related to Lynparza (which includes capitalized sales-based and regulatory milestone payments) was $743 million at December 31, 2018 and is included in Other Assets on the Consolidated Balance Sheet. The amount is being amortized over its estimated useful life through 2028 as supported by projected future cash flows, subject to impairment testing.

Summarized information related to this collaboration is as follows:

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

December 31	2018	2017
Receivables from AstraZeneca included in Other current assets	$52	$ 12
Payables to AstraZeneca included in Accrued and other current liabilities [3]	405	543
Payables to AstraZeneca included Other Noncurrent Liabilities [3]	250	100

[1] Represents amortization of capitalized milestone payments.

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

[3] Includes accrued milestone and license option payments.

Eisai

In March 2018, Merck and Eisai announced a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima, an orally available tyrosine kinase inhibitor discovered by Eisai. Under the agreement, Merck and Eisai will develop and commercialize Lenvima jointly, both as monotherapy and in combination with Merck’s anti-PD-1 therapy, Keytruda. Eisai records Lenvima product sales globally (Eisai is the principal on Lenvima sales transactions), and Merck and Eisai share gross profits equally. Merck records its share of Lenvima product sales, net of cost of sales and commercialization costs, as alliance revenue. Expenses incurred during co-development, including for studies evaluating Lenvima as monotherapy, are shared equally by the two companies and reflected in Research and development expenses.

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Under the agreement, Merck made an upfront payment to Eisai of $750 million and will make payments of up to $650 million for certain option rights through 2021 (of which $325 million will be paid in March 2019, $200 million is expected to be paid in 2020 and $125 million is expected to be paid in 2021). The Company recorded an aggregate charge of $1.4 billion in Research and development expenses in 2018 related to the upfront payment and future option payments. In addition, the agreement provides for Eisai to receive up to $385 million associated with the achievement of certain clinical and regulatory milestones and up to $3.97 billion for the achievement of milestones associated with sales of Lenvima.

In 2018, Merck determined it was probable that annual sales of Lenvima in the future would trigger three sales-based milestone payments from Merck to Eisai aggregating $268 million. Accordingly, in 2018, Merck recorded $268 million of liabilities and a corresponding increase to the intangible asset related to Lenvima, and recognized $24 million of cumulative amortization expense within Cost of sales. The remaining $3.71 billion of potential future sales-based milestone payments have not yet been accrued as they are not deemed by the Company to be probable at this time.

In 2018, Lenvima was approved for the treatment of patients with unresectable hepatocellular carcinoma in the United States, the European Union, Japan and China, triggering capitalized milestone payments to Eisai of $250 million in the aggregate. Potential future regulatory milestone payments of $135 million remain under the agreement.

The asset balance related to Lenvima (which includes capitalized sales-based and regulatory milestone payments) was $479 million at December 31, 2018 and is included in Other Assets on the Consolidated Balance Sheet. The amount is being amortized over its estimated useful life through 2026 as supported by projected future cash flows, subject to impairment testing.

Summarized information related to this collaboration is as follows:

Year Ended December 31	2018
Alliance revenue	$ 149
Cost of sales [1]	39
Selling, general and administrative	13
Research and development [2]	1,489

December 31	2018
Receivables from Eisai included in Other current assets	$ 71
Payables to Eisai included in Accrued and other current liabilities [3]	375
Payables to Eisai included in Other Noncurrent Liabilities [3]	543

[1] Represents amortization of capitalized milestone payments.

[2] Includes $1.4 billion related to the upfront payment and future option payments.

[3] Includes accrued milestone and option payments.

Bayer AG

In 2014, the Company entered into a worldwide clinical development collaboration with Bayer AG (Bayer) to market and develop soluble guanylate cyclase (sGC) modulators including Bayer's Adempas, which is approved to treat pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension. The two companies have implemented a joint development and commercialization strategy. The collaboration also includes clinical development of Bayer's vericiguat, which is in Phase 3 trials for worsening heart failure, as well as opt-in rights for other early-stage sGC compounds in development by Bayer. Merck in turn made available its early-stage sGC compounds under similar terms. Under the agreement, Bayer leads commercialization of Adempas in the Americas, while Merck leads commercialization in the rest of the world. For vericiguat and other potential opt-in products, Bayer will lead commercialization in the rest of world and Merck will lead in the Americas. For all products and candidates included in the agreement, both companies will share in development costs and profits on sales and will have the right to co-promote in territories where they are not the lead. In 2016, Merck began promoting and distributing Adempas in Europe. Transition from Bayer in other Merck territories, including Japan, continued in 2017. Revenue from Adempas includes sales in Merck's marketing territories, as well as Merck's share of profits from the sale of Adempas in Bayer's

marketing territories.

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In 2018, Merck determined it was probable that annual worldwide sales of Adempas in the future would trigger a $375 million sales-based milestone payment from Merck to Bayer. Accordingly, Merck recorded a $375 million noncurrent liability and a corresponding increase to the intangible asset related to Adempas, and recognized $106 million of cumulative amortization expense within Cost of sales. In 2018, the Company made a $350 million milestone payment to Bayer, which was accrued for in 2016 when Merck deemed the payment to be probable. There is an additional $400 million potential future sales-based milestone payment that has not yet been accrued as it is not deemed by the Company to be probable at this time.

The intangible asset balance related to Adempas (which includes the remaining acquired intangible asset balance, as well as capitalized sales-based milestone payments) was $1.0 billion at December 31, 2018 and is included in Other Intangibles, Net on the Consolidated Balance Sheet. The amount is being amortized over its estimated useful life through 2027 as supported by projected future cash flows, subject to impairment testing.

Summarized information related to this collaboration is as follows:

Years Ended December 31	2018	2017	2016
Net product sales recorded by Merck	$190	$149	$ 88
Merck’s profit share from sales in Bayer’s marketing territories	139	151	81
Total sales	329	300	169
Cost of sales [1]	216	99	133
Selling, general and administrative	35	27	26
Research and development	127	101	82

December 31	2018	2017
Receivables from Bayer included in Other current assets	$32	$ 33
Payables to Bayer included in Accrued and other current liabilities [2]	—	350
Payables to Bayer included in Other Noncurrent Liabilities [2]	375	—

[1] Includes amortization of intangible assets.

[2] Includes accrued milestone payments.

Aggregate amortization expense related to capitalized license costs recorded within Cost of sales was $186 million in 2018, $39 million in 2017 and $30 million in 2016. The estimated aggregate amortization expense for each of the next five years is as follows: 2019, $196 million; 2020, $193 million; 2021, $191 million; 2022, $187 million; 2023, $181 million.

5. Restructuring

In 2010 and 2013, the Company commenced actions under global restructuring programs designed to streamline its cost structure. The actions under these programs include the elimination of positions in sales, administrative and headquarters organizations, as well as the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities. The Company also continues to reduce its global real estate footprint and improve the efficiency of its manufacturing and supply network.

The Company recorded total pretax costs of $658 million in 2018, $927 million in 2017 and $1.1 billion in 2016 related to restructuring program activities. Since inception of the programs through December 31, 2018, Merck has recorded total pretax accumulated costs of approximately $14.1 billion and eliminated approximately 45,510 positions comprised of employee separations, as well as the elimination of contractors and vacant positions. The Company estimates that approximately two-thirds of the cumulative pretax costs are cash outlays, primarily related to employee separation expense. Approximately one-third of the cumulative pretax costs are non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested. The Company has substantially completed the actions under these programs.

For segment reporting, restructuring charges are unallocated expenses.

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

	Separation Costs	Accelerated Depreciation	Other	Total
Year Ended December 31, 2018				
Cost of sales	$ —	$ 10	$ 11	$ 21
Selling, general and administrative	—	2	1	3
Research and development	—	(13)	15	2
Restructuring costs	473	—	159	632
	$ 473	$ (1)	$ 186	$ 658
Year Ended December 31, 2017				
Cost of sales	$ —	$ 52	$ 86	$ 138
Selling, general and administrative	—	2	—	2
Research and development	—	6	5	11
Restructuring costs	552	—	224	776
	$ 552	$ 60	$ 315	$ 927
Year Ended December 31, 2016				
Cost of sales	$ —	$ 77	$ 104	$ 181
Selling, general and administrative	—	8	87	95
Research and development	—	142	—	142
Restructuring costs	216	—	435	651
	$ 216	$ 227	$ 626	$ 1,069

Separation costs are associated with actual headcount reductions, as well as those headcount reductions which were probable and could be reasonably estimated. Positions eliminated under restructuring program activities were approximately 2,160 in 2018, 2,450 in 2017 and 2,625 in 2016.

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

Other activity in 2018, 2017 and 2016 includes $141 million, $267 million and $409 million, respectively, of asset abandonment, shut-down and other related costs. Additionally, other activity includes certain employee-related costs associated with pension and other postretirement benefit plans (see Note 14) and share-based compensation. Other activity also reflects net pretax losses resulting from sales of facilities and related assets of $151 million in 2016.

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

	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2017	$ 395	$ —	$ 146	$ 541
Expenses	552	60	315	927
(Payments) receipts, net	(328)	—	(394)	(722)
Non-cash activity	—	(60)	61	1
Restructuring reserves December 31, 2017	619	—	128	747
Expenses	473	(1)	186	658
(Payments) receipts, net	(649)	—	(238)	(887)
Non-cash activity	—	1	15	16
Restructuring reserves December 31, 2018 [1]	$ 443	$ —	$ 91	$ 534

(1) The remaining cash outlays are expected to be substantially completed by the end of 2020.

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6. Financial Instruments

Derivative Instruments and Hedging Activities

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

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

Foreign Currency Risk Management

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

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

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

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

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

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The Company also uses forward exchange contracts to hedge its net investment in foreign operations against movements in exchange rates. The forward contracts are designated as hedges of the net investment in a foreign operation. The Company hedges a portion of the net investment in certain of its foreign operations. The unrealized gains or losses on these contracts are recorded in foreign currency translation adjustment within OCI, and remain in AOCI until either the sale or complete or substantially complete liquidation of the subsidiary. The Company excludes certain portions of the change in fair value of its derivative instruments from the assessment of hedge effectiveness (excluded component). Changes in fair value of the excluded components are recognized in OCI. In accordance with the new guidance adopted on January 1, 2018 (see Note 2), the Company has elected to recognize in earnings the initial value of the excluded component on a straight-line basis over the life of the derivative instrument, rather than using the mark-to-market approach. The cash flows from these contracts are reported as investing activities in the Consolidated Statement of Cash Flows.

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

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

	Amount of Pretax (Gain) Loss Recognized in Other Comprehensive Income [1]			Amount of Pretax (Gain) Loss Recognized in Other (income) expense, net for Amounts Excluded from Effectiveness Testing		
Years Ended December 31	2018	2017	2016	2018	2017	2016
Net Investment Hedging Relationships						
Foreign exchange contracts	$(18)	$—	$2	$(11)	$—	$(1)
Euro-denominated notes	(183)	520	(193)	—	—	—

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

Interest Rate Risk Management

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

In May 2018, four interest rate swaps with notional amounts aggregating $1.0 billion matured. These swaps effectively converted the Company's $1.0 billion, 1.30% fixed-rate notes due 2018 to variable rate debt. In December 2018, in connection with the early repayment of debt, the Company settled three interest rate swaps with notional amounts aggregating $550 million. These swaps effectively converted a portion of the Company's $1.25 billion, 5.00% notes due 2019 to variable rate debt. At December 31, 2018, the Company was a party to 19 pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes as detailed in the table below.

Debt Instrument	2018 Par Value of Debt	Number of Interest Rate Swaps	Total Swap Notional Amount

		Held	
1.85% notes due 2020	$1,250	5	$ 1,250
3.875% notes due 2021	1,150	5	1,150
2.40% notes due 2022	1,000	4	1,000
2.35% notes due 2022	1,250	5	1,250

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

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

	Carrying Amount of Hedged Liabilities		Cumulative Amount of Fair Value Hedging Adjustment Increase (Decrease) Included in the Carrying Amount	
	2018	2017	2018	2017
Balance Sheet Line Item in which Hedged Item is Included				
Loans payable and current portion of long-term debt	$ —	$ 983	$ —	$ (17)
Long-Term Debt [1]	4,560	6,146	(82)	(41)

[1] Amounts include hedging adjustment gains related to discontinued hedging relationships of $11 million at December 31, 2017.

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

		2018			2017		
	Balance Sheet Caption	Fair Value of Derivative Asset	Fair Value of Derivative Liability	U.S. Dollar Notional	Fair Value of Derivative Asset	Fair Value of Derivative Liability	U.S. Dollar Notional
Derivatives Designated as Hedging Instruments							
Interest rate swap contracts	Other assets	$—	$ —	$ —	$2	$ —	$ 550
Interest rate swap contracts	Accrued and other current liabilities	—	—	—	—	3	1,000
Interest rate swap contracts	Other noncurrent liabilities	—	81	4,650	—	52	4,650
Foreign exchange contracts	Other current assets	263	—	6,222	51	—	4,216
Foreign exchange contracts	Other assets	75	—	2,655	38	—	1,936
Foreign exchange contracts	Accrued and other current liabilities	—	7	774	—	71	2,014
Foreign exchange contracts	Other noncurrent liabilities	—	1	89	—	1	20
		$338	$ 89	$ 14,390	$91	$ 127	$ 14,386
Derivatives Not Designated as Hedging Instruments							
Foreign exchange contracts	Other current assets	$116	$ —	$ 5,430	$39	$ —	$ 3,778
Foreign exchange contracts	Accrued and other current liabilities	—	71	9,922	—	90	7,431
		$116	$ 71	$ 15,352	$39	$ 90	$ 11,209
		$454	$ 160	$ 29,742	$130	$ 217	$ 25,595

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

	2018		2017	
	Asset	Liability	Asset	Liability
Gross amounts recognized in the consolidated balance sheet	$454	$ 160	$130	$ 217
Gross amount subject to offset in master netting arrangements not offset in the consolidated balance sheet	(121)	(121)	(94)	(94)
Cash collateral received	(107)	—	(3)	—
Net amounts	$226	$ 39	$33	$ 123

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

	Sales			Other (income) expense, net [1]			Other comprehensive income (loss)		
Years Ended December 31	2018	2017	2016	2018	2017	2016	2018	2017	2016
Financial Statement Line Items in which Effects of Fair Value or Cash Flow Hedges are Recorded	$42,294	$40,122	$39,807	$(402)	(500)	189	$(361)	$316	$(1,078)
(Gain) loss on fair value hedging relationships									
Interest rate swap contracts									
Hedged items	—	—	—	(27)	(48)	(29)	—	—	—
Derivatives designated as hedging instruments	—	—	—	50	12	(35)	—	—	—
Impact of cash flow hedging relationships									
Foreign exchange contracts									
Amount of gain (loss) recognized in OCI on derivatives	—	—	—	—	—	—	228	(562)	210
(Decrease) increase in Sales as a result of AOCI reclassifications	(160)	138	311	—	—	—	160	(138)	(311)

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

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

		Amount of Derivative Pretax (Gain) Loss Recognized in Income		
Years Ended December 31	Income Statement Caption	2018	2017	2016
Derivatives Not Designated as Hedging Instruments				
Foreign exchange contracts [1]	Other (income) expense, net	$ (260)	$ 110	$ 132
Foreign exchange contracts [2]	Sales	(8)	(3)	—

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

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

At December 31, 2018, the Company estimates $186 million of pretax net unrealized gains on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from AOCI to Sales. The amount ultimately reclassified to Sales may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.

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Investments in Debt and Equity Securities

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

	2018				2017			
	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses
Corporate notes and bonds	$4,920	$ 4,985	$ 3	$ (68)	$9,806	$ 9,837	$ 9	$ (40)
Asset-backed securities	1,275	1,285	1	(11)	1,542	1,548	1	(7)
U.S. government and agency securities	892	895	2	(5)	2,042	2,059	—	(17)
Foreign government bonds	166	167	—	(1)	733	739	—	(6)
Mortgage-backed securities	8	8	—	—	626	634	1	(9)
Commercial paper	—	—	—	—	159	159	—	—
Total debt securities	7,261	7,340	6	(85)	14,908	14,976	11	(79)
Publicly traded equity securities [1]	456				275	265	16	(6)
Total debt and publicly traded equity securities	$7,717				$15,183	$ 15,241	$ 27	$ (85)

[1] Pursuant to the adoption of ASU 2016-01 (see Note 2), beginning on January 1, 2018, changes in the fair value of publicly traded equity securities are recognized in net income. Unrealized net losses of $35 million were recognized in Other (income) expense, net during 2018 on equity securities still held at December 31, 2018.

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

Available-for-sale debt securities included in Short-term investments totaled $894 million at December 31, 2018. Of the remaining debt securities, $5.8 billion mature within five years. At December 31, 2018 and 2017, there were no debt securities pledged as collateral.

Fair Value Measurements

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

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

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

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

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

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

	Fair Value Measurements Using				Fair Value Measurements Using			
	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
	2018				2017			
Assets								
Investments								
Corporate notes and bonds	$—	$ 4,835	$ —	$4,835	$—	$ 9,678	$ —	$9,678
Asset-backed securities [1]	—	1,253	—	1,253	—	1,476	—	1,476
U.S. government and agency securities	—	731	—	731	68	1,767	—	1,835
Foreign government bonds	—	166	—	166	—	732	—	732
Mortgage-backed securities	—	—	—	—	—	547	—	547
Commercial paper	—	—	—	—	—	159	—	159
Publicly traded equity securities	147	—	—	147	104	—	—	104
	147	6,985	—	7,132	172	14,359	—	14,531
Other assets [2]								
U.S. government and agency securities	55	106	—	161	—	207	—	207
Corporate notes and bonds	—	85	—	85	—	128	—	128
Asset-backed securities [1]	—	22	—	22	—	66	—	66
Mortgage-backed securities	—	8	—	8	—	79	—	79
Foreign government bonds	—	—	—	—	—	1	—	1
Publicly traded equity securities	309	—	—	309	171	—	—	171
	364	221	—	585	171	481	—	652
Derivative assets [3]								
Forward exchange contracts	—	241	—	241	—	48	—	48
Purchased currency options	—	213	—	213	—	80	—	80
Interest rate swaps	—	—	—	—	—	2	—	2
	—	454	—	454	—	130	—	130
Total assets	$511	$ 7,660	$ —	$8,171	$343	$ 14,970	$ —	$15,313
Liabilities								
Other liabilities								
Contingent consideration	$—	$ —	$ 788	$788	$—	$ —	$ 935	$935
Derivative liabilities [3]								
Interest rate swaps	—	81	—	81	—	55	—	55
Forward exchange contracts	—	74	—	74	—	162	—	162
Written currency options	—	5	—	5	—	—	—	—
	—	160	—	160	—	217	—	217
Total liabilities	$—	$ 160	$ 788	$948	$—	$ 217	$ 935	$1,152

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

weighted-average lives of primarily 5 years or less.

(2) Investments included in other assets are restricted as to use, primarily for the payment of benefits under employee benefit plans.

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

There were no transfers between Level 1 and Level 2 during 2018. As of December 31, 2018, Cash and cash equivalents of $8.0 billion include $7.2 billion of cash equivalents (which would be considered Level 2 in the fair value hierarchy).

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Contingent Consideration

Summarized information about the changes in liabilities for contingent consideration is as follows:

	2018	2017
Fair value January 1	$935	$891
Changes in estimated fair value [1]	89	141
Additions	8	3
Payments	(244)	(100)
Fair value December 31 [2]	$788	$935

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

[2] Balance at December 31, 2018 includes $89 million recorded as a current liability for amounts expected to be paid within the next 12 months.

The changes in the estimated fair value of liabilities for contingent consideration in 2018 were largely attributable to increases in the liabilities recorded in connection with the termination of the SPMSD joint venture in 2016 (see Note 9), partially offset by the reversal of a liability related to the discontinuation of a program obtained in connection with the acquisition of SmartCells (see Note 8). The changes in the estimated fair value of liabilities for contingent consideration in 2017 primarily relate to increases in the liabilities recorded in connection with the termination of the SPMSD joint venture and the clinical progression of a program related to the Afferent acquisition. The payments of contingent consideration in 2018 include $175 million related to the achievement of a clinical milestone in connection with the acquisition of Afferent (see Note 3). The remaining payments in 2018 relate to liabilities recorded in connection with the termination of the SPMSD joint venture. The payments of contingent consideration in 2017 relate to the achievement of a clinical milestone in connection with the acquisition of IOmet (see Note 3).

Other Fair Value Measurements

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

The estimated fair value of loans payable and long-term debt (including current portion) at December 31, 2018, was $25.6 billion compared with a carrying value of $25.1 billion and at December 31, 2017, was $25.6 billion compared with a carrying value of $24.4 billion. Fair value was estimated using recent observable market prices and would be considered Level 2 in the fair value hierarchy.

Concentrations of Credit Risk

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

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

The Company’s customers with the largest accounts receivable balances are: McKesson Corporation, AmerisourceBergen Corporation and Cardinal Health, Inc., which represented, in aggregate, approximately 40% of total accounts receivable at December 31, 2018. The Company monitors the creditworthiness of its customers to which it grants credit terms in the normal course of business. Bad debts have been minimal. The Company does not normally require collateral or other security to support credit sales.

Derivative financial instruments are executed under International Swaps and Derivatives Association master agreements. The master agreements with several of the Company’s financial institution counterparties also include

credit support annexes. These annexes contain provisions that require collateral to be exchanged depending on the value of the derivative assets and liabilities, the Company's credit rating, and the credit rating of the counterparty. Cash collateral received by the Company from various counterparties was $107 million and $3 million at December 31, 2018

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and 2017, respectively. The obligation to return such collateral is recorded in Accrued and other current liabilities. No cash collateral was advanced by the Company to counterparties as of December 31, 2018 or 2017.

7. Inventories

Inventories at December 31 consisted of:

	2018	2017
Finished goods	$1,658	$1,334
Raw materials and work in process	5,004	4,703
Supplies	194	201
Total (approximates current cost)	6,856	6,238
Increase to LIFO costs	1	45
	$6,857	$6,283
Recognized as:		
Inventories	$5,440	$5,096
Other assets	1,417	1,187

Inventories valued under the LIFO method comprised approximately $2.5 billion and $2.2 billion at December 31, 2018 and 2017, respectively. Amounts recognized as Other assets are comprised almost entirely of raw materials and work in process inventories. At December 31, 2018 and 2017, these amounts included $1.4 billion and $1.1 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included $7 million and $80 million at December 31, 2018 and 2017, respectively, of inventories produced in preparation for product launches.

8. Goodwill and Other Intangibles

The following table summarizes goodwill activity by segment:

	Pharmaceutical	Animal Health	All Other	Total
Balance January 1, 2017	$ 16,075	$1,708	$379	$18,162
Acquisitions	—	177	—	177
Impairments	—	—	(38)	(38)
Other [1]	(9)	(8)	—	(17)
Balance December 31, 2017 [2]	16,066	1,877	341	18,284
Acquisitions	—	17	24	41
Impairments	—	—	(144)	(144)
Other [1]	96	(24)	—	72
Balance December 31, 2018 [2]	$ 16,162	$1,870	$221	$18,253

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

[2] Accumulated goodwill impairment losses at December 31, 2018 and 2017 were $369 million and $225 million, respectively.

The additions to goodwill within the Animal Health segment in 2017 primarily relate to the acquisition of Vallée (see Note 3). The impairments of goodwill within other non-reportable segments in 2018 and 2017 relate to certain businesses within the Healthcare Services segment.

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Other intangibles at December 31 consisted of:

	2018			2017		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Products and product rights	$46,615	$ 37,585	$9,030	$46,693	$ 34,950	$11,743
IPR&D	1,064	—	1,064	1,194	—	1,194
Tradenames	209	107	102	209	97	112
Other	2,403	1,168	1,235	2,035	901	1,134
	$50,291	$ 38,860	$11,431	$50,131	$ 35,948	$14,183

Acquired intangibles include products and product rights, tradenames and patents, which are initially recorded at fair value, assigned an estimated useful life, and amortized primarily on a straight-line basis over their estimated useful lives. Some of the Company's more significant acquired intangibles related to marketed products (included in products and product rights above) at December 31, 2018 include Zerbaxa, $2.7 billion; Sivextro, $833 million; Implanon/Nexplanon $470 million; Dificid, $395 million; Gardasil/Gardasil 9, $384 million; Bridion, $275 million; and Simponi, $194 million. The Company has an intangible asset related to Adempas as a result of a collaboration with Bayer (see Note 4) that had a carrying value of $1.0 billion at December 31, 2018 reflected in "Other" in the table above.

During 2017 and 2016, the Company recorded impairment charges related to marketed products and other intangibles of $58 million and $347 million, respectively, within Cost of sales. During 2017, the Company recorded an intangible asset impairment charge of $47 million related to Intron A, a treatment for certain types of cancers. Sales of Intron A are being adversely affected by the availability of new therapeutic options. In 2017, sales of Intron A in the United States eroded more rapidly than previously anticipated by the Company, which led to changes in the cash flow assumptions for Intron A. These revisions to cash flows indicated that the Intron A intangible asset value was not fully recoverable on an undiscounted cash flows basis. The Company utilized market participant assumptions to determine its best estimate of the fair value of the intangible asset related to Intron A that, when compared with its related carrying value, resulted in the impairment charge noted above. The remaining charges in 2017 relate to the impairment of customer relationship, tradename and developed technology intangibles for certain businesses in the Healthcare Services segment. In 2016, the Company lowered its cash flow projections for Zontivity, a product for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction or with peripheral arterial disease, following several business decisions that reduced sales expectations for Zontivity in the United States and Europe. The Company utilized market participant assumptions and considered several different scenarios to determine the fair value of the intangible asset related to Zontivity that, when compared with its related carrying value, resulted in an impairment charge of $252 million. Also during 2016, the Company wrote-off $95 million that had been capitalized in connection with in-licensed products Grastek and Ragwitek, allergy immunotherapy tablets that, for business reasons, the Company returned to the licensor.

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

In 2018, the Company recorded $152 million of IPR&D impairment charges within Research and development expenses. Of this amount, $139 million relates to the write-off of the remaining intangible asset balance for a program obtained in connection with the SmartCells acquisition following a decision to terminate the program due to product development issues. The Company previously recorded an impairment charge in 2016 for the other programs obtained in connection with the acquisition of SmartCells as described below. The discontinuation of this clinical development program resulted in a reversal of the related liability for contingent consideration of $60 million (see Note 6).

In 2017, the Company recorded $483 million of IPR&D impairment charges. Of this amount, $240 million resulted from a strategic decision to discontinue the development of the investigational combination regimens

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MK-3682B (grazoprevir/ruzasvir/uprifosbuvir) and MK-3682C (ruzasvir/uprifosbuvir) for the treatment of chronic hepatitis C virus (HCV) infection. This decision was made based on a review of available Phase 2 efficacy data and in consideration of the evolving marketplace and the growing number of treatment options available for patients with chronic HCV infection, including Zepatier, which is marketed by the Company for the treatment of adult patients with chronic HCV infection. As a result of this decision, the Company recorded an IPR&D impairment charge to write-off the remaining intangible asset related to uprifosbuvir. The Company had previously recorded an impairment charge for uprifosbuvir in 2016 as described below. The IPR&D impairment charges in 2017 also include a charge of $226 million to write-off the intangible asset related to verubecestat, an investigational small molecule inhibitor of the beta-site amyloid precursor protein cleaving enzyme 1 (BACE1), resulting from a decision in February 2018 to stop a Phase 3 study evaluating verubecestat in people with prodromal Alzheimer's disease. The decision to stop the study followed a recommendation by the external Data Monitoring Committee (eDMC), which assessed overall benefit/risk during an interim safety analysis. The eDMC concluded that it was unlikely that positive benefit/risk could be established if the trial continued.

During 2016, the Company recorded $3.6 billion of IPR&D impairment charges. Of this amount, $2.9 billion related to the clinical development program for uprifosbuvir, a nucleotide prodrug that was being evaluated for the treatment of HCV. The Company determined that changes to the product profile, as well as changes to Merck's expectations for pricing and the market opportunity, taken together constituted a triggering event that required the Company to evaluate the uprifosbuvir intangible asset for impairment. Utilizing market participant assumptions, and considering different scenarios, the Company concluded that its best estimate of the fair value of the intangible asset related to uprifosbuvir was $240 million, resulting in the recognition of the impairment charge noted above. The IPR&D impairment charges in 2016 also included charges of $180 million and $143 million related to the discontinuation of programs obtained in connection with the acquisitions of cCAM Biotherapeutics Ltd. and OncoEthix, respectively, resulting from unfavorable efficacy data. An additional $72 million related to programs obtained in connection with the SmartCells acquisition following a decision to terminate the lead compound due to a lack of efficacy and to pursue a back-up compound which reduced projected future cash flows. The IPR&D impairment charges in 2016 also included $112 million related to an in-licensed program for house dust mite allergies that, for business reasons, was returned to the licensor. The remaining IPR&D impairment charges in 2016 primarily related to deprioritized pipeline programs that were deemed to have no alternative use during the period, including a $79 million impairment charge for an investigational candidate for contraception. The discontinuation or delay of certain of these clinical development programs resulted in a reduction of the related liabilities for contingent consideration.

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

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

Aggregate amortization expense primarily recorded within Cost of sales was $2.9 billion in 2018, $3.2 billion in 2017 and $3.8 billion in 2016. The estimated aggregate amortization expense for each of the next five years is as follows: 2019, $1.5 billion; 2020, $1.2 billion; 2021, $1.1 billion; 2022, $1.1 billion; 2023, $1.1 billion.

9. Joint Ventures and Other Equity Method Affiliates

Sanofi Pasteur MSD

In 1994, Merck and Pasteur Mérieux Connaught (now Sanofi Pasteur S.A.) established an equally-owned joint venture (SPMSD) to market vaccines in Europe and to collaborate in the development of combination vaccines for distribution in Europe. Joint venture vaccine sales were $1.0 billion for 2016.

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On December 31, 2016, Merck and Sanofi Pasteur (Sanofi) terminated SPMSD and ended their joint vaccines operations in Europe. Under the terms of the termination, Merck acquired Sanofi's 50% interest in SPMSD in exchange for consideration of $657 million comprised of cash, as well as future royalties of 11.5% on net sales of all Merck products that were previously sold by the joint venture through December 31, 2024, which the Company determined had a fair value of $416 million on the date of termination. The Company accounted for this transaction as a step acquisition, which required that Merck remeasure its ownership interest (previously accounted for as an equity method investment) to fair value at the acquisition date. Merck in turn sold to Sanofi its intellectual property rights held by SPMSD in exchange for consideration of $596 million comprised of cash and future royalties of 11.5% on net sales of all Sanofi products that were previously sold by the joint venture through December 31, 2024, which the Company determined had a fair value of $302 million on the date of termination. Excluded from this arrangement are sales of Vaxelis (a jointly developed pediatric hexavalent combination vaccine that was approved by the European Commission in 2016 and by the U.S. Food and Drug Administration in 2018). The European marketing rights for Vaxelis were transferred to a separate equally-owned joint venture between Sanofi and Merck.

The net impact of the termination of the SPMSD joint venture is as follows:

Products and product rights (8-year useful life)	$936
Accounts receivable	133
Income taxes payable	(221)
Deferred income tax liabilities	(147)
Other, net	47
Net assets acquired	748
Consideration payable to Sanofi, net	(392)
Derecognition of Merck's previously held equity investment in SPMSD	(183)
Increase in net assets	173
Merck's share of restructuring costs related to the termination	(77)
Net gain on termination of SPMSD joint venture [(1)]	$96

[(1)] Recorded in Other (income) expense, net.

The estimated fair values of identifiable intangible assets related to products and product rights were determined using an income approach through which fair value is estimated based on market participant expectations of each asset's projected net cash flows. The projected net cash flows were then discounted to present value utilizing a discount rate of 11.5%. Actual cash flows are likely to be different than those assumed. Of the amount recorded for products and product rights, $468 million related to Gardasil/Gardasil 9.

The fair value of liabilities for contingent consideration related to Merck's future royalty payments to Sanofi of $416 million (reflected in the consideration payable to Sanofi, net, in the table above) was determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows and a risk-adjusted discount rate of 8% used to present value the cash flows. Changes in the inputs could result in a different fair value measurement.

Based on an existing accounting policy election, Merck did not record the $302 million estimated fair value of contingent future royalties to be received from Sanofi on the sale of Sanofi products, but rather is recognizing such amounts as sales occur and the royalties are earned.

The Company incurred $24 million of transaction costs related to the termination of SPMSD included in Selling, general and administrative expenses in 2016.

Pro forma financial information for this transaction has not been presented as the results are not significant when compared with the Company's financial results.

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AstraZeneca LP

In 1982, Merck entered into an agreement with Astra AB (Astra) to develop and market Astra products under a royalty-bearing license. In 1993, Merck's total sales of Astra products reached a level that triggered the first step in the establishment of a joint venture business carried on by Astra Merck Inc. (AMI), in which Merck and Astra each owned a 50% share. This joint venture, formed in 1994, developed and marketed most of Astra's new prescription medicines in the United States. In 1998, Merck and Astra completed a restructuring of the ownership and operations of the joint venture whereby Merck acquired Astra's interest in AMI, renamed KBI Inc. (KBI), and contributed KBI's operating assets to a new U.S. limited partnership, Astra Pharmaceuticals L.P. (the Partnership), in exchange for a 1% limited partner interest. Astra contributed the net assets of its wholly owned subsidiary, Astra USA, Inc., to the Partnership in exchange for a 99% general partner interest. The Partnership, renamed AstraZeneca LP (AZLP) upon Astra's 1999 merger with Zeneca Group Plc, became the exclusive distributor of the products for which KBI retained rights. Merck earned revenue based on sales of KBI products and earned certain Partnership returns from AZLP.

On June 30, 2014, AstraZeneca exercised its option to purchase Merck's interest in KBI (and redeem Merck's remaining interest in AZLP). A portion of the exercise price, which remained subject to a true-up in 2018 based on actual sales of Nexium and Prilosec from closing in 2014 to June 2018, was deferred and recognized as income as the contingency was eliminated as sales occurred. Once the deferred income amount was fully recognized, in 2016, the Company began recognizing income and a corresponding receivable for amounts that would be due to Merck from AstraZeneca based on the sales performance of Nexium and Prilosec subject to the true-up in June 2018. The Company recognized income of $99 million in 2018, $232 million in 2017, and $98 million in 2016 (including $5 million of remaining deferred income) in Other (income) expense, net related to these amounts. In January 2019, the Company received $424 million from AstraZeneca in settlement of these amounts, which concludes the transactions related to the 2014 termination of Company's relationship with AZLP.

10. Loans Payable, Long-Term Debt and Other Commitments

Loans payable at December 31, 2018 included $5.1 billion of commercial paper and $149 million of long-dated notes that are subject to repayment at the option of the holders. Loans payable at December 31, 2017 included $3.0 billion of notes due in 2018 and $73 million of long-dated notes that are subject to repayment at the option of the holders. The weighted-average interest rate of commercial paper borrowings was 2.09% and 0.85% for the years ended December 31, 2018 and 2017, respectively.

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Long-term debt at December 31 consisted of:

	2018	2017
2.75% notes due 2025	$2,490	$2,488
3.70% notes due 2045	1,974	1,973
2.80% notes due 2023	1,745	1,744
4.15% notes due 2043	1,237	1,237
1.85% notes due 2020	1,231	1,232
2.35% notes due 2022	1,214	1,220
1.125% euro-denominated notes due 2021	1,134	1,185
3.875% notes due 2021	1,132	1,140
1.875% euro-denominated notes due 2026	1,127	1,178
2.40% notes due 2022	983	993
6.50% notes due 2033	726	729
Floating-rate notes due 2020	699	699
0.50% euro-denominated notes due 2024	565	591
1.375% euro-denominated notes due 2036	561	587
2.50% euro-denominated notes due 2034	560	585
3.60% notes due 2042	490	489
6.55% notes due 2037	414	415
5.75% notes due 2036	338	338
5.95% debentures due 2028	306	306
5.85% notes due 2039	270	270
6.40% debentures due 2028	250	250
6.30% debentures due 2026	135	135
5.00% notes due 2019	—	1,260
Other	225	309
	$19,806	$21,353

Other (as presented in the table above) includes $223 million and $300 million at December 31, 2018 and 2017, respectively, of borrowings at variable rates that resulted in effective interest rates of 2.27% and 1.42% for 2018 and 2017, respectively.

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

In December 2018, the Company exercised a make-whole provision on its $1.25 billion, 5.00% notes due 2019 and repaid this debt. In November 2017, the Company launched tender offers for certain outstanding notes and debentures. The Company paid $810 million in aggregate consideration (applicable purchase price together with accrued interest) to redeem $585 million principal amount of debt that was validly tendered in connection with the tender offers and recognized a loss on extinguishment of debt of $191 million in 2017.

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

Certain of the Company’s borrowings require that Merck comply with covenants and, at December 31, 2018, the Company was in compliance with these covenants.

The aggregate maturities of long-term debt for each of the next five years are as follows: 2019, no maturities; 2020, $1.9 billion; 2021, $2.3 billion; 2022, $2.2 billion; 2023, $1.7 billion.

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The Company has a $6.0 billion credit facility that matures in June 2023. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

Rental expense under operating leases, net of sublease income, was $322 million in 2018, $327 million in 2017 and $292 million in 2016. The minimum aggregate rental commitments under noncancellable leases are as follows: 2019, $188 million; 2020, $198 million; 2021, $150 million; 2022, $134 million; 2023, $84 million and thereafter, $243 million. The Company has no significant capital leases.

11. Contingencies and Environmental Liabilities

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

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

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

The Company's decision to obtain insurance coverage is dependent on market conditions, including cost and availability, existing at the time such decisions are made. The Company has evaluated its risks and has determined that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and, as such, has no insurance for most product liabilities effective August 1, 2004.

Product Liability Litigation

Fosamax

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving Fosamax (Fosamax Litigation). As of December 31, 2018, approximately 3,900 cases have been filed and either are pending or conditionally dismissed (as noted below) against Merck in either federal or state court. Plaintiffs in the vast majority of these cases generally allege that they sustained femur fractures and/or other bone injuries (Femur Fractures) in association with the use of Fosamax.

In March 2011, Merck submitted a Motion to Transfer to the Judicial Panel on Multidistrict Litigation (JPML) seeking to have all federal cases alleging Femur Fractures consolidated into one multidistrict litigation for coordinated pre-trial proceedings. All federal cases involving allegations of Femur Fracture have been or will be transferred to a multidistrict litigation in the District of New Jersey (Femur Fracture MDL). In the only bellwether case tried to date in the Femur Fracture MDL, Glynn v. Merck, the jury returned a verdict in Merck's favor. In addition, in June 2013, the Femur Fracture MDL court granted Merck's motion for judgment as a matter of law in the Glynn case and held that the plaintiff's failure to warn claim was preempted by federal law.

In August 2013, the Femur Fracture MDL court entered an order requiring plaintiffs in the Femur Fracture MDL to show cause why those cases asserting claims for a femur fracture injury that took place prior to September 14, 2010, should not be dismissed based on the court's preemption decision in the Glynn case. Pursuant to the show cause order, in March 2014, the Femur Fracture MDL court dismissed with prejudice approximately 650 cases on preemption grounds. Plaintiffs in approximately 515 of those cases appealed that decision to the U.S. Court of Appeals for the Third Circuit (Third Circuit). In March 2017, the Third Circuit issued a decision reversing the Femur Fracture MDL

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court's preemption ruling and remanding the appealed cases back to the Femur Fracture MDL court. Merck filed a petition for a writ of certiorari to the U.S. Supreme Court in August 2017, seeking review of the Third Circuit's decision. In December 2017, the Supreme Court invited the Solicitor General to file a brief in the case expressing the views of the United States, and in May 2018, the Solicitor General submitted a brief stating that the Third Circuit's decision was wrongly decided and recommended that the Supreme Court grant Merck's cert petition. The Supreme Court granted Merck's petition in June 2018, and an oral argument before the Supreme Court was held on January 7, 2019. The final decision on the Femur Fracture MDL court's preemption ruling is now pending before the Supreme Court.

Accordingly, as of December 31, 2018, nine cases were actively pending in the Femur Fracture MDL, and approximately 1,055 cases have either been dismissed without prejudice or administratively closed pending final resolution by the Supreme Court of the appeal of the Femur Fracture MDL court's preemption order.

As of December 31, 2018, approximately 2,555 cases alleging Femur Fractures have been filed in New Jersey state court and are pending before Judge James Hyland in Middlesex County. The parties selected an initial group of 30 cases to be reviewed through fact discovery. Two additional groups of 50 cases each to be reviewed through fact discovery were selected in November 2013 and March 2014, respectively. A further group of 25 cases to be reviewed through fact discovery was selected by Merck in July 2015, and Merck has continued to select additional cases to be reviewed through fact discovery from 2016 to the present.

As of December 31, 2018, approximately 275 cases alleging Femur Fractures have been filed and are pending in California state court. All of the Femur Fracture cases filed in California state court have been coordinated before a single judge in Orange County, California. In March 2014, the court directed that a group of 10 discovery pool cases be reviewed through fact discovery and subsequently scheduled the Galper v. Merck case, which plaintiffs selected, as the first trial. The Galper trial began in February 2015 and the jury returned a verdict in Merck's favor in April 2015, and plaintiff appealed that verdict to the California appellate court. In April 2017, the California appellate court issued a decision affirming the lower court's judgment in favor of Merck. The next Femur Fracture trial in California that was scheduled to begin in April 2016 was stayed at plaintiffs' request and a new trial date has not been set.

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

Discovery is ongoing in the Femur Fracture MDL and in state courts where Femur Fracture cases are pending and the Company intends to defend against these lawsuits.

Januvia/Janumet

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving Januvia and/or Janumet. As of December 31, 2018, Merck is aware of approximately 1,290 product users alleging that Januvia and/or Janumet caused the development of pancreatic cancer and other injuries.

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

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

Plaintiffs appealed in both forums. In November 2017, the U.S. Court of Appeals for the Ninth Circuit vacated the judgment and remanded for further discovery, which is ongoing. In November 2018, the California state appellate court reversed and remanded on similar grounds.

As of December 31, 2018, eight product users have claims pending against Merck in state courts other than California, including Illinois. In June 2017, the Illinois trial court denied Merck's motion for summary judgment based on federal preemption. Merck appealed, and the Illinois appellate court affirmed in December 2018. Merck intends to appeal that ruling.

In addition to the claims noted above, the Company has agreed to toll the statute of limitations for approximately 50 additional claims. The Company intends to continue defending against these lawsuits.

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Vioxx

As previously disclosed, Merck is a defendant in a lawsuit brought by the Attorney General of Utah alleging that Merck misrepresented the safety of Vioxx. The lawsuit is pending in Utah state court. Utah seeks damages and penalties under the Utah False Claims Act. A bench trial in this matter is currently scheduled for July 2019.

Propecia/Proscar

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving Propecia and/or Proscar. The lawsuits were filed in various federal courts and in state court in New Jersey. The federal lawsuits were then consolidated for pretrial purposes in a federal multidistrict litigation before Judge Brian Cogan of the Eastern District of New York. The matters pending in state court in New Jersey were consolidated before Judge Hyland in Middlesex County (NJ Coordinated Proceedings).

As previously disclosed, on April 9, 2018, Merck and the Plaintiffs' Executive Committee in the Propecia MDL and the Plaintiffs' Liaison Counsel in the NJ Coordinated Proceedings entered into an agreement to resolve the above mentioned Propecia/Proscar lawsuits for an aggregate amount of $4.3 million. The settlement was subject to certain contingencies, including 95% plaintiff participation and a per plaintiff clawback if the participation rate was less than 100%. The contingencies were satisfied and the settlement agreement was finalized. After the settlement, fewer than 25 cases remain pending in the United States.

The Company intends to defend against any remaining unsettled lawsuits.

Governmental Proceedings

As previously disclosed, the Company has learned that the Prosecution Office of Milan, Italy is investigating interactions between the Company's Italian subsidiary, certain employees of the subsidiary and certain Italian health care providers. The Company understands that this is part of a larger investigation involving engagements between various health care companies and those health care providers. The Company is cooperating with the investigation.

As previously disclosed, the United Kingdom (UK) Competition and Markets Authority (CMA) issued a Statement of Objections against the Company and MSD Sharp & Dohme Limited (MSD UK) in May 2017. In the Statement of Objections, the CMA alleges that MSD UK abused a dominant position through a discount program for Remicade over the period from March 2015 to February 2016. The Company and MSD UK are contesting the CMA's allegations.

As previously disclosed, the Company has received an investigative subpoena from the California Insurance Commissioner's Fraud Bureau (Bureau) seeking information from January 1, 2007 to the present related to the pricing and promotion of Cubicin. The Bureau is investigating whether Cubist Pharmaceuticals, Inc., which the Company acquired in 2015, unlawfully induced the presentation of false claims for Cubicin to private insurers under the California Insurance Code False Claims Act. The Company is cooperating with the investigation.

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

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

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Commercial and Other Litigation

Zetia Antitrust Litigation

As previously disclosed, Merck, MSD, Schering Corporation and MSP Singapore Company LLC (collectively, the Merck Defendants) are defendants in putative class action and opt-out lawsuits filed in 2018 on behalf of direct and indirect purchasers of Zetia alleging violations of federal and state antitrust laws, as well as other state statutory and common law causes of action. The cases have been consolidated for pretrial purposes in a federal multidistrict litigation before Judge Rebecca Beach Smith in the Eastern District of Virginia. On December 6, 2018, the court denied the Merck Defendants' motions to dismiss or stay the direct purchaser putative class actions pending bilateral arbitration. On February 6, 2019, the magistrate judge issued a report and recommendation recommending that the district judge grant in part and deny in part defendants' motions to dismiss on non-arbitration issues. On February 20, 2019, defendants and retailer opt-out plaintiffs filed objections to the report and recommendation. After responses are filed, the parties will await a decision from the district judge.

Rotavirus Vaccines Antitrust Litigation

As previously disclosed, MSD is a defendant in putative class action lawsuits filed in 2018 on behalf of direct purchasers of RotaTeq, alleging violations of federal antitrust laws. The cases were consolidated in the Eastern District of Pennsylvania. On January 23, 2019, the court denied MSD's motions to compel arbitration and to dismiss the consolidated complaint. On February 19, 2019, MSD appealed the court's order on arbitration to the Third Circuit, and on February 22, 2019, the court granted MSD's motion to vacate existing deadlines in the district court in light of the appeal.

Sales Force Litigation

As previously disclosed, in May 2013, Ms. Kelli Smith filed a complaint against the Company in the U.S. District Court for the District of New Jersey on behalf of herself and a putative class of female sales representatives and a putative sub-class of female sales representatives with children, claiming (a) discriminatory policies and practices in selection, promotion and advancement, (b) disparate pay, (c) differential treatment, (d) hostile work environment and (e) retaliation under federal and state discrimination laws. In January 2014, plaintiffs filed an amended complaint adding four additional named plaintiffs. In October 2014, the court denied the Company's motion to dismiss or strike the class claims as premature. In September 2015, plaintiffs filed additional motions, including a motion for conditional certification under the Equal Pay Act; a motion to amend the pleadings seeking to add ERISA and constructive discharge claims and a Company subsidiary as a named defendant; and a motion for equitable relief. Merck filed papers in opposition to the motions. In April 2016, the court granted plaintiff's motion for conditional certification but denied plaintiffs' motions to extend the liability period for their Equal Pay Act claims back to June 2009. In April 2016, the Magistrate Judge granted plaintiffs' request to amend the complaint to add the following: (i) a Company subsidiary as a corporate defendant; (ii) an ERISA claim and (iii) an individual constructive discharge claim for one of the named plaintiffs. Approximately 700 individuals opted-in to this action; the opt-in period has closed. In August 2017, plaintiffs filed their motion for class certification. This motion sought to certify a Title VII pay discrimination class and also sought final collective action certification of plaintiffs' Equal Pay Act claim.

On October 1, 2018, the parties entered into an agreement to fully resolve the Smith sales force litigation. As part of the settlement and in exchange for a full and general release of all individual and class claims, the Company agreed to pay $8.5 million. The settlement agreement, which contains an "opt-out" clause allowing Merck to pull out of the agreement if 30 or more individuals opt out, will be subject to court approval.

On December 18, 2018, plaintiffs filed a motion with the court seeking preliminary approval of the settlement.

Qui Tam Litigation

As previously disclosed, in June 2012, the U.S. District Court for the Eastern District of Pennsylvania unsealed a complaint that has been filed against the Company under the federal False Claims Act by two former employees alleging, among other things, that the Company defrauded the U.S. government by falsifying data in connection with a clinical study conducted on the mumps component of the Company's M-M-R II vaccine. The complaint alleges the fraud took place between 1999 and 2001. The U.S. government had the right to participate in and take over the prosecution of this lawsuit, but notified the court that it declined to exercise that right. The two former employees are pursuing the lawsuit without the involvement of the U.S. government. In addition, as previously disclosed, two

putative class action lawsuits on behalf of direct purchasers of the M M R II vaccine, which charge that the Company misrepresented the efficacy of the M-M-R II vaccine in violation of federal antitrust laws and various state consumer

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protection laws, are pending in the Eastern District of Pennsylvania. In September 2014, the court denied Merck's motion to dismiss the False Claims Act suit and granted in part and denied in part its motion to dismiss the then-pending antitrust suit. As a result, both the False Claims Act suit and the antitrust suits have proceeded into discovery, which is ongoing. The Company continues to defend against these lawsuits.

Merck KGaA Litigation

As previously disclosed, in January 2016, to protect its long-established brand rights in the United States, the Company filed a lawsuit against Merck KGaA, Darmstadt, Germany (KGaA), historically operating as the EMD Group in the United States, alleging it improperly uses the name "Merck" in the United States. KGaA has filed suit against the Company in France, the UK, Germany, Switzerland, Mexico, India, Australia, Singapore, Hong Kong, and China alleging, among other things, unfair competition, trademark infringement and/or corporate name infringement. In the UK, Australia, Singapore, Hong Kong, and India, KGaA also alleges breach of the parties' coexistence agreement. In December 2015, the Paris Court of First Instance issued a judgment finding that certain activities by the Company directed towards France did not constitute trademark infringement and unfair competition while other activities were found to infringe and constitute unfair competition. The Company and KGaA appealed the decision, and the appeal was heard in May 2017. In June 2017, the French appeals court held that certain of the activities by the Company directed to France constituted unfair competition or trademark infringement and, in December 2017, the Company decided not to pursue any further appeal. In January 2016, the UK High Court issued a judgment finding that the Company had breached the co-existence agreement and infringed KGaA's trademark rights as a result of certain activities directed towards the UK based on use of the word MERCK on promotional and information activity. As noted in the UK decision, this finding was not based on the Company's use of the sign MERCK in connection with the sale of products or any material pharmaceutical business transacted in the UK. The Company and KGaA have both appealed this decision, and the appeal was heard in June 2017. In November 2017, the UK Court of Appeals affirmed the decision on the co-existence agreement and remitted for re-hearing issues of trademark infringement, the scope of KGaA's UK trademarks for pharmaceutical products, and the relief to which KGaA would be entitled. The re-hearing was held, and no decision has been handed down. In November 2018, the District Court in Hamburg, Germany dismissed all of KGaA's claims concerning KGaA's EU trademark with respect to the territory of the EU. In accordance with the Judgment of the Court of Justice of the EU delivered in October 2017, the District Court in Hamburg further held that it had no jurisdiction over the claim by KGaA insofar as the claim related to the territory of the UK. KGaA has appealed this decision. Further decisions from the District Court in Hamburg, Germany, in connection with claims concerning KGaA's EU trademark, German trademark and trade name rights as well as unfair competition law with respect to the territory of Germany are expected on February 28, 2019. In January 2019, the Mexican Trademark Office issued a decision on KGaA's action. The court found no trademark infringement by the Company and dismissed all of KGaA's claims for trademark infringement. The court ruled against the Company on KGaA's unfair competition claim. Both KGaA and the Company have appealed this decision.

Patent Litigation

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

Inegy — The patents protecting Inegy in Europe have expired but supplemental protection certificates (SPCs) have been granted to the Company in many European countries that will expire in April 2019. There are multiple challenges to the SPCs related to Inegy throughout Europe and generic products have been launched in Austria, France, Italy, Ireland, Spain, Portugal, Germany, and the Netherlands. The Company has filed for preliminary injunctions in many countries that are still pending decision. Preliminary injunctions are presently in force in Austria, Czech Republic,

Greece, Norway, Portugal, and Slovakia. Preliminary injunctions have been denied or revoked in Germany, Ireland, the Netherlands and Spain. The Company is appealing those decisions. In France and Belgium, preliminary injunctions were granted against some companies and denied against others, and appeals are pending. The SPC was held valid in

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merits proceedings in Portugal and France. The Company has filed and will continue to file actions for patent infringement seeking damages against those companies that launch generic products before April 2019.

Noxafil — In August 2015, the Company filed a lawsuit against Actavis Laboratories Fl, Inc. (Actavis) in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of Noxafil. In October 2017, the district court held the patent valid and infringed. Actavis appealed this decision. While the appeal was pending, the parties reached a settlement, subject to certain terms of the agreement being met, whereby Actavis can launch its generic version prior to expiry of the patent and pediatric exclusivity under certain conditions. In March 2016, the Company filed a lawsuit against Roxane Laboratories, Inc. (Roxane) in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of Noxafil. In November 2017, the parties reached a settlement whereby Roxane can launch its generic version prior to expiry of the patent under certain conditions. In February 2016, the Company filed a lawsuit against Par Sterile Products LLC, Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc. and Par Pharmaceutical Holdings, Inc. (collectively, Par) in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of Noxafil injection. In October 2016, the parties reached a settlement whereby Par can launch its generic version in January 2023, or earlier under certain conditions. In February 2018, the Company filed a lawsuit against Fresenius Kabi USA, LLC (Fresenius) in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of Noxafil. In November 2018, the Company reached a settlement with Fresenius, whereby Fresenius can launch its generic version of the intravenous product prior to expiry of the patent under certain conditions. In March 2018, the Company filed a lawsuit against Mylan Laboratories Limited in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of Noxafil.

Nasonex — Nasonex lost market exclusivity in the United States in 2016. Prior to that, in April 2015, the Company filed a patent infringement lawsuit against Apotex Inc. and Apotex Corp. (Apotex) in respect of Apotex's marketed product that the Company believed was infringing. In January 2018, the Company and Apotex settled this matter with Apotex agreeing to pay the Company $115 million plus certain other consideration.

Januvia, Janumet, Janumet XR — In February 2019, Par Pharmaceutical, Inc. (Par Pharmaceutical) filed suit against the Company in the U.S. District Court for the District of New Jersey, seeking a declaratory judgment of invalidity of a patent owned by the Company covering certain salt and polymorphic forms of sitagliptin that expires in 2026. A judgment in its favor may allow Par Pharmaceutical to bring to market a generic version of Janumet XR following the expiration of key patent protection in 2022, but prior to the expiration of the later-granted patent it is challenging. In response, the Company filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Par Pharmaceutical and additional companies that also indicated an intent to market generic versions of Januvia, Janumet, and Janumet XR following expiration of key patent protection in 2022, but prior to the expiration of the later-granted patent owned by the Company covering certain salt and polymorphic forms of sitagliptin that expires in 2026, and a later granted patent owned by the Company covering the Janumet formulation which expires in 2028. No schedule for the cases has been set by the court.

Gilead Patent Litigation and Opposition

The Company, through its Idenix Pharmaceuticals, Inc. subsidiary, has pending litigation against Gilead in the United States, Germany, and France based on different patent estates that would be infringed by Gilead's sales of their two products, Sovaldi and Harvoni. Gilead opposed the European patent at the European Patent Office (EPO). Trial in the United States was held in December 2016 and the jury returned a verdict for the Company, awarding damages of $2.54 billion. The Company submitted post-trial motions, including on the issues of enhanced damages and future royalties. Gilead submitted post-trial motions for judgment as a matter of law. A hearing on the motions was held in September 2017. Also, in September 2017, the court denied the Company's motion on enhanced damages, granted its motion on prejudgment interest and deferred its motion on future royalties. In February 2018, the court granted Gilead's motion for judgment as a matter of law and found the patent was invalid for a lack of enablement. The Company appealed this decision. The appellate briefing is completed and the Company is waiting for the oral argument to be scheduled. The EPO opposition division revoked the European patent, and the Company appealed this decision. The cases in France and Germany have been stayed pending the final decision of the EPO.

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Other Litigation

There are various other pending legal proceedings involving the Company, principally product liability and intellectual property lawsuits. While it is not feasible to predict the outcome of such proceedings, in the opinion of the Company, either the likelihood of loss is remote or any reasonably possible loss associated with the resolution of such proceedings is not expected to be material to the Company's financial position, results of operations or cash flows either individually or in the aggregate.

Legal Defense Reserves

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of December 31, 2018 and 2017 of approximately $245 million and $160 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

Environmental Matters

As previously disclosed, Merck's facilities in Oss, the Netherlands, were inspected in 2012 by the Province of Brabant (Province) pursuant to the Dutch Hazards of Major Accidents Decree and the sites' environmental permits. The Province issued penalties for alleged violations of regulations governing preventing and managing accidents with hazardous substances, and the government also issued a fine for alleged environmental violations at one of the Oss facilities, which together totaled $235 thousand. The Company was subsequently advised that a criminal investigation had been initiated based upon certain of the issues that formed the basis of the administrative enforcement action by the Province. As previously disclosed, the matter was settled, without any admission of liability, for an aggregate payment of €400 thousand.

The Company and its subsidiaries are parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund, and other federal and state equivalents. These proceedings seek to require the operators of hazardous waste disposal facilities, transporters of waste to the sites and generators of hazardous waste disposed of at the sites to clean up the sites or to reimburse the government for cleanup costs. The Company has been made a party to these proceedings as an alleged generator of waste disposed of at the sites. In each case, the government alleges that the defendants are jointly and severally liable for the cleanup costs. Although joint and several liability is alleged, these proceedings are frequently resolved so that the allocation of cleanup costs among the parties more nearly reflects the relative contributions of the parties to the site situation. The Company's potential liability varies greatly from site to site. For some sites the potential liability is de minimis and for others the final costs of cleanup have not yet been determined. While it is not feasible to predict the outcome of many of these proceedings brought by federal or state agencies or private litigants, in the opinion of the Company, such proceedings should not ultimately result in any liability which would have a material adverse effect on the financial position, results of operations, liquidity or capital resources of the Company. The Company has taken an active role in identifying and accruing for these costs and such amounts do not include any reduction for anticipated recoveries of cleanup costs from former site owners or operators or other recalcitrant potentially responsible parties.

In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $71 million and $82 million at December 31, 2018 and 2017, respectively. These liabilities are undiscounted, do not consider potential recoveries from other parties and will be paid out over the periods of

remediation for the applicable sites, which are expected to occur primarily over the next 15 years. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued

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should exceed $60 million in the aggregate. Management also does not believe that these expenditures should result in a material adverse effect on the Company's financial position, results of operations, liquidity or capital resources for any year.

12. Equity

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

Capital Stock

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

	2018		2017		2016	
	Common Stock	Treasury Stock	Common Stock	Treasury Stock	Common Stock	Treasury Stock
Balance January 1	3,577	880	3,577	828	3,577	796
Purchases of treasury stock	—	122	—	67	—	60
Issuances [1]	—	(17)	—	(15)	—	(28)
Balance December 31	3,577	985	3,577	880	3,577	828

[1] Issuances primarily reflect activity under share-based compensation plans.

On October 25, 2018, the Company entered into accelerated share repurchase (ASR) agreements with two third-party financial institutions (Dealers). Under the ASR agreements, Merck agreed to purchase $5 billion of Merck's common stock, in total, with an initial delivery of 56.7 million shares of Merck's common stock, based on the then-current market price, made by the Dealers to Merck, and payments of $5 billion made by Merck to the Dealers on October 29, 2018, which were funded with existing cash and investments, as well as short-term borrowings. The payments to the Dealers were recorded as reductions to shareholders' equity, consisting of a $4 billion increase in treasury stock, which reflects the value of the initial 56.7 million shares received on October 29, 2018, and a $1 billion decrease in other-paid-in capital, which reflects the value of the stock held back by the Dealers pending final settlement. The number of shares of Merck's common stock that Merck may receive, or may be required to remit, upon final settlement under the ASR agreements will be based upon the average daily volume weighted-average price of Merck's common stock during the term of the ASR program, less a negotiated discount. Final settlement of the transaction under the ASR agreements is expected to occur in the first half of 2019, but may occur earlier at the option of the Dealers, or later under certain circumstances. If Merck is obligated to make adjustment payments to the Dealers under the ASR agreements, Merck may elect to satisfy such obligations in cash or in shares of Merck's common stock.

13. Share-Based Compensation Plans

The Company has share-based compensation plans under which the Company grants restricted stock units (RSUs) and performance share units (PSUs) to certain management level employees. In addition, employees and non-employee directors may be granted options to purchase shares of Company common stock at the fair market value at the time of grant. These plans were approved by the Company's shareholders.

At December 31, 2018, 111 million shares collectively were authorized for future grants under the Company's share-based compensation plans. These awards are settled primarily with treasury shares.

Employee stock options are granted to purchase shares of Company stock at the fair market value at the time of grant. These awards generally vest one-third each year over a three-year period, with a contractual term of 7-10 years. RSUs are stock awards that are granted to employees and entitle the holder to shares of common stock as the awards vest. The fair value of the stock option and RSU awards is determined and fixed on the grant date based on the Company's stock price. PSUs are stock awards where the ultimate number of shares issued will be contingent on the Company's performance against a pre-set objective or set of objectives. The fair value of each PSU is determined on the date of grant based on the Company's stock price. For RSUs and PSUs, dividends declared during the vesting period are payable to the employees only upon vesting. Over the PSU performance period, the number of shares of stock that are expected to be issued will be adjusted based on the probability of achievement of a performance target and final compensation expense will be recognized based on the ultimate number of shares issued. RSU and PSU

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distributions will be in shares of Company stock after the end of the vesting or performance period, subject to the terms applicable to such awards. PSU awards generally vest after three years. Prior to 2018, RSU awards generally vested after three years; beginning with awards granted in 2018, RSU awards generally vest one-third each year over a three-year period.

Total pretax share-based compensation cost recorded in 2018, 2017 and 2016 was $348 million, $312 million and $300 million, respectively, with related income tax benefits of $55 million, $57 million and $92 million, respectively.

The Company uses the Black-Scholes option pricing model for determining the fair value of option grants. In applying this model, the Company uses both historical data and current market data to estimate the fair value of its options. The Black-Scholes model requires several assumptions including expected dividend yield, risk-free interest rate, volatility, and term of the options. The expected dividend yield is based on historical patterns of dividend payments. The risk-free rate is based on the rate at grant date of zero-coupon U.S. Treasury Notes with a term equal to the expected term of the option. Expected volatility is estimated using a blend of historical and implied volatility. The historical component is based on historical monthly price changes. The implied volatility is obtained from market data on the Company's traded options. The expected life represents the amount of time that options granted are expected to be outstanding, based on historical and forecasted exercise behavior.

The weighted average exercise price of options granted in 2018, 2017 and 2016 was $58.15, $63.88 and $54.63 per option, respectively. The weighted average fair value of options granted in 2018, 2017 and 2016 was $8.26, $7.04 and $5.89 per option, respectively, and were determined using the following assumptions:

Years Ended December 31	2018	2017	2016
Expected dividend yield	3.4 %	3.6 %	3.8 %
Risk-free interest rate	2.9 %	2.0 %	1.4 %
Expected volatility	19.1%	17.8%	19.6%
Expected life (years)	6.1	6.1	6.2

Summarized information relative to stock option plan activity (options in thousands) is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2018	36,274	$ 46.77		
Granted	3,520	58.15		
Exercised	(14,598)	40.51		
Forfeited	(1,389)	53.80		
Outstanding December 31, 2018	23,807	$ 51.89	5.95	$ 584
Exercisable December 31, 2018	16,184	$ 48.85	4.82	$ 446

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

Years Ended December 31	2018	2017	2016
Total intrinsic value of stock options exercised	$348	$236	$444
Fair value of stock options vested	29	30	28
Cash received from the exercise of stock options	591	499	939

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A summary of nonvested RSU and PSU activity (shares in thousands) is as follows:

	RSUs		PSUs	
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested January 1, 2018	13,609	$ 59.32	1,868	$ 60.03
Granted	7,270	58.46	1,081	57.17
Vested	(3,766)	59.66	(758)	57.59
Forfeited	(985)	59.30	(152)	60.06
Nonvested December 31, 2018	16,128	$ 58.85	2,039	$ 59.42

At December 31, 2018, there was $560 million of total pretax unrecognized compensation expense related to nonvested stock options, RSU and PSU awards which will be recognized over a weighted average period of 1.9 years. For segment reporting, share-based compensation costs are unallocated expenses.

14. Pension and Other Postretirement Benefit Plans

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

Net Periodic Benefit Cost

The net periodic benefit cost (credit) for pension and other postretirement benefit plans consisted of the following components:

	Pension Benefits								
	U.S.			International			Other Postretirement Benefits		
Years Ended December 31	2018	2017	2016	2018	2017	2016	2018	2017	2016
Service cost	$326	$312	$282	$238	$252	$238	$ 57	$ 57	$ 54
Interest cost	432	454	456	178	172	204	69	81	82
Expected return on plan assets	(851)	(862)	(831)	(431)	(393)	(382)	(83)	(78)	(107)
Amortization of unrecognized prior service cost	(50)	(53)	(55)	(13)	(11)	(11)	(84)	(98)	(106)
Net loss amortization	232	180	119	84	98	87	1	1	3
Termination benefits	19	44	23	2	4	4	3	8	4
Curtailments	10	3	5	1	(4)	(1)	(8)	(31)	(18)
Settlements	5	—	—	13	5	6	—	—	—
Net periodic benefit cost (credit)	$123	$78	$(1)	$72	$123	$145	$ (45)	$ (60)	$ (88)

The changes in net periodic benefit cost (credit) year over year for pension plans are largely attributable to changes in the discount rate affecting net loss amortization.

In connection with restructuring actions (see Note 5), termination charges were recorded in 2018, 2017 and 2016 on pension and other postretirement benefit plans related to expanded eligibility for certain employees exiting Merck. Also, in connection with these restructuring activities, curtailments were recorded on pension and other postretirement benefit plans and settlements were recorded on certain U.S. and international pension plans as reflected in the table above.

The components of net periodic benefit cost (credit) other than the service cost component are included in Other (income) expense, net (see Note 15), with the exception of certain amounts for termination benefits, curtailments and settlements, which are recorded in Restructuring costs if the event giving rise to the termination benefits, curtailment or settlement is related to restructuring actions as noted above.

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Obligations and Funded Status

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

	Pension Benefits				Other Postretirement Benefits	
	U.S.		International			
	2018	2017	2018	2017	2018	2017
Fair value of plan assets January 1	$10,896	$9,766	$9,339	$7,794	$1,114	$1,019
Actual return on plan assets	(810)	1,723	(289)	677	(72)	161
Company contributions, net	378	58	167	226	6	(4)
Effects of exchange rate changes	—	—	(352)	843	—	—
Benefits paid	(772)	(651)	(202)	(198)	(80)	(62)
Settlements	(44)	—	(106)	(17)	—	—
Other	—	—	23	14	—	—
Fair value of plan assets December 31	$9,648	$10,896	$8,580	$9,339	$968	$1,114
Benefit obligation January 1	$11,904	$10,849	$9,483	$8,372	$1,922	$1,922
Service cost	326	312	238	252	57	57
Interest cost	432	454	178	172	69	81
Actuarial (gains) losses [1]	(1,258)	881	(154)	(7)	(341)	(87)
Benefits paid	(772)	(651)	(202)	(198)	(80)	(62)
Effects of exchange rate changes	—	—	(387)	916	(6)	3
Plan amendments	—	—	10	(22)	(9)	—
Curtailments	13	15	(2)	(3)	—	—
Termination benefits	19	44	2	4	3	8
Settlements	(44)	—	(106)	(17)	—	—
Other	—	—	23	14	—	—
Benefit obligation December 31	$10,620	$11,904	$9,083	$9,483	$1,615	$1,922
Funded status December 31	$(972)	$(1,008)	$(503)	$(144)	$(647)	$(808)
Recognized as:						
Other assets	$—	$—	$659	$828	$—	$—
Accrued and other current liabilities	(47)	(59)	(14)	(17)	(10)	(11)
Other noncurrent liabilities	(925)	(949)	(1,148)	(955)	(637)	(797)

[1] Actuarial (gains) losses in 2018 and 2017 primarily reflect changes in discount rates.

At December 31, 2018 and 2017, the accumulated benefit obligation was $19.0 billion and $20.5 billion, respectively, for all pension plans, of which $10.4 billion and $11.5 billion, respectively, related to U.S. pension plans.

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Information related to the funded status of selected pension plans at December 31 is as follows:

	U.S.		International	
	2018	2017	2018	2017
Pension plans with a projected benefit obligation in excess of plan assets				
Projected benefit obligation	$10,620	$11,904	$6,251	$3,323
Fair value of plan assets	9,648	10,896	5,089	2,352
Pension plans with an accumulated benefit obligation in excess of plan assets				
Accumulated benefit obligation	$9,702	$676	$5,936	$2,120
Fair value of plan assets	8,966	—	5,071	1,346

Plan Assets

Entities are required to use a fair value hierarchy which maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest:

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

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

Level 3 — Unobservable inputs that are supported by little or no market activity. The Level 3 assets are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as instruments for which the determination of fair value requires significant judgment or estimation. At December 31, 2018 and 2017, $826 million and $488 million, respectively, or approximately 5% and 2%, respectively, of the Company’s pension investments were categorized as Level 3 assets.

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

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

	Fair Value Measurements Using				Fair Value Measurements Using			
	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
	2018				2017			
U.S. Pension Plans								
Assets								
Cash and cash equivalents	$40	$ —	$ —	$40	$6	$ —	$ —	$6
Investment funds								
Developed markets equities	169	—	—	169	390	—	—	390
Emerging markets equities	121	—	—	121	138	—	—	138
Equity securities								
Developed markets	2,172	—	—	2,172	2,743	—	—	2,743
Fixed income securities								
Government and agency obligations	—	1,509	—	1,509	—	757	—	757
Corporate obligations	—	1,246	—	1,246	—	900	—	900
Mortgage and asset-backed securities	—	262	—	262	—	240	—	240
Other investments	—	—	13	13	—	—	15	15
Net assets in fair value hierarchy	$2,502	$ 3,017	$ 13	$5,532	$3,277	$ 1,897	$ 15	$5,189
Investments measured at NAV [1]				4,116				5,707
Plan assets at fair value				$9,648				$10,896
International Pension Plans								
Assets								
Cash and cash equivalents	$50	$ 3	$ —	$53	$54	$ 19	$ —	$73
Investment funds								
Developed markets equities	461	3,071	—	3,532	562	3,326	—	3,888
Emerging markets equities	56	112	—	168	62	176	—	238
Government and agency obligations	372	2,082	—	2,454	249	2,095	—	2,344
Corporate obligations	4	7	—	11	5	329	—	334
Fixed income obligations	7	4	—	11	7	4	—	11
Real estate [2]	—	1	1	2	—	1	2	3
Equity securities								
Developed markets	544	—	—	544	660	—	—	660
Fixed income securities								
Government and agency obligations	2	291	—	293	2	266	—	268
Corporate obligations	1	113	—	114	1	118	—	119
Mortgage and asset-backed securities	—	55	—	55	—	55	—	55
Other investments								

Insurance contracts [3]	—	66	811	877	—	67	470	537
Other	—	4	1	5	—	6	1	7
Net assets in fair value hierarchy	$1,497	$ 5,809	$ 813	$8,119	$1,602	$ 6,462	$ 473	$8,537
Investments measured at NAV [1]				461				802
Plan assets at fair value				$8,580				$9,339

(1) Certain investments that were measured at net asset value (NAV) per share or its equivalent as a practical expedient have not been classified in the fair value hierarchy. The fair value amounts presented in this table are intended to permit reconciliation of the fair value hierarchy to the fair value of plan assets at December 31, 2018 and 2017.

(2) The plans' Level 3 investments in real estate funds are generally valued by market appraisals of the underlying investments in the funds.

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

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

	2018				2017			
	Insurance Contracts	Real Estate	Other	Total	Insurance Contracts	Real Estate	Other	Total
U.S. Pension Plans								
Balance January 1	$—	$ —	$ 15	$15	$—	$ —	$ 18	$18
Actual return on plan assets:								
Relating to assets still held at December 31	—	—	(3)	(3)	—	—	(2)	(2)
Relating to assets sold during the year	—	—	4	4	—	—	4	4
Purchases and sales, net	—	—	(3)	(3)	—	—	(5)	(5)
Balance December 31	$—	$ —	$ 13	$13	$—	$ —	$ 15	$15
International Pension Plans								
Balance January 1	$470	$ 2	$ 1	$473	$412	$ 4	$ 1	$417
Actual return on plan assets:								
Relating to assets still held at December 31	(32)	—	—	(32)	52	—	—	52
Purchases and sales, net	380	(1)	—	379	5	(2)	—	3
Transfers into Level 3	(7)	—	—	(7)	1	—	—	1
Balance December 31	$811	$ 1	$ 1	$813	$470	$ 2	$ 1	$473

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

	Fair Value Measurements Using				Fair Value Measurements Using			
	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
	2018				2017			
Assets								
Cash and cash equivalents	$78	$ —	$ —	$78	$97	$ —	$ —	$97
Investment funds								
Developed markets equities	16	—	—	16	37	—	—	37
Emerging markets equities	12	—	—	12	13	—	—	13
Government and agency obligations	1	—	—	1	1	—	—	1
Equity securities								
Developed markets	200	—	—	200	256	—	—	256
Fixed income securities								
Government and agency obligations	—	141	—	141	—	71	—	71
Corporate obligations	—	116	—	116	—	84	—	84
Mortgage and asset-backed securities	—	24	—	24	—	23	—	23
Net assets in fair value hierarchy	$307	$ 281	$ —	$588	$404	$ 178	$ —	$582
Investments measured at NAV [1]				380				532
Plan assets at fair value				$968				$1,114

[1] Certain investments that were measured at net asset value (NAV) per share or its equivalent as a practical expedient have not been classified in the fair value hierarchy. The fair value amounts presented in this table are intended to permit reconciliation of the fair value hierarchy to the fair value of plan assets at December 31, 2018

and 2017.

The Company has established investment guidelines for its U.S. pension and other postretirement plans to create an asset allocation that is expected to deliver a rate of return sufficient to meet the long-term obligation of each

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plan, given an acceptable level of risk. The target investment portfolio of the Company's U.S. pension and other postretirement benefit plans is allocated 30% to 50% in U.S. equities, 15% to 30% in international equities, 30% to 45% in fixed-income investments, and up to 5% in cash and other investments. The portfolio's equity weighting is consistent with the long-term nature of the plans' benefit obligations. The expected annual standard deviation of returns of the target portfolio, which approximates 11%, reflects both the equity allocation and the diversification benefits among the asset classes in which the portfolio invests. For international pension plans, the targeted investment portfolio varies based on the duration of pension liabilities and local government rules and regulations. Although a significant percentage of plan assets are invested in U.S. equities, concentration risk is mitigated through the use of strategies that are diversified within management guidelines.

Expected Contributions

Expected contributions during 2019 are approximately $50 million for U.S. pension plans, approximately $150 million for international pension plans and approximately $15 million for other postretirement benefit plans.

Expected Benefit Payments

Expected benefit payments are as follows:

	U.S. Pension Benefits	International Pension Benefits	Other Postretirement Benefits
2019	$ 638	$ 225	$ 91
2020	661	213	95
2021	680	221	98
2022	685	239	102
2023	709	249	105
2024 — 2028	3,805	1,349	577

Expected benefit payments are based on the same assumptions used to measure the benefit obligations and include estimated future employee service.

Amounts Recognized in Other Comprehensive Income

Net loss amounts reflect experience differentials primarily relating to differences between expected and actual returns on plan assets as well as the effects of changes in actuarial assumptions. Net loss amounts in excess of certain thresholds are amortized into net periodic benefit cost over the average remaining service life of employees. The following amounts were reflected as components of OCI:

	Pension Plans						Other Postretirement Benefit Plans		
	U.S.			International					
Years Ended December 31	2018	2017	2016	2018	2017	2016	2018	2017	2016
Net (loss) gain arising during the period	$(397)	$(19)	$(743)	$(505)	$309	$(380)	$186	$170	$(45)
Prior service (cost) credit arising during the period	(4)	(13)	(10)	(10)	22	(2)	2	(31)	(19)
	$(401)	$(32)	$(753)	$(515)	$331	$(382)	$188	$139	$(64)
Net loss amortization included in benefit cost	$232	$180	$119	$84	$98	$87	$1	$1	$3
Prior service (credit) cost amortization included in benefit cost	(50)	(53)	(55)	(13)	(11)	(11)	(84)	(98)	(106)
	$182	$127	$64	$71	$87	$76	$(83)	$(97)	$(103)

The estimated net loss (gain) and prior service cost (credit) amounts that will be amortized from AOCI into net periodic benefit cost during 2019 are $204 million and $(62) million, respectively, for pension plans (of which $141 million and $(50) million, respectively, relates to U.S. pension plans) and $(7) million and $(78) million, respectively, for other postretirement benefit plans.

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Actuarial Assumptions

The Company reassesses its benefit plan assumptions on a regular basis. The weighted average assumptions used in determining U.S. pension and other postretirement benefit plan and international pension plan information are as follows:

	U.S. Pension and Other Postretirement Benefit Plans			International Pension Plans		
December 31	2018	2017	2016	2018	2017	2016
Net periodic benefit cost						
Discount rate	3.70 %	4.30 %	4.70 %	2.10 %	2.20 %	2.80 %
Expected rate of return on plan assets	8.20 %	8.70 %	8.60 %	5.10 %	5.10 %	5.60 %
Salary growth rate	4.30 %	4.30 %	4.30 %	2.90 %	2.90 %	2.90 %
Benefit obligation						
Discount rate	4.40 %	3.70 %	4.30 %	2.20 %	2.10 %	2.20 %
Salary growth rate	4.30 %	4.30 %	4.30 %	2.80 %	2.90 %	2.90 %

For both the pension and other postretirement benefit plans, the discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due. The expected rate of return for both the pension and other postretirement benefit plans represents the average rate of return to be earned on plan assets over the period the benefits included in the benefit obligation are to be paid and is determined on a plan basis. The expected rate of return within each plan is developed considering long-term historical returns data, current market conditions, and actual returns on the plan assets. Using this reference information, the long-term return expectations for each asset category and a weighted average expected return for each plan's target portfolio is developed, according to the allocation among those investment categories. The expected portfolio performance reflects the contribution of active management as appropriate. For 2019, the expected rate of return for the Company's U.S. pension and other postretirement benefit plans will range from 7.70% to 8.10%, as compared to a range of 7.70% to 8.30% in 2018. The decrease is primarily due to a modest shift in asset allocation. The change in the weighted-average expected return on U.S. pension and other postretirement benefit plan assets from 2016 to 2018 is due to the relative weighting of the referenced plans' assets.

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

December 31	2018	2017
Health care cost trend rate assumed for next year	7.0 %	7.2 %
Rate to which the cost trend rate is assumed to decline	4.5 %	4.5 %
Year that the trend rate reaches the ultimate trend rate	2032	2032

A one percentage point change in the health care cost trend rate would have had the following effects:

	One Percentage Point	
	Increase	Decrease
Effect on total service and interest cost components	$ 11	$ (9)
Effect on benefit obligation	88	(74)

Savings Plans

The Company also maintains defined contribution savings plans in the United States. The Company matches a percentage of each employee's contributions consistent with the provisions of the plan for which the employee is eligible. Total employer contributions to these plans in 2018, 2017 and 2016 were $136 million, $131 million and $126 million, respectively.

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15. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

Years Ended December 31	2018	2017	2016
Interest income	$(343)	$(385)	$(328)
Interest expense	772	754	693
Exchange losses (gains)	145	(11)	174
Income on investments in equity securities, net [1]	(324)	(352)	(43)
Net periodic defined benefit plan (credit) cost other than service cost	(512)	(512)	(531)
Other, net	(140)	6	224
	$(402)	$(500)	$189

[1] Includes net realized and unrealized gains and losses on investments in equity securities either owned directly or through ownership interests in investment funds.

Income on investments in equity securities, net, in 2018 reflects the recognition of unrealized net gains pursuant to the prospective adoption of ASU 2016-01 on January 1, 2018 (see Note 2). The increase in income on investments in equity securities, net, in 2017 was driven primarily by higher realized gains on sales.

Other, net (as presented in the table above) in 2018 includes a gain of $115 million related to the settlement of certain patent litigation (see Note 11), income of $99 million related to AstraZeneca's option exercise (see Note 9), and a gain of $85 million resulting from the receipt of a milestone payment for an out-licensed migraine clinical development program. Other, net in 2018 also includes $144 million of goodwill impairment charges related to certain businesses in the Healthcare Services segment (see Note 8), as well as $41 million of charges related to the write-down of assets held for sale to fair value in anticipation of the dissolution of the Company's joint venture with Supera Farma Laboratorios S.A. in Brazil.

Other, net in 2017 includes income of $232 million related to AstraZeneca's option exercise and a $191 million loss on extinguishment of debt (see Note 10).

Other, net in 2016 includes a charge of $625 million related to the previously disclosed settlement of worldwide patent litigation related to Keytruda, a gain of $117 million related to the settlement of other patent litigation, gains of $100 million resulting from the receipt of milestone payments for out-licensed migraine clinical development programs, and $98 million of income related to AstraZeneca's option exercise.

Interest paid was $777 million in 2018, $723 million in 2017 and $686 million in 2016.

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16. Taxes on Income

A reconciliation between the effective tax rate and the U.S. statutory rate is as follows:

	2018		2017		2016	
	Amount	Tax Rate	Amount	Tax Rate	Amount	Tax Rate
U.S. statutory rate applied to income before taxes	$1,827	21.0 %	$2,282	35.0 %	$1,631	35.0 %
Differential arising from:						
Impact of the TCJA	289	3.3	2,625	40.3	—	—
Valuation allowances	269	3.1	632	9.7	(5)	(0.1)
Impact of purchase accounting adjustments, including amortization	267	3.1	713	10.9	623	13.4
State taxes	201	2.3	77	1.2	173	3.7
Restructuring	56	0.6	142	2.2	145	3.1
Foreign earnings	(245)	(2.8)	(1,654)	(25.4)	(1,546)	(33.2)
R&D tax credit	(96)	(1.1)	(71)	(1.1)	(58)	(1.3)
Tax settlements	(22)	(0.3)	(356)	(5.5)	—	—
Other [1]	(38)	(0.4)	(287)	(4.4)	(245)	(5.2)
	$2,508	28.8 %	$4,103	62.9 %	$718	15.4 %

[1] Other includes the tax effects of losses on foreign subsidiaries and miscellaneous items.

The Company's 2017 effective tax rate reflected a provisional impact of 40.3% for the Tax Cuts and Jobs Act (TCJA), which was enacted on December 22, 2017. Among other provisions, the TCJA reduced the U.S. federal corporate statutory tax rate from 35% to 21% effective January 1, 2018, requires companies to pay a one-time transition tax on undistributed earnings of certain foreign subsidiaries, and creates new taxes on certain foreign sourced earnings.

The Company reflected the impact of the TCJA in its 2017 financial statements. However, since application of certain provisions of the TCJA remained subject to further interpretation, in certain instances the Company made reasonable estimates of the effects of the TCJA. In 2018, these amounts were finalized as described below.

The one-time transition tax is based on the Company's post-1986 undistributed earnings and profits (E&P). For a substantial portion of these undistributed E&P, the Company had not previously provided deferred taxes as these earnings were deemed by Merck to be retained indefinitely by subsidiary companies for reinvestment. The Company recorded a provisional amount in 2017 for its one-time transition tax liability of $5.3 billion. This provisional amount was reduced by the reversal of $2.0 billion of deferred taxes that were previously recorded in connection with the merger of Schering-Plough Corporation in 2009 for certain undistributed foreign E&P. On the basis of revised calculations of post-1986 undistributed foreign E&P and finalization of the amounts held in cash or other specified assets, the Company recognized a measurement-period adjustment of $124 million in 2018 related to the transition tax obligation, with a corresponding adjustment to income tax expense during the period, resulting in a revised transition tax obligation of $5.5 billion. The Company anticipates that it will be able to utilize certain foreign tax credits to partially reduce the transition tax payment. As permitted under the TCJA, the Company has elected to pay the one-time transition tax over a period of eight years. After payment of the amount due in 2018, the remaining transition tax liability at December 31, 2018, is $4.9 billion, of which $275 million is included in Income Taxes Payable and the remainder of $4.6 billion is included in Other Noncurrent Liabilities. As a result of the TCJA, the Company has made a determination it is no longer indefinitely reinvested with respect to its undistributed earnings from foreign subsidiaries and has provided a deferred tax liability for withholding tax that would apply.

In 2017, the Company remeasured its deferred tax assets and liabilities at the new federal statutory tax rate of 21%, which resulted in a provisional deferred tax benefit of $779 million. On the basis of clarifications to the deferred tax benefit calculation, the Company recorded measurement-period adjustments in 2018 of $32 million related to deferred income taxes.

Beginning in 2018, the TCJA includes a tax on "global intangible low-taxed income" (GILTI) as defined in the TCJA. The Company has made an accounting policy election to account for the tax effects of the GILTI tax in the income tax provision in future periods as the tax arises.

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The foreign earnings tax rate differentials in the tax rate reconciliation above primarily reflect the impacts of operations in jurisdictions with different tax rates than the United States, particularly Ireland and Switzerland, as well as Singapore and Puerto Rico which operate under tax incentive grants (which begin to expire in 2022), where the earnings had been indefinitely reinvested, thereby yielding a favorable impact on the effective tax rate compared with the U.S. statutory rate of 35% in 2017 and 2016 and 21% in 2018. The foreign earnings tax rate differentials do not include the impact of intangible asset impairment charges, amortization of purchase accounting adjustments or restructuring costs. These items are presented separately as they each represent a significant, separately disclosed pretax cost or charge, and a substantial portion of each of these items relates to jurisdictions with lower tax rates than the United States. Therefore, the impact of recording these expense items in lower tax rate jurisdictions is an unfavorable impact on the effective tax rate compared to the U.S. statutory rate of 35% in 2017 and 2016 and 21% in 2018.

Income before taxes consisted of:

Years Ended December 31	2018	2017	2016
Domestic	$3,717	$3,483	$518
Foreign	4,984	3,038	4,141
	$8,701	$6,521	$4,659

Taxes on income consisted of:

Years Ended December 31	2018	2017	2016
Current provision			
Federal	$536	$5,585	$1,166
Foreign	2,281	1,229	916
State	200	(90)	157
	3,017	6,724	2,239
Deferred provision			
Federal	(402)	(2,958)	(1,255)
Foreign	(64)	75	(225)
State	(43)	262	(41)
	(509)	(2,621)	(1,521)
	$2,508	$4,103	$718

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Deferred income taxes at December 31 consisted of:

	2018		2017	
	Assets	Liabilities	Assets	Liabilities
Product intangibles and licenses	$720	$ 1,640	$307	$ 2,256
Inventory related	32	377	29	499
Accelerated depreciation	—	582	28	642
Pensions and other postretirement benefits	565	151	498	192
Compensation related	291	—	314	—
Unrecognized tax benefits	174	—	156	—
Net operating losses and other tax credit carryforwards	715	—	654	—
Other	621	66	909	52
Subtotal	3,118	2,816	2,895	3,641
Valuation allowance	(1,348)		(900)	
Total deferred taxes	$1,770	$ 2,816	$1,995	$ 3,641
Net deferred income taxes		$ 1,046		$ 1,646
Recognized as:				
Other assets	$656		$573	
Deferred income taxes		$ 1,702		$ 2,219

The Company has net operating loss (NOL) carryforwards in several jurisdictions. As of December 31, 2018, $715 million of deferred taxes on NOL carryforwards relate to foreign jurisdictions. Valuation allowances of $1.3 billion have been established on these foreign NOL carryforwards and other foreign deferred tax assets. The Company has no NOL carryforwards relating to U.S. jurisdictions.

Income taxes paid in 2018, 2017 and 2016 were $1.5 billion, $4.9 billion and $1.8 billion, respectively. Tax benefits relating to stock option exercises were $77 million in 2018, $73 million in 2017 and $147 million in 2016.

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

	2018	2017	2016
Balance January 1	$1,723	$3,494	$3,448
Additions related to current year positions	221	146	196
Additions related to prior year positions	142	520	75
Reductions for tax positions of prior years [1]	(73)	(1,038)	(90)
Settlements [1]	(91)	(1,388)	(92)
Lapse of statute of limitations	(29)	(11)	(43)
Balance December 31	$1,893	$1,723	$3,494

[1] Amounts reflect the settlements with the IRS as discussed below.

If the Company were to recognize the unrecognized tax benefits of $1.9 billion at December 31, 2018, the income tax provision would reflect a favorable net impact of $1.8 billion.

The Company is under examination by numerous tax authorities in various jurisdictions globally. The Company believes that it is reasonably possible that the total amount of unrecognized tax benefits as of December 31, 2018 could decrease by up to approximately $750 million in the next 12 months as a result of various audit closures, settlements or the expiration of the statute of limitations. The ultimate finalization of the Company’s examinations with relevant taxing authorities can include formal administrative and legal proceedings, which could have a significant impact on the timing of the reversal of unrecognized tax benefits. The Company believes that its reserves for uncertain tax positions are adequate to cover existing risks or exposures.

Expenses for interest and penalties associated with uncertain tax positions amounted to $51 million in 2018, $183 million in 2017 and $134 million in 2016. These amounts reflect the beneficial impacts of various tax settlements, including those discussed below. Liabilities for accrued interest and penalties were $372 million and $341 million as of December 31, 2018 and 2017, respectively.

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In 2017, the Internal Revenue Service (IRS) concluded its examinations of Merck's 2006-2011 U.S. federal income tax returns. As a result, the Company was required to make a payment of approximately $2.8 billion. The Company's reserves for unrecognized tax benefits for the years under examination exceeded the adjustments relating to this examination period and therefore the Company recorded a net $234 million tax benefit in 2017. This net benefit reflects reductions in reserves for unrecognized tax benefits for tax positions relating to the years that were under examination, partially offset by additional reserves for tax positions not previously reserved for, as well as adjustments to reserves for unrecognized tax benefits relating to years which remain open to examination that are affected by this settlement.

The IRS is currently conducting examinations of the Company's tax returns for the years 2012 through 2014. In addition, various state and foreign tax examinations are in progress and for these jurisdictions, the Company's income tax returns are open for examination for the period 2003 through 2018.

17. Earnings per Share

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

Years Ended December 31	2018	2017	2016
Net income attributable to Merck & Co., Inc.	$6,220	$2,394	$3,920
Average common shares outstanding	2,664	2,730	2,766
Common shares issuable [1]	15	18	21
Average common shares outstanding assuming dilution	2,679	2,748	2,787
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	$2.34	$0.88	$1.42
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	$2.32	$0.87	$1.41

[1] Issuable primarily under share-based compensation plans.

In 2018, 2017 and 2016, 6 million, 5 million and 13 million, respectively, of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

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18. Other Comprehensive Income (Loss)

Changes in AOCI by component are as follows:

	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance January 1, 2016, net of taxes	$ 404	$ 41	$ (2,407)	$ (2,186)	$ (4,148)
Other comprehensive income (loss) before reclassification adjustments, pretax	210	(38)	(1,199)	(150)	(1,177)
Tax	(72)	16	363	(19)	288
Other comprehensive income (loss) before reclassification adjustments, net of taxes	138	(22)	(836)	(169)	(889)
Reclassification adjustments, pretax	(314) (1)	(31) (2)	37 (3)	—	(308)
Tax	110	9	—	—	119
Reclassification adjustments, net of taxes	(204)	(22)	37	—	(189)
Other comprehensive income (loss), net of taxes	(66)	(44)	(799)	(169)	(1,078)
Balance December 31, 2016, net of taxes	338	(3)	(3,206)	(2,355)	(5,226)
Other comprehensive income (loss) before reclassification adjustments, pretax	(561)	212	438	235	324
Tax	207	(35)	(106)	166	232
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(354)	177	332	401	556
Reclassification adjustments, pretax	(141) (1)	(291) (2)	117 (3)	—	(315)
Tax	49	56	(30)	—	75
Reclassification adjustments, net of taxes	(92)	(235)	87	—	(240)
Other comprehensive income (loss), net of taxes	(446)	(58)	419	401	316
Balance December 31, 2017, net of taxes	(108)	(61)	(2,787) (4)	(1,954)	(4,910)
Other comprehensive income (loss) before reclassification adjustments, pretax	228	(108)	(728)	(84)	(692)
Tax	(55)	1	169	(139)	(24)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	173	(107)	(559)	(223)	(716)
Reclassification adjustments, pretax	157 (1)	97 (2)	170 (3)	—	424
Tax	(33)	—	(36)	—	(69)
Reclassification adjustments, net of taxes	124	97	134	—	355
Other comprehensive income (loss), net of taxes	297	(10)	(425)	(223)	(361)
Adoption of ASU 2018-02 (see Note 2)	(23)	1	(344)	100	(266)
Adoption of ASU 2016-01 (see Note 2)	—	(8)	—	—	(8)
Balance December 31, 2018, net of taxes	$ 166	$ (78)	$ (3,556) (4)	$ (2,077)	$ (5,545)

(1) Relates to foreign currency cash flow hedges that were reclassified from AOCI to Sales.

(2) Represents net realized (gains) losses on the sales of available-for-sale investments that were reclassified from AOCI to Other (income) expense, net. In 2017 and 2016, these amounts included both investments in debt and equity securities; however, as a result of the adoption of ASU 2016-01 (see Note 2), in 2018, these amounts relate only to investments in available-for-sale debt securities.

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

(4) Includes pension plan net loss of $4.4 billion and $3.5 billion at December 31, 2018 and 2017, respectively, and other postretirement benefit plan net (gain) loss of $(170) million and $(16) million at December 31, 2018 and 2017, respectively, as well as pension plan prior service credit of $314 million and $326 million at December 31, 2018 and 2017, respectively, and other postretirement benefit plan prior service credit of $375 million and $383 million at December 31, 2018 and 2017, respectively.

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19. Segment Reporting

The Company's operations are principally managed on a products basis and include four operating segments, which are the Pharmaceutical, Animal Health, Healthcare Services and Alliances segments. The Pharmaceutical and Animal Health segments are the only reportable segments. The Animal Health segment met the criteria for separate reporting and became a reportable segment in 2018.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. A large component of pediatric and adolescent vaccine sales are made to the U.S. Centers for Disease Control and Prevention Vaccines for Children program, which is funded by the U.S. government. Additionally, the Company sells vaccines to the Federal government for placement into vaccine stockpiles. Sales of vaccines in most major European markets were marketed through the Company's SPMSD joint venture until its termination on December 31, 2016 (see Note 9).

The Animal Health segment discovers, develops, manufactures and markets animal health products, including pharmaceutical and vaccine products, for the prevention, treatment and control of disease in all major livestock and companion animal species, which the Company sells to veterinarians, distributors and animal producers.

The Healthcare Services segment provides services and solutions that focus on engagement, health analytics and clinical services to improve the value of care delivered to patients.

The Alliances segment primarily includes activity from the Company's relationship with AstraZeneca LP related to sales of Nexium and Prilosec, which concluded in 2018 (see Note 9).

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Sales of the Company's products were as follows:

Years Ended December 31	2018			2017			2016		
	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	Total
Pharmaceutical:									
Oncology									
Keytruda	$4,150	$3,021	$7,171	$2,309	$1,500	$3,809	$792	$610	$1,402
Emend	312	210	522	342	213	556	356	193	549
Temodar	6	209	214	16	256	271	15	268	283
Alliance revenue - Lynparza	127	61	187	—	20	20	—	—	—
Alliance revenue - Lenvima	95	54	149	—	—	—	—	—	—
Vaccines [(1)]									
Gardasil/Gardasil 9	1,873	1,279	3,151	1,565	743	2,308	1,780	393	2,173
ProQuad/M-M-R II/Varivax	1,430	368	1,798	1,374	303	1,676	1,362	279	1,640
Pneumovax 23	627	281	907	581	240	821	447	193	641
RotaTeq	496	232	728	481	204	686	482	169	652
Zostavax	22	195	217	422	246	668	518	168	685
Hospital Acute Care									
Bridion	386	531	917	239	465	704	77	405	482
Noxafil	353	389	742	309	327	636	284	312	595
Invanz	253	243	496	361	241	602	329	233	561
Cubicin	191	176	367	189	193	382	906	181	1,087
Cancidas	12	314	326	20	402	422	25	533	558
Primaxin	7	258	265	10	270	280	4	293	297
Immunology									
Simponi	—	893	893	—	819	819	—	766	766
Remicade	—	582	582	—	837	837	—	1,268	1,268
Neuroscience									
Belsomra	96	164	260	98	112	210	84	70	154
Virology									
Isentress/Isentress HD	513	627	1,140	565	639	1,204	721	666	1,387
Zepatier	8	447	455	771	888	1,660	488	67	555
Cardiovascular									
Zetia	45	813	857	352	992	1,344	1,588	972	2,560
Vytorin	10	487	497	124	627	751	473	668	1,141
Atozet	—	347	347	—	225	225	1	146	146
Adempas	—	329	329	—	300	300	—	169	169
Diabetes									
Januvia	1,969	1,718	3,686	2,153	1,584	3,737	2,286	1,622	3,908
Janumet	811	1,417	2,228	863	1,296	2,158	984	1,217	2,201
Women's Health									
NuvaRing	722	180	902	564	197	761	576	202	777
Implanon/Nexplanon	495	208	703	496	191	686	420	186	606
Diversified Brands									
Singulair	20	688	708	40	692	732	40	874	915
Cozaar/Hyzaar	23	431	453	18	466	484	16	494	511
Nasonex	23	353	376	54	333	387	184	352	537
Arcoxia	—	335	335	—	363	363	—	450	450
Follistim AQ	115	153	268	123	174	298	157	197	355
Dulera	186	28	214	261	26	287	412	24	436

Fosamax	4	205	209	6	235	241	5	279	284
Other pharmaceutical [2]	1,228	2,855	4,090	1,148	2,917	4,065	1,261	3,158	4,420
Total Pharmaceutical segment sales	16,608	21,081	37,689	15,854	19,536	35,390	17,073	18,077	35,151
Animal Health:									
Livestock	528	2,102	2,630	471	2,013	2,484	446	1,841	2,287
Companion Animals	710	872	1,582	619	772	1,391	543	648	1,191
Total Animal Health segment sales	1,238	2,974	4,212	1,090	2,785	3,875	989	2,489	3,478
Other segment sales [3]	248	2	250	396	1	397	385	—	385
Total segment sales	18,094	24,057	42,151	17,340	22,322	39,662	18,447	20,566	39,014
Other [4]	118	26	143	84	376	460	31	763	793
	$18,212	$24,083	$42,294	$17,424	$22,698	$40,122	$18,478	$21,329	$39,807

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

(1) On December 31, 2016, Merck and Sanofi terminated their equally-owned joint venture, SPMSD, which marketed vaccines in most major European markets (see Note 9). Accordingly, vaccine sales in 2018 and 2017 include sales in the European markets that were previously part of SPMSD. Amounts for 2016 do not include sales of vaccines sold through SPMSD, the results of which are reflected in equity income from affiliates included in Other (income) expense, net. Amounts for 2016 do, however, include supply sales to SPMSD.

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

(3) Represents the non-reportable segments of Healthcare Services and Alliances.

(4) Other is primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, as well as third-party manufacturing sales. Other in 2018, 2017 and 2016 also includes approximately $95 million, $85 million and $170 million, respectively, related to the sale of the marketing rights to certain products.

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Consolidated revenues by geographic area where derived are as follows:

Years Ended December 31	2018	2017	2016
United States	$18,212	$17,424	$18,478
Europe, Middle East and Africa	12,213	11,478	10,953
Japan	3,212	3,122	2,846
Asia Pacific (other than Japan and China)	2,909	2,751	2,483
Latin America	2,415	2,339	2,155
China	2,184	1,586	1,435
Other	1,149	1,422	1,457
	$42,294	$40,122	$39,807

A reconciliation of segment profits to Income before taxes is as follows:

Years Ended December 31	2018	2017	2016
Segment profits:			
Pharmaceutical segment	$24,292	$22,495	$22,141
Animal Health segment	1,659	1,552	1,357
Other segments	103	275	146
Total segment profits	26,054	24,322	23,644
Other profits	6	26	481
Unallocated:			
Interest income	343	385	328
Interest expense	(772)	(754)	(693)
Depreciation and amortization	(1,334)	(1,378)	(1,585)
Research and development	(8,853)	(9,481)	(9,218)
Amortization of purchase accounting adjustments	(2,664)	(3,056)	(3,692)
Restructuring costs	(632)	(776)	(651)
Charge related to termination of collaboration agreement with Samsung	(423)	—	—
Loss on extinguishment of debt	—	(191)	—
Gain on sale of certain migraine clinical development programs	—	—	100
Charge related to the settlement of worldwide Keytruda patent litigation	—	—	(625)
Other unallocated, net	(3,024)	(2,576)	(3,430)
	$8,701	$6,521	$4,659

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

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

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Other unallocated, net includes expenses from corporate and manufacturing cost centers, goodwill and other intangible asset impairment charges, gains or losses on sales of businesses, expense or income related to changes in the estimated fair value of liabilities for contingent consideration, and other miscellaneous income or expense items. In 2018, the Company adopted a new accounting standard related to the classification of certain defined benefit plan costs (see Note 2), which resulted in a change to the measurement of segment profits. Net periodic benefit cost (credit) other than service cost is no longer included as a component of segment profits. Prior period amounts have been recast to conform to the new presentation.

Equity (income) loss from affiliates and depreciation and amortization included in segment profits is as follows:

	Pharmaceutical	Animal Health	All Other	Total
Year Ended December 31, 2018				
Included in segment profits:				
Equity (income) loss from affiliates	$ 4	$ —	$ —	$4
Depreciation and amortization	243	82	10	335
Year Ended December 31, 2017				
Included in segment profits:				
Equity (income) loss from affiliates	$ 7	$ —	$ —	$7
Depreciation and amortization	125	75	12	212
Year Ended December 31, 2016				
Included in segment profits:				
Equity (income) loss from affiliates	$ (105)	$ —	$ —	$(105)
Depreciation and amortization	160	10	13	183

Property, plant and equipment, net, by geographic area where located is as follows:

December 31	2018	2017	2016
United States	$8,306	$8,070	$8,114
Europe, Middle East and Africa	3,706	3,151	2,732
Asia Pacific (other than Japan and China)	684	632	623
Latin America	264	271	234
China	167	150	152
Japan	159	158	164
Other	5	7	7
	$13,291	$12,439	$12,026

The Company does not disaggregate assets on a products and services basis for internal management reporting and, therefore, such information is not presented.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Merck & Co., Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Merck & Co., Inc and its subsidiaries (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of income, comprehensive income, equity and cash flows for each of the three years in the period ended December 31, 2018, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for retirement benefits in 2018.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of

internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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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.

PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 27, 2019

We have served as the Company's auditor since 2002.

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(b) Supplementary Data

Selected quarterly financial data for 2018 and 2017 are contained in the Condensed Interim Financial Data table below.

Condensed Interim Financial Data (Unaudited)

($ in millions except per share amounts)	4th Q [1]	3rd Q [2]	2nd Q	1st Q [3]
2018 [4]				
Sales	$10,998	$10,794	$10,465	$10,037
Cost of sales	3,289	3,619	3,417	3,184
Selling, general and administrative	2,643	2,443	2,508	2,508
Research and development	2,214	2,068	2,274	3,196
Restructuring costs	138	171	228	95
Other (income) expense, net	110	(172)	(48)	(291)
Income before taxes	2,604	2,665	2,086	1,345
Net income attributable to Merck & Co., Inc.	1,827	1,950	1,707	736
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	$0.70	$0.73	$0.64	$0.27
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	$0.69	$0.73	$0.63	$0.27
2017 [4] [5]				
Sales	$10,433	$10,325	$9,930	$9,434
Cost of sales	3,440	3,307	3,116	3,049
Selling, general and administrative	2,643	2,459	2,500	2,472
Research and development	2,314	4,413	1,782	1,830
Restructuring costs	306	153	166	151
Other (income) expense, net	(149)	(207)	(73)	(71)
Income before taxes	1,879	200	2,439	2,003
Net (loss) income attributable to Merck & Co., Inc.	(1,046)	(56)	1,946	1,551
Basic (loss) earnings per common share attributable to Merck & Co., Inc. common shareholders	$(0.39)	$(0.02)	$0.71	$0.56
(Loss) earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	$(0.39)	$(0.02)	$0.71	$0.56

[1] Amounts for 2017 include a provisional net tax charge related to the enactment of U.S. tax legislation (see Note 16).

[2] Amounts for 2017 include a charge related to the formation of a collaboration with AstraZeneca (see Note 4).

[3] Amounts for 2018 include a charge related to the formation of a collaboration with Eisai (see Note 4).

[4] Amounts for 2018 and 2017 reflect acquisition and divestiture-related costs (see Note 8) and the impact of restructuring actions (see Note 5).

[5] Amounts have been recast as a result of the adoption, on January 1, 2018, of a new accounting standard related to the classification of certain defined benefit plan costs. There was no impact to net income as a result of adopting the new accounting standard (see Note 2).

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Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures. Based on their evaluation, as of the end of the period covered by this Form 10-K, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Act)) are effective. For the fourth quarter of 2018, there have been no changes in internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Act. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in Internal Control — Integrated Framework issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2018.

PricewaterhouseCoopers LLP, an independent registered public accounting firm, has performed its own assessment of the effectiveness of the Company's internal control over financial reporting and its attestation report is included in this Form 10-K filing.

Management's Report

Management's Responsibility for Financial Statements

Responsibility for the integrity and objectivity of the Company's financial statements rests with management. The financial statements report on management's stewardship of Company assets. These statements are prepared in conformity with generally accepted accounting principles and, accordingly, include amounts that are based on management's best estimates and judgments. Nonfinancial information included in the Annual Report on Form 10-K has also been prepared by management and is consistent with the financial statements.

To assure that financial information is reliable and assets are safeguarded, management maintains an effective system of internal controls and procedures, important elements of which include: careful selection, training and development of operating and financial managers; an organization that provides appropriate division of responsibility; and communications aimed at assuring that Company policies and procedures are understood throughout the organization. A staff of internal auditors regularly monitors the adequacy and application of internal controls on a worldwide basis. To ensure that personnel continue to understand the system of internal controls and procedures, and policies concerning good and prudent business practices, annually all employees of the Company are required to complete Code of Conduct training. This training reinforces the importance and understanding of internal controls by reviewing key corporate policies, procedures and systems. In addition, the Company has compliance programs, including an ethical business practices program to reinforce the Company's long-standing commitment to high ethical standards in the conduct of its business.

The financial statements and other financial information included in the Annual Report on Form 10-K fairly present, in all material respects, the Company's financial condition, results of operations and cash flows. Our formal certification to the Securities and Exchange Commission is included in this Form 10-K filing.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in Internal Control — Integrated Framework issued

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in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2018.
Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.
The effectiveness of the Company's internal control over financial reporting as of December 31, 2018, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Kenneth C. Frazier	Robert M. Davis
Chairman, President	Executive Vice President, Global Services,
and Chief Executive Officer	and Chief Financial Officer

Item 9B. Other Information.
None.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The required information on directors and nominees is incorporated by reference from the discussion under Proposal 1. Election of Directors of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 28, 2019. Information on executive officers is set forth in Part I of this document on page 32.

The required information on compliance with Section 16(a) of the Securities Exchange Act of 1934 is incorporated by reference from the discussion under the heading "Section 16(a) Beneficial Ownership Reporting Compliance" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 28, 2019.

The Company has a Code of Conduct — Our Values and Standards applicable to all employees, including the principal executive officer, principal financial officer, principal accounting officer and Controller. The Code of Conduct is available on the Company's website at www.merck.com/about/code_of_conduct.pdf. The Company intends to disclose future amendments to certain provisions of the Code of Conduct, and waivers of the Code of Conduct granted to executive officers and directors, if any, on the website within four business days following the date of any amendment or waiver. Every Merck employee is responsible for adhering to business practices that are in accordance with the law and with ethical principles that reflect the highest standards of corporate and individual behavior.

The required information on the identification of the audit committee and the audit committee financial expert is incorporated by reference from the discussion under the heading "Board Meetings and Committees" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 28, 2019.

Item 11. Executive Compensation.

The information required on executive compensation is incorporated by reference from the discussion under the headings "Compensation Discussion and Analysis", "Summary Compensation Table", "All Other Compensation" table, "Grants of Plan-Based Awards" table, "Outstanding Equity Awards" table, "Option Exercises and Stock Vested" table, "Pension Benefits" table, "Nonqualified Deferred Compensation" table, Potential Payments Upon Termination or a Change in Control, including the discussion under the subheadings "Separation" and "Change in Control", as well as all footnote information to the various tables, of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 28, 2019.

The required information on director compensation is incorporated by reference from the discussion under the heading "Director Compensation" and related "Director Compensation" table and "Schedule of Director Fees" table of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 28, 2019.

The required information under the headings "Compensation and Benefits Committee Interlocks and Insider Participation" and "Compensation and Benefits Committee Report" is incorporated by reference from the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 28, 2019.

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Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information with respect to security ownership of certain beneficial owners and management is incorporated by reference from the discussion under the heading “Stock Ownership Information” of the Company’s Proxy Statement for the Annual Meeting of Shareholders to be held May 28, 2019.

Equity Compensation Plan Information

The following table summarizes information about the options, warrants and rights and other equity compensation under the Company’s equity compensation plans as of the close of business on December 31, 2018. The table does not include information about tax qualified plans such as the Merck U.S. Savings Plan.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders[1]	23,807,101[2]	$ 51.89	110,977,283
Equity compensation plans not approved by security holders	—	—	—
Total	23,807,101	$ 51.89	110,977,283

(1) Includes options to purchase shares of Company Common Stock and other rights under the following shareholder-approved plans: the Merck Sharp & Dohme 2004, 2007 and 2010 Incentive Stock Plans, the Merck & Co., Inc. 2006 and 2010 Non-Employee Directors Stock Option Plans, and the Merck & Co., Inc. Schering-Plough 2002 and 2006 Stock Incentive Plans.

(2) Excludes approximately 16,128,455 shares of restricted stock units and 2,039,065 performance share units (assuming maximum payouts) under the Merck Sharp & Dohme 2004, 2007 and 2010 Incentive Stock Plans. Also excludes 224,599 shares of phantom stock deferred under the MSD Employee Deferral Program and 582,155 shares of phantom stock deferred under the Merck & Co., Inc. Plan for Deferred Payment of Directors’ Compensation.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The required information on transactions with related persons is incorporated by reference from the discussion under the heading “Related Person Transactions” of the Company’s Proxy Statement for the Annual Meeting of Shareholders to be held May 28, 2019.

The required information on director independence is incorporated by reference from the discussion under the heading “Independence of Directors” of the Company’s Proxy Statement for the Annual Meeting of Shareholders to be held May 28, 2019.

Item 14. Principal Accountant Fees and Services.

The information required for this item is incorporated by reference from the discussion under Proposal 4. Ratification of Appointment of Independent Registered Public Accounting Firm for 2019 beginning with the caption “Pre-Approval Policy for Services of Independent Registered Public Accounting Firm” through “Fees for Services Provided by the Independent Registered Public Accounting Firm” of the Company’s Proxy Statement for the Annual Meeting of Shareholders to be held May 28, 2019.

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PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this Form 10-K

1. Financial Statements

Consolidated statement of income for the years ended December 31, 2018, 2017 and 2016

Consolidated statement of comprehensive income for the years ended December 31, 2018, 2017 and 2016

Consolidated balance sheet as of December 31, 2018 and 2017

Consolidated statement of equity for the years ended December 31, 2018, 2017 and 2016

Consolidated statement of cash flows for the years ended December 31, 2018, 2017 and 2016

Notes to consolidated financial statements

Report of PricewaterhouseCoopers LLP, independent registered public accounting firm

2. Financial Statement Schedules

Schedules are omitted because they are either not required or not applicable.

Financial statements of affiliates carried on the equity basis have been omitted because, considered individually or in the aggregate, such affiliates do not constitute a significant subsidiary.

3. Exhibits

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) — Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
3.2	By-Laws of Merck & Co., Inc. (effective July 22, 2015) — Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed July 28, 2015 (No. 1-6571)
4.1	Indenture, dated as of April 1, 1991, between Merck Sharp & Dohme Corp. (f/k/a Schering Corporation) and U.S. Bank Trust National Association (as successor to Morgan Guaranty Trust Company of New York), as Trustee (the 1991 Indenture) — Incorporated by reference to Exhibit 4 to MSD's Registration Statement on Form S-3 (No. 33-39349)
4.2	First Supplemental Indenture to the 1991 Indenture, dated as of October 1, 1997 — Incorporated by reference to Exhibit 4(b) to MSD's Registration Statement on Form S-3 filed September 25, 1997 (No. 333-36383)
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)

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4.8	Fifth Supplemental Indenture to the 2003 Indenture, dated November 3, 2009 — Incorporated by reference to Exhibit 4.4 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
4.9	Indenture, dated as of January 6, 2010, between Merck & Co., Inc. and U.S. Bank Trust National Association, as Trustee — Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed December 10, 2010 (No. 1-6571)
4.10	Long-term debt instruments under which the total amount of securities authorized does not exceed 10% of Merck & Co., Inc.'s total consolidated assets are not filed as exhibits to this report. Merck & Co., Inc. will furnish a copy of these agreements to the Securities and Exchange Commission on request.
*10.1	Merck & Co., Inc. Executive Incentive Plan (as amended and restated effective June 1, 2015) — Incorporated by reference to Merck & Co., Inc.'s Schedule 14A filed April 13, 2015 (No. 1-6571)
*10.2	Merck & Co., Inc. Deferral Program Including the Base Salary Deferral Plan (Amended and Restated effective December 1, 2015) — Incorporated by reference to Exhibit 10.2 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2016 filed February 28, 2017 (No. 1-6571)
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*10.4	Amendment One to the Merck Sharp & Dohme Corp. 2007 Incentive Stock Plan (effective February 15, 2010) — Incorporated by reference to Exhibit 10.2 to Merck & Co., Inc.'s Current Report on Form 8-K filed February 18, 2010 (No. 1-6571)
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*10.11	Form of stock option terms for 2015 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.20 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2015 filed February 26, 2016 (No. 1-6571)
10.12	Form of stock option terms for 2018 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by referent to Exhibit 10.12 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2017 filed February 27, 2018 (No. 1-6571)

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*10.13	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)
*10.14	Form of restricted stock unit terms for 2016 quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.20 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2016 filed February 28, 2017 (No. 1-6571)
*10.15	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)
*10.16	Form of performance share unit terms for 2016 grants under the Merck & Co., Inc. 2010 Stock Incentive Plan — Incorporated by reference to Exhibit 10.21 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2016 filed February 28, 2017 (No. 1-6571)
10.17	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)
*10.18	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)
*10.19	Merck & Co., Inc. U.S. Separation Benefits Plan (amended and restated as of January 1, 2019)
*10.20	Merck & Co., Inc. 2006 Non-Employee Directors Stock Option Plan (amended and restated as of November 3, 2009) — Incorporated by reference to Exhibit 10.5 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
*10.21	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)
*10.22	Retirement Plan for the Directors of Merck & Co., Inc. (amended and restated June 21, 1996) —Incorporated by reference to Exhibit 10.C to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1996 filed August 13, 1996 (No. 1-3305)
*10.23	Merck & Co., Inc. Plan for Deferred Payment of Directors' Compensation (effective as amended and restated as of January 1, 2018) — Incorporated by reference to Exhibit 10.24 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2017 filed February 27, 2018 (No. 1-6571)
10.24	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)†
10.25	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)†
10.26	Accelerated Share Purchase Agreement between Merck & Co., Inc. and Goldman, Sachs & Co., dated May 20, 2013 — Incorporated by reference to Exhibit 10 to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the period ended June 30, 2013 filed August 7, 2013 (No. 1-6571)
10.27	Severance Agreement and General Release between Merck & Co., Inc. and Adam H. Schechter, dated December 1, 2018
10.28	Offer Letter between Merck & Co., Inc. and Jennifer Zachary, dated March 16, 2018
21	Subsidiaries of Merck & Co., Inc.
23	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney

24.2 —Certified Resolution of Board of Directors

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Exhibit Number	Description
31.1	—Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
31.2	—Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer
32.1	—Section 1350 Certification of Chief Executive Officer
32.2	—Section 1350 Certification of Chief Financial Officer
101	—The following materials from Merck & Co., Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2018, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statement of Income, (ii) the Consolidated Statement of Comprehensive Income, (iii) the Consolidated Balance Sheet, (iv) the Consolidated Statement of Equity, (v) the Consolidated Statement of Cash Flows, and (vi) Notes to Consolidated Financial Statements.

* Management contract or compensatory plan or arrangement.

† Certain portions of the exhibit have been omitted pursuant to a request for confidential treatment. The non-public information has been filed separately with the Securities and Exchange Commission pursuant to rule 24b-2 under the Securities Exchange Act of 1934, as amended.

Item 16. Form 10-K Summary

Not applicable.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: February 27, 2019

MERCK & CO., INC.

By: KENNETH C. FRAZIER
(Chairman, President and Chief Executive Officer)

By: /s/ JENNIFER ZACHARY
Jennifer Zachary
(Attorney-in-Fact)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signatures	Title	Date
KENNETH C. FRAZIER	Chairman, President and Chief Executive Officer; Principal Executive Officer; Director	February 27, 2019
ROBERT M. DAVIS	Executive Vice President, Global Services, and Chief Financial Officer; Principal Financial Officer	February 27, 2019
RITA A. KARACHUN	Senior Vice President Finance-Global Controller; Principal Accounting Officer	February 27, 2019
LESLIE A. BRUN	Director	February 27, 2019
THOMAS R. CECH	Director	February 27, 2019
PAMELA J. CRAIG	Director	February 27, 2019
THOMAS H. GLOCER	Director	February 27, 2019
ROCHELLE B. LAZARUS	Director	February 27, 2019
JOHN H. NOSEWORTHY	Director	February 27, 2019
PAUL B. ROTHMAN	Director	February 27, 2019
PATRICIA F. RUSSO	Director	February 27, 2019
INGE G. THULIN	Director	February 27, 2019
WENDELL P. WEEKS	Director	February 27, 2019
PETER C. WENDELL	Director	February 27, 2019

Jennifer Zachary, by signing her name hereto, does hereby sign this document pursuant to powers of attorney duly executed by the persons named, filed with the Securities and Exchange Commission as an exhibit to this document, on behalf of such persons, all in the capacities and on the date stated, such persons including a majority of the directors of

the Company.

By: /S/ JENNIFER ZACHARY
Jennifer Zachary
(Attorney-in-Fact)

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*10.6	Form of stock option terms for a non-qualified stock option under the Merck Sharp & Dohme Corp. 2007 Incentive Stock Plan and the Schering-Plough 2006 Stock Incentive Plan — Incorporated by reference to Exhibit 10.3 to Merck & Co., Inc.'s Current Report on Form 8-K filed February 18, 2010 (No. 1-6571)
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*10.19	Merck & Co., Inc. U.S. Separation Benefits Plan (amended and restated as of January 1, 2019)
*10.20	Merck & Co., Inc. 2006 Non-Employee Directors Stock Option Plan (amended and restated as of November 3, 2009) — Incorporated by reference to Exhibit 10.5 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
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23	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney
24.2	Certified Resolution of Board of Directors
31.1	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
31.2	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer
32.1	Section 1350 Certification of Chief Executive Officer
32.2	Section 1350 Certification of Chief Financial Officer
101	The following materials from Merck & Co., Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2018, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statement of Income, (ii) the Consolidated Statement of Comprehensive Income, (iii) the Consolidated Balance Sheet, (iv) the Consolidated Statement of Equity, (v) the Consolidated Statement of Cash Flows, and (vi) Notes to Consolidated Financial Statements.

* Management contract or compensatory plan or arrangement.

† Certain portions of the exhibit have been omitted pursuant to a request for confidential treatment. The non-public information has been filed separately with the Securities and Exchange Commission pursuant to rule 24b-2 under the Securities Exchange Act of 1934, as amended.