## 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, 2017

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:

<u>Title of Each Class</u>	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, 2018 : 2,696,190,502.

Aggregate market value of Common Stock (0.50 par value) held by non-affiliates on June 30, 2017 based on closing price on June 30, 2017: 174,700,000,000. Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No  $\Box$ 

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  $\square$  No  $\square$ 

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T ( $\S$  232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  $\boxtimes$  No  $\square$ 

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	$\square$ (Do not check if a smaller reporting company)	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.  $\Box$ 

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:**

1 0	
Document	Part of Form 10-K
Proxy Statement for the Annual Meeting of Shareholders to be held May 22, 2018, to be filed with the	Part III
Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this report	

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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 is the only reportable segment.

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. 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 Company also has an Animal Health segment that discovers, develops, manufactures and markets animal health products, including vaccines, which the Company sells to veterinarians, distributors and animal producers. The Company's Healthcare Services segment provides services and solutions that focus on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company was incorporated in New Jersey in 1970.

For financial information and other information about the Company's segments, see Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Item 8. "Financial Statements and Supplementary Data" below.

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 total sales of animal health products, were as follows:

(\$ in millions)	2017	2016		2015
Total Sales	\$ 40,122	\$ 39,8	07	\$ 39,498
Pharmaceutical	35,390	35,1	51	34,782
Januvia/Janumet	5,896	6,1	09	6,014
Keytruda	3,809	1,4	02	566
Gardasil/Gardasil 9	2,308	2,1	73	1,908
Zetia/Vytorin	2,095	3,7	01	3,777
ProQuad/M-M-R II /Varivax	1,676	1,6	40	1,505
Zepatier	1,660	5	55	_
Isentress/Isentress HD	1,204	1,3	87	1,511
Remicade	837	1,2	68	1,794
Pneumovax 23	821	6	41	542
Simponi	819	7	66	690
Animal Health	3,875	3,4	78	3,331
Other Revenues <sup>(1)</sup>	857	1,1	78	1,385

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

#### Pharmaceutical

The Company's pharmaceutical products include therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. Certain of the products within the Company's franchises are as follows:

#### Primary Care and Women's Health

Cardiovascular: Zetia (ezetimibe) (marketed as *Ezetrol* in most countries outside the United States); *Vytorin* (ezetimibe/simvastatin) (marketed as *Inegy* outside the United States); and *Atozet* (ezetimibe and atorvastatin) (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.

General Medicine and Women's Health: *NuvaRing* (etonogestrel/ethinyl estradiol vaginal ring), a vaginal contraceptive product ; *Implanon* (etonogestrel implant), a single-rod subdermal contraceptive implant/ *Nexplanon* (etonogestrel implant), a single, radiopaque, rod-shaped subdermal contraceptive implant; and *Follistim AQ* (follitropin beta injection) (marketed as *Puregon* in most countries outside the United States), a fertility treatment.

#### Hospital and Specialty

Hepatitis: 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.

HIV: Isentress/Isentress HD (raltegravir), an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection.

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; *Cancidas* (caspofungin acetate), an anti-fungal product; *Cubicin* ( daptomycin for injection), an I.V. antibiotic for complicated skin and skin structure infections or bacteremia, when caused by designated susceptible organisms; and *Primaxin* (imipenem and cilastatin sodium), an anti-bacterial product.

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

#### 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 lunch 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 pemetrexed and carboplatin in certain patients with 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.

#### **Diversified Brands**

Respiratory: *Singulair* (montelukast), a medicine indicated for the chronic treatment of asthma and the relief of symptoms of allergic rhinitis; *Nasonex* (mometasone furoate monohydrate), an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms; and *Dulera* Inhalation Aerosol (mometasone furoate/formoterol fumarate dihydrate), a combination medicine for the treatment of asthma.

Other: *Cozaar* (losartan potassium) and *Hyzaar* (losartan potassium and hydrochlorothiazide), treatments for hypertension; *Arcoxia* (etoricoxib) for the treatment of arthritis and pain, which the Company markets outside the United States; and *Fosamax* (alendronate sodium) (marketed as *Fosamac* in Japan) for the treatment and prevention of osteoporosis.

#### 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 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).

#### Animal Health

The Animal Health segment discovers, develops, manufactures and markets animal health products, including vaccines. 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; and *Porcilis* (Lawsonia intracellularis baterin) and *Circumvent* (Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector) vaccine lines for infectious diseases in swine.

Poultry Products: Nobilis / Innovax (Live Marek's Disease Vector), vaccine lines for poultry; Paracox and Coccivac coccidiosis vaccines and Exzolt, a systemic treatment for poultry red mite infestations.

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 *Activyl* (Indoxacrb) /*Scalibor* (Deltamethrin) /*Exspot* for protecting against bites from fleas, ticks, mosquitoes and sandflies.

Aquaculture Products: *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.

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.



## 2017 Product Approvals

Set forth below is a summary of significant product approvals received by the Company in 2017.

Product	Date	Approval
	December 2017	Japanese Ministry of Health, Labour and Welfare approved <i>Keytruda</i> for the treatment of patients with radically unresectable urothelial carcinoma who progressed after cancer chemotherapy.
	September 2017	The U.S. Food and Drug Administration (FDA) approved <i>Keytruda</i> for previously treated patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction cancer whose tumors express PD-L1.
	September 2017	The European Commission (EC) approved <i>Keytruda</i> for the treatment of certain patients with locally advanced or metastatic urothelial carcinoma, a type of bladder cancer.
	May 2017	FDA approved <i>Keytruda</i> for the treatment of adult and pediatric patients with previously treated unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient, solid tumors.
Keytruda	May 2017	FDA approved <i>Keytruda</i> for the treatment of certain patients with locally advanced or metastatic urothelial carcinoma, a type of bladder cancer.
	May 2017	FDA approved <i>Keytruda</i> in combination with pemetrexed and carboplatin for the first-line treatment of patients with metastatic nonsquamous NSCLC.
	May 2017	EC approved <i>Keytruda</i> for the treatment of adult patients with relapsed or refractory classical Hodgkin Lymphoma (cHL) who have failed autologous stem cell transplant (ASCT) and brentuximab vedotin (BV), or who are transplant-eligible and have failed BV.
	March 2017	FDA approved <i>Keytruda</i> for the treatment of adult and pediatric patients with refractory cHL, or who have relapsed after three or more prior lines of therapy.
	January 2017	EC approved <i>Keytruda</i> for the first-line treatment of metastatic NSCLC in adults whose tumors have high PD-L1 expression with no EGFR or ALK positive tumor mutations.
Lynparza <sup>(1)</sup>	August 2017	<ul> <li>FDA approved the oral poly (ADP-ribose) polymerase (PARP) inhibitor, Lynparza (olaparib), as follows:</li> <li>New use of Lynparza as a maintenance treatment for recurrent, epithelial ovarian, fallopian tube or primary peritoneal adult cancer who are in response to platinum-based chemotherapy, regardless of BRCA status;</li> <li>New use of Lynparza tablets (2 tablets twice daily) as opposed to capsules (8 capsules twice daily);</li> <li>Lynparza tablets also now indicated for the use in patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer, who have been treated with three or more prior lines of chemotherapy.</li> </ul>
Isentress	November 2017	FDA approved <i>Isentress</i> for use in combination with other antiretroviral agents for the treatment of HIV-1 in neonates - newborn patients from birth to four weeks of age - weighing at least 2 kg.

July 2017 Isentress HD May 2017		EC approved <i>Isentress</i> 600 mg film-coated tablets, in combination with other anti-retroviral medicinal products, as a once-daily treatment of HIV-1 infection in patients who are treatment-naïve or who are virologically suppressed on an initial regimen of <i>Isentress</i> 400 mg twice daily.
		FDA approved <i>Isentress HD</i> , a once-daily dose of <i>Isentress</i> , in combination with other antiretroviral agents, for the treatment of HIV-1 infection patients who are treatment-naïve or whose virus has been suppressed on an initial regimen of <i>Isentress</i> 400 mg given twice daily.
Prevymis	November 2017	FDA approved <i>Prevymis</i> (letermovir) for prophylaxis (prevention) of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).
Steglatro/ Steglujan/ Segluromet <sup>(2)</sup>	December 2017	FDA approved <i>Steglatro</i> (ertugliflozin) tablets, an oral sodium-glucose cotransporter 2 (SGLT2) inhibitor, the fixed-dose combination <i>Steglujan</i> (ertugliflozin and sitagliptin) tablets, and the fixed-dose combination <i>Segluromet</i> (ertugliflozin and metformin hydrochloride) for the treatment of type 2 diabetes.

(1) 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.
 (2) 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, 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 further 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 \$385 million, \$415 million and \$550 million was recorded by Merck as a reduction to revenue in 2017, 2016 and 2015, 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 \$4.0 billion in 2017 and will increase to \$4.1 billion in 2018. The annual fee will decline 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 \$210 million, \$193 million and \$173 million of costs within Marketing and administrative expenses in 2017, 2016 and 2015, respectively, for the annual health care reform fee. In February 2016, the Centers for 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.

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 results of operations, financial condition or business.

Also, during 2016, the Vermont legislature passed a pharmaceutical cost transparency law. The law requires manufacturers identified by the Vermont Green Mountain Care Board to report certain product price information to the Vermont Attorney General. The Attorney General is then required to submit a report to the legislature. During 2017, Nevada and California passed similar price transparency bills requiring manufacturers to disclose certain pricing information and to provide advance notification of price increases. A number of other states have introduced legislation of this kind and the Company expects that states will continue their focus on pharmaceutical price transparency. The extent to which these proposals will pass into law is unknown at this time.

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 pricing or 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 utilization 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 recently posted on its website its Pricing Action Transparency Report for the United States for the years 2010 - 2017. 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. The report shows that the Company's average annual net price increases (after taking sales deductions such as rebates, discounts and returns into account) across the U.S. human health portfolio have been in the low to mid-single digits from 2010 - 2016. In 2017, the average net price across the Company's portfolio declined by 1.9%, reflecting specific in-year dynamics, including the impact of loss of patent protection for three major Merck medicines. Additionally, the weighted average annual discount rate has been steadily increasing over time, reflecting the competitive market for branded medicines and the impact of the ACA. In 2017, the Company's gross U.S. sales were reduced by 45.1% as a result of rebates, discounts and returns.

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

In addition, in Japan, the pharmaceutical industry is subject to government-mandated biennial price reductions of pharmaceutical products and certain vaccines, which will occur again 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 2018 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, 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 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 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 a new EU General Data Protection Regulation, which will become effective in 2018 and impose penalties up to 4% of global revenue, additional laws and regulations enacted in the United States, Europe, Asia and Latin America, increased enforcement and litigation activity in the United States and other developed markets, and increased regulatory cooperation among privacy authorities globally. The Company has adopted a comprehensive global privacy program to manage these evolving risks which has been certified as compliant with and approved by the Asia Pacific Economic Cooperation Cross-Border Privacy Rules System, the EU-U.S. 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.

#### 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 studies 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:

CancidasExpiredExpired2022ZostavaxExpired2018 (use)N/AZetiaExpired20182019VytorinExpired20192019Asmanex2018 (formulation)2020 (formulation)	
Zetia         Expired         2018         2019           Vytorin         Expired         2019         2019	
VytorinExpired20192019	
Assurance 2018 (formulation) 2018 (formulation) 2020 (formulation)	
NuvaRing2018 (delivery system)2018 (delivery system)N/A	
<i>Emend</i> for Injection 2019 <sup>(2)</sup> 2020 <sup>(2)</sup> 2020	
Follistim AQ2019 (formulation)2019 (formulation)2019 (formulation)	
<i>Noxafil</i> 2019 2019 N/A	
RotaTeq 2019 Expired Expired	
Recombivax 2020 (method of making) Expired Expired	
Dulera 2020 (combination) N/A N/A	
Januvia 2022 <sup>(2)</sup> 2022 <sup>(2)</sup> 2025-2026 <sup>(3)</sup>	
<i>Janumet</i> 2022 <sup>(2)</sup> 2023 N/A	
<i>Janumet XR</i> 2022 <sup>(2)</sup> N/A N/A	
<i>Isentress</i> 2024 2022 <sup>(2)</sup> 2022	
<i>Simponi</i> N/A <sup>(4)</sup> 2024 N/A <sup>(4)</sup>	
Adempas <sup>(5)</sup> 2026 <sup>(2)</sup> 2023 (patents), 2028 <sup>(2)</sup> (SPCs)         2027-2028 <sup>(3)</sup>	
<i>Bridion</i> 2026 <sup>(2)</sup> (with pending PTE) 2023 2024	
Nexplanon2027 (device)2025 (device)Not Marketed	
Bravecto         2027 (with pending PTE)         2025 (patents), 2029 (SPCs)         2029	
<i>Gardasil</i> 2028 2021 <sup>(2)</sup> 2017	
Gardasil 9         2028         2025 (patents), 2030 <sup>(2)</sup> (SPCs)         N/A	
Keytruda         2028         2028 (patents), 2030 <sup>(2)</sup> (SPCs)         2032	
Lynparza <sup>(6)</sup> 2028 <sup>(2)</sup> (with pending PTE) 2024 (patents), 2029 <sup>(2)</sup> (SPCs) 2024 <sup>(7)</sup>	
Zerbaxa         2028 <sup>(2)</sup> (with pending PTE)         2023 (patents), 2028 <sup>(2)</sup> (SPCs)         N/A	
<i>Sivextro</i> 2028 <sup>(2)</sup> 2024 (patents), 2029 <sup>(2)</sup> (SPCs) N/A	
<i>Belsomra</i> 2029 <sup>(2)</sup> N/A 2031	
<i>Prevymis</i> 2029 <sup>(2)</sup> (with pending PTE) 2024 <sup>(8)</sup> N/A	
Steglatro <sup>(9)</sup> 2031 <sup>(2)</sup> (with pending PTE) N/A N/A	
Steglujan <sup>(9)</sup> 2031 (with pending PTE) N/A N/A	
Segluromet <sup>(9)</sup> 2031 (with pending PTE) N/A N/A	
<i>Zepatier</i> 2031 <sup>(2)</sup> 2030 (patents), 2031 <sup>(2)</sup> (SPCs) 2034 (with pending PTE)	

N/A: Currently no marketing approval.

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

(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 an SPC has been granted in some but not all Major EU Markets, both the patent expiry date and the SPC expiry date are listed.

(2)

the patent expiry date dual in sort C expiry and are tisted. Eligible for 6 months Pediatric Exclusivity. 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. The Company has no marketing rights in the U.S. and Japan. Being commercialized in a worldwide collaboration with Bayer AG. (3) (4)

(5)

Being developed and commercialized in a global strategic oncology collaboration with AstraZeneca. PTE application to be filed by April 2018. Expected expiry 2029. (6)

(7) (8)

SPC applications to be filed by July 2018. Expected expiry 2029. Eligible for Pediatric Exclusivity. Being developed and promoted in a worldwide, except Japan, collaboration with Pfizer.

(9)

While the expiration of a product patent normally results in a loss of market exclusivity for the covered pharmaceutical product, commercial benefits may continue to be derived from: (i) later-granted patents on processes and intermediates related to the most economical method of manufacture of the active ingredient of such product; (ii) patents relating to the use of such product; (iii) patents relating to novel compositions and formulations; and (iv) in

the United States and certain other countries, market exclusivity that may be available under relevant law. The effect of product patent expiration on pharmaceutical products also depends upon many other factors such as the nature of the market and the position of the product in it, the growth of the market, the complexities and economics of the process for manufacture of the active ingredient of the product and the requirements of new drug provisions of the Federal Food, Drug and Cosmetic Act or similar laws and regulations in other countries.

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

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 Davian (in the U.S.)	Currently Anticipated
<u>Under Review (in the U.S.)</u>	<u>Year of Expiration (in the U.S.)</u>
V419 (pediatric hexavalent combination vaccine)	2020 (method of making)
MK-1439 (doravirine)	2031
MK-1439A (doravirine/lamivudine/tenofovir disoproxil fumarate)	2031

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

Phase 3 Drug Candidate	Currently Anticipated <u>Year of Expiration (in the U.S.)</u>
V920 (ebola vaccine)	2023
MK-5618 (selumetinib) <sup>(1)</sup>	2023
MK-7655A (relebactam + imipenem/cilastatin)	2030
MK-1242 (vericiguat) <sup>(2)</sup>	2031

*(*1) Being developed and commercialized in a global strategic oncology collaboration with AstraZeneca. 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 2017 on patent and know-how licenses and other rights amounted to \$158 million. Merck also incurred royalty expenses amounting to \$944 million in 2017 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, 2017, approximately 12,650 people were employed in the Company's research activities. Research and development expenses were \$10.2 billion in 2017.

\$10.1 billion in 2016 and \$6.7 billion in 2015 (which included restructuring costs and acquisition and divestiture-related costs in all years). The Company prioritizes its research and development efforts and focuses on candidates that it believes represent breakthrough science that will make a difference for patients and payers.

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

The Company 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 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 vorld 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 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 December 2017, the FDA accepted for review a supplemental BLA for *Keytruda* for the treatment of adult and pediatric patients with refractory primary mediastinal B-cell lymphoma (PMBCL), or who have relapsed after two or more prior lines of therapy. The FDA granted Priority Review status with a PDUFA, or target action, date of April 3, 2018.

Additionally, *Keytruda* has received Breakthrough Therapy designation from the FDA in combination with axitnib as a first-line treatment for patients with advanced or metastatic renal cell carcinoma; for the treatment of high-risk early-stage triple-negative breast cancer in combination with neoadjuvant chemotherapy; and for the treatment of Merkel cell carcinoma. Also, in January 2018, Merck and Eisai Co., Ltd. (Eisai) announced receipt of Breakthrough Therapy designation from the FDA for Eisai's multiple receptor tyrosine kinase inhibitor Lenvima (lenvatinib) in combination with *Keytruda* for the potential treatment of patients with advanced and/or metastatic renal cell carcinoma. The Lenvima and *Keytruda* combination therapy is being jointly developed by Eisai and Merck. This marks the 12 <sup>th</sup> Breakthrough Therapy designation granted to *Keytruda*. The FDA's Breakthrough Therapy designation is intended to expedite the development and review of a candidate that is planned for use, alone or in combination, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

In January 2018, Merck announced that the pivotal Phase 3 KEYNOTE-189 trial investigating *Keytruda* in combination with pemetrexed (Alimta) and cisplatin or carboplatin, for the first-line treatment of patients with metastatic non-squamous NSCLC, met its dual primary endpoints of overall survival (OS) and progression-free survival (PFS). Based on an interim analysis conducted by the independent Data Monitoring Committee, treatment with *Keytruda* in combination with pemetrexed plus platinum chemotherapy resulted in significantly longer OS and PFS than pemetrexed plus platinum chemotherapy alone. Results from KEYNOTE-189 will be presented at an upcoming medical meeting and submitted to regulatory authorities.

In 2017, the FDA placed a full clinical hold on KEYNOTE-183 and KEYNOTE-185 and a partial clinical hold on Cohort 1 of KEYNOTE-023, three combination studies of *Keytruda* with lenalidomide or pomalidomide versus lenalidomide or pomalidomide alone in the blood cancer multiple myeloma. This decision followed a review of data by the Data Monitoring Committee in which more deaths were observed in the *Keytruda* arms of KEYNOTE-183 and KEYNOTE-185. The FDA determined that the data available at the time indicated that the risks of *Keytruda* plus pomalidomide or lenalidomide outweighed any potential benefit for patients with multiple myeloma. All patients enrolled in KEYNOTE-183 and KEYNOTE-185 and those in the *Keytruda* /lenalidomide/dexamethasone cohort in KEYNOTE-023 have discontinued investigational treatment with *Keytruda*. This clinical hold does not apply to other studies with *Keytruda*.

The *Keytruda* clinical development program consists of more than 700 clinical trials, including more than 400 trials that combine *Keytruda* with other cancer treatments. These studies encompass more than 30 cancer types including: bladder, colorectal, esophageal, gastric, head and neck, hepatocellular, Hodgkin lymphoma, non-Hodgkin lymphoma, melanoma, 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.

MK-8835, ertugliflozin, an investigational oral SGLT-2 inhibitor in development to help improve glycemic control in adults with type 2 diabetes, and two fixed-dose combination products (MK-8835A, ertugliflozin and *Januvia*, and MK-8835B, ertugliflozin and metformin) are under review in the EU. In January 2018, the Committee for Medicinal Products for Human Use (CHMP) of the EMA adopted a positive opinion recommending approval of these medicines. The CHMP positive opinion will be considered by the EC. Ertugliflozin and the two fixed-dose combination products were approved by the FDA in December 2017.

MK-0431J is an investigational fixed-dose combination of sitagliptin and ipragliflozin under review with the Japan Pharmaceuticals and Medical Devices Agency. MK-0431 is being developed for commercialization in Japan

in collaboration with Astellas Pharma Inc. (Astellas). Ipragliflozin, an SGLT2 inhibitor, co-developed by Astellas and Kotobuki Pharmaceutical Co., Ltd. (Kotobuki), is approved for use in Japan and is being co-promoted with Merck and Kotobuki.

MK-1439, doravirine, is an investigational, non-nucleoside reverse transcriptase inhibitor for the treatment of HIV-1 infection. In January 2018, Merck announced that the FDA accepted for review two NDAs for doravirine. The NDAs include data for doravirine as a once-daily tablet for use in combination with other antiretroviral agents, and for use of doravirine with lamivudine and tenofovir disoproxil fumarate in a once-daily fixed-dose combination single tablet as a complete regimen (MK-1439A). The PDUFA action date for both applications is October 23, 2018.

V419 is an investigational pediatric hexavalent combination vaccine, DTaP5-IPV-Hib-HepB, under review with the FDA that is being developed and, if approved, will be commercialized through a joint venture between Merck and Sanofi. This vaccine is designed to help protect against six important diseases - diphtheria, tetanus, pertussis (whooping cough), polio (poliovirus types 1, 2, and 3), invasive disease caused by *Haemophilus influenzae* type b (Hib), and hepatitis B. In November 2015, the FDA issued a CRL with respect to the BLA for V419. Both companies are working to provide additional data requested by the FDA. V419 is being marketed as *Vaxelis* in the EU.

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-7655A is a combination of relebactam, an investigational beta-lactamase inhibitor, and imipenem/cilastatin (an approved carbapenem antibiotic). The FDA has designated this combination a QIDP 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.

MK-7339, Lynparza (olaparib), 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.

MK-5618, selumetinib, is an oral, potent, selective inhibitor of MEK, part of the mitogen-activated protein kinase (MAPK) pathway, currently being developed for multiple cancer types. Additionally, in February 2018, the FDA granted Orphan Drug designation for selumetinib for the treatment of neurofibromatosis type 1. The development of selumetinib is part of the global strategic oncology collaboration between Merck and AstraZeneca reference above.

V920 is an investigational rVSV-ZEBOV (Ebola) vaccine candidate being studied in large scale Phase 2/3 clinical trials. In November 2014, Merck and NewLink Genetics announced an exclusive licensing and collaboration agreement for the investigational Ebola vaccine. 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 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 December 2016, end of study results from the WHO ring vaccination trial were reported in Lancet supporting the July 2015 interim assessment that V920 offers substantial protection against Ebola virus disease, with no reported cases among vaccinated individuals from 10 days after vaccination in both randomized and non-randomized clusters. Results from other ongoing studies to be included in the first regulatory filing are anticipated in the first half of 2018.

MK-1242, vericiguat, is an investigational treatment for heart failure being studied in patients suffering from chronic heart failure. The development of vericiguat is part of a worldwide strategic collaboration between Merck and Bayer.

V212 is an inactivated varicella zoster virus (VZV) vaccine in development for the prevention of herpes zoster. The Company completed a Phase 3 trial in autologous hematopoietic cell transplant patients and another Phase 3 trial in patients with solid tumor malignancies undergoing chemotherapy and hematological malignancies. The study in autologous hematopoietic cell transplant patients met its primary endpoints and Merck presented the results from this study at the American Society for Blood and Marrow Transplantation Meetings in February 2017. The study in

patients with solid tumor malignancies undergoing chemotherapy met its primary endpoints, but the primary efficacy endpoint was not met in patients with hematologic malignancies. Merck will present the results from this study at an upcoming scientific meeting. Due to the competitive environment, the development of V212 is currently on hold.

MK-7264 is a selective, non-narcotic, orally-administered P2X3-receptor agonist being developed for the treatment of refractory, chronic cough. Merck plans to initiate a Phase 3 clinical trial in the first half of 2018. MK-7264 was originally developed by Afferent Pharmaceuticals, which was acquired by the Company in 2016.

The Company also discontinued certain drug candidates.

In February 2018, Merck announced that it will be stopping protocol 019, also known as the APECS study, a Phase 3 study evaluating verubecestat, MK-8931, an investigational small molecule inhibitor of the beta-site amyloid precursor protein cleaving enzyme 1 (BACE1), in people with prodromal Alzheimer's disease. The decision to stop the study follows a recommendation by the external Data Monitoring Committee (eDMC), which assessed overall benefit/risk during a recent interim safety analysis. The eDMC concluded that it was unlikely that positive benefit/risk could be established if the trial continued.

In 2017, Merck announced that it will not submit applications for regulatory approval for MK-0859, anacetrapib, the Company's investigational cholesteryl ester transfer protein (CETP) inhibitor. The decision followed a thorough review of the clinical profile of anacetrapib, including discussions with external experts.

Also in 2017, Merck made a strategic decision to discontinue the development of the investigational combination regimens MK-3682B (grazoprevir/ruzasvir/uprifosbuvir) and MK-3682C (ruzasvir/uprifosbuvir) for the treatment of 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 currently marketed by the Company for the treatment of adult patients with chronic HCV infection.

The chart below reflects the Company's research pipeline as of February 23, 2018. 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 *Keytruda*) and additional claims, line extensions or formulations for in-line products are not shown.

Phase 2	Phase 3 (Phase 3 entry date)	Under Review
Cancer MK-3475 Keytruda Advanced Solid Tumors Ovarian Prostate Chronic Cough MK-7264 Diabetes Mellitus MK-8521 (2) HIV Infection MK-8591 Pneumoconjugate Vaccine V114 Schizophrenia MK-8189	Bacterial Infection         MK-7655A (relebactam+imipenem/cilastatin)         (October 2015)         Cancer         MK-3475 Keytruda         Breast (October 2015)         Colorectal (November 2015)         Esophageal (December 2015)         Gastric (May 2015) (EU)         Head and Neck (November 2014) (EU)         Hepatocellular (May 2016)         Nasopharyngeal (April 2016)         Renal (October 2016)         Small-Cell Lung (May 2017)         MK-7339 Lynparza (I)         Pancreatic (December 2014)         Prostate (April 2017)         MK-5618 (selumetinib) (I)         Thyroid (June 2013)         Ebola Vaccine         V920 (March 2015)         Heart Failure         MK-1242 (vericiguat) (September 2016) (I)         Herpes Zoster         V212 (inactivated VZV vaccine)         (December 2010) (2)         HW         MK-1439 (doravirine) (December 2014) (EU)         MK-1439A (doravirine/lamivudine/tenofovir disoproxil fumarate) (June 2015) (EU)	New Molecular Entities/Vaccines           Diabetes Mellitus           MK-04311 (sitagliptin+ipragliflozin) (Japan) (I)           MK-8835 (ertugliflozin) (EU) (I)           MK-88353 (ertugliflozin+sitagliptin) (EU) (I)           MK-88354 (ertugliflozin+metformin) (EU) (I)           MK-88354 (ertugliflozin+metformin) (EU) (I)           MK-88354 (ertugliflozin+metformin) (EU) (I)           MK-1439 (doravirine) (U.S.)           MK-1439A (doravirine/lamivudine/tenofovir disoproxil fumarate) (U.S.)           Pediatric Hexavalent Combination Vaccine           V419 (U.S.) (3)           Certain Supplemental Filings           MK-3475 Keytruda           Relapsed or Refractory Primary Mediastinal B-Cell Lymphoma (PMBCL) (U.S.)           MK-7339 Lynparza (I)           Broader Approval for Ovarian Cancer (EU)           Footnotes:           (I)           Being developed in a collaboration.           (2)         Development is currently on hold.           (3)         V419 is an investigational pediatric hexavalent combination vaccine, DTaP5-IPV-Hib-HepB, that is being developed and, if approved, will be commercialized through a partnership of Merck and Sanofi. In November 2015, the FDA issued a CRL with respect to V419. Both companies are working to provide additional data requested by the FDA.

#### Employees

As of December 31, 2017, the Company had approximately 69,000 employees worldwide, with approximately 26,700 employed in the United States, including Puerto Rico. Approximately 29% of worldwide employees of the Company are represented by various collective bargaining groups.

#### **Restructuring Activities**

The Company incurs substantial costs for restructuring program activities related to Merck's productivity and cost reduction initiatives, as well as in connection with the integration of certain acquired businesses. 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. Since inception of the programs through December 31, 2017, Merck has eliminated approximately 43,350 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 \$11 million in 2017, and are estimated at \$56 million in the aggregate for the years 2018 through 2022. 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 \$82 million and \$83 million at December 31, 2017 and 2016, 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 \$63 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 2017, 54% of sales in 2016 and 56% of sales in 2015.

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.

Financial information about geographic areas of the Company's business is provided in Item 8. "Financial Statements and Supplementary Data" below.

#### **Available Information**

The Company's Internet website address is <u>www.merck.com</u>. 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). 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 Merck Shareholder Services, Merck & Co., Inc., 2000 Galloping Hill Road, K1-3049, 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 <u>www.merck.com/about/leadership</u> and all such information is available in print to any stockholder who requests it from the Company.

#### Item 1A. Risk Factors.

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

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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 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. In addition, if products that were measured at fair value and capitalized in connection with acquisitions experience difficulties in the market that negatively impact product cash flows, the Company may recognize material non-cash impairment charges with respect to the value of those products. The Company's results of operations may be adversely affected by the lost sales unless and until the Company has successfully launched commercially successful replacement 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 Phase 3 candidates is set forth above in Item 1. "Business — Patents, Trademarks and Licenses."

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

The Company depends upon patents to provide it with exclusive marketing rights for its products for some period of time. Loss of patent protection for one of the Company's products typically leads to a significant and rapid loss of sales for that product, as lower priced generic versions of that drug become available. In the case of products that contribute significantly to the Company's sales, the loss of market exclusivity can have a material adverse effect on the Company's business, cash flow, results of operations, financial 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 the Company expects will continue in 2018. In addition, the patent that provides U.S. market exclusivity for *NuvaRing* will expire in April 2018 and the Company anticipates a significant decline in U.S. *NuvaRing* 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 *Januvia*, *Janumet*, *Keytruda*, *Gardasil/Gardasil* 9 and *Isentress*. 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, the Company anticipates that sales of *Zepatier* will be materially unfavorably affected by increasing competition and declining patient volumes. The Company also anticipates that sales of *Zostavax* will be materially unfavorably affected due to competition.

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

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

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

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 manufacturing and marketing 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 and Japan. In the United States, the FDA is of particular importance to the Company, as it 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, cost reduction. 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 new products in that jurisdiction until approval is obtained, if ever. 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 market, certain developments following regulatory approval, including results in post-approval Phase 4 trials or other studies, may decrease demand for the Company's products, including the following:

- 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 which, in addition to other factors, could in certain circumstances lead to non-cash impairment charges.

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 or 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 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. 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 recently posted on its website its Pricing Action Transparency Report for the United States for the years 2010 - 2017. 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. The report shows that the Company's average annual net price increases (after taking sales deductions such as rebates, discounts and returns into account) across the U.S. human health portfolio have been in the low to mid-single digits from 2010 - 2016. In 2017, the average net price across the Company's portfolio declined by 1.9%, reflecting specific in-year dynamics, including the impact of loss of patent protection for three major Merck medicines. Additionally, the weighted average annual discount rate has been steadily increasing over time, reflecting the competitive market for branded medicines and the impact of the ACA. In 2017, the Company's gross U.S. sales were reduced by 45.1% as a result of rebates, discounts and returns.

Outside the United States, numerous major markets, including the EU and Japan, 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 2017, the Company's revenue was reduced by \$385 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 \$4.0 billion in 2017 and will be \$4.1 billion in 2018. 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 2017, the Company recorded \$210 million of costs for this annual fee.

On January 21, 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.

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 results of operations, financial condition or business.

# 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.

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. All of the Company's manufacturing sites are now operational, manufacturing active pharmaceutical ingredient (API), formulating, packaging and shipping product. The Company's external manufacturing was not impacted. Throughout this time, Merck continued to fulfill orders and ship product.

Due to the cyber-attack, as anticipated, 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 *Materials and Production* costs, as well as expenses related to remediation efforts in *Marketing 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, the Company anticipates that in 2018 sales will be unfavorably affected in certain markets by approximately \$200 million from the cyber-attack. Merck does not expect a significant impairment to the value of intangible assets related to marketed products or inventories as a result of the cyber-attack.

The Company has insurance coverage insuring against costs resulting from cyber-attacks and has received proceeds. However, there may be disputes with the insurers about the availability of the insurance coverage for claims related to this incident.

Additionally, the temporary production shut-down from the cyber-attack contributed to the Company's inability to meet higher than expected demand for *Gardasil* 9, which resulted in Merck's decision to borrow doses of *Gardasil* 9 from the U.S. Centers for Disease Control and Prevention Pediatric Vaccine Stockpile. The Company subsequently replenished a portion of the borrowed doses in 2017. The net effect of the borrowing and subsequent partial replenishment was a reduction in sales of \$125 million in 2017. The Company anticipates it will replenish the remaining borrowed doses in the second half of 2018.

The Company has implemented a variety of measures to further enhance 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 June 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 June 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.

#### Changes in laws and regulations could materially adversely affect the Company's business.

All aspects of the Company's business, including research and development, manufacturing, marketing, pricing, sales, litigation and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a material adverse effect on the Company's business.

In particular, there is significant uncertainty about the future of the ACA 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 results of operations, financial condition or business.

# The uncertainty in global economic conditions together with austerity 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. In addition, other austerity measures negatively affected the Company's revenue performance in 2017. The Company anticipates these pricing actions, including the biennial price reductions in Japan that will occur again in 2018, and other austerity measures will continue to negatively affect revenue performance in 2018.

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.

On June 23, 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 the referendum, the British government has begun negotiating the terms of the UK's future relationship with the EU. Although it is unknown what those terms will be, it is possible that there will be greater restrictions on imports and exports between the UK and EU countries, increased regulatory complexities, and cross boarder labor issues that could adversely impact the Company's business operations in the UK.

#### Failure to attract and retain highly qualified personnel could affect its 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. 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.

In addition, in China, commercial and economic conditions may adversely affect the Company's growth prospects in that market. While the Company continues to believe that China represents an important growth opportunity, these events, coupled with heightened scrutiny of the health care industry, may continue to have an impact on product pricing and market access generally. 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 business, financial condition or results of the Company's operations.

#### 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 acquisition, licensing, borrowings or other financial transactions that may give rise to currency and interest rate exposure.

Since the Company cannot, with certainty, foresee and mitigate against such adverse fluctuations, fluctuations in currency exchange rates and interest rates could negatively affect the Company's results of operations, financial position and cash flows as occurred with respect to Venezuela in 2015 and 2016.

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, such as tax rate changes, new tax laws, and revised tax law interpretations in domestic and foreign jurisdictions.

Further, on December 22, 2017, the U.S. Tax Cuts and Jobs Act of 2017 (TCJA) became law. The final impact of the TCJA on the Company may differ from the estimates reported, possibly materially, due to such factors as changes in interpretations and assumptions made, additional guidance that may be issued, and actions taken by the Company as a result of the TCJA, among others.

#### 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, 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 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 web site 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.

#### **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 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 global 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, 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 \$1.9 billion in 2017, \$1.6 billion in 2016 and \$1.3 billion in 2015. In the United States, these amounted to \$1.2 billion in 2017, \$1.0 billion in 2016 and \$879 million in 2015. Abroad, such expenditures amounted to \$728 million in 2017, \$594 million in 2016 and \$404 million in 2015.

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.

### Item 3. Legal Proceedings.

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

### Item 4. Mine Safety Disclosures.

Not Applicable.

### Executive Officers of the Registrant (ages as of February 1, 2018)

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	63	Chairman, President and Chief Executive Officer (since December 2011)
Sanat Chattopadhyay	58	Executive Vice President and President, Merck Manufacturing Division (since March 2016); Senior Vice President, Operations, Merck Manufacturing Division (November 2009-March 2016)
Robert M. Davis	51	Executive Vice President, Chief Financial Officer & Global Services (since April 2016); Executive Vice President and Chief Financial Officer (April 2014-April 2016); Corporate Vice President and President, Medical Products, Baxter International, Inc. (2010-March 2014)
Richard R. DeLuca, Jr.	55	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)
Mirian M. Graddick-Weir	63	Executive Vice President, Human Resources (since November 2009)
Michael J. Holston*	55	Executive Vice President and General Counsel (since July 2015); Executive Vice President and Chief Ethics and Compliance Officer (June 2012-July 2015)
Rita A. Karachun	54	Senior Vice President Finance - Global Controller (since March 2014); Assistant Controller (November 2009-March 2014)
Roger M. Perlmutter, M.D., Ph.D.	65	Executive Vice President and President, Merck Research Laboratories (since April 2013)
Adam H. Schechter	53	Executive Vice President and President, Global Human Health (since May 2010)
Ashley Watson	49	Senior Vice President, Chief Ethics and Compliance Officer (since March 2015); Senior Vice President, Deputy General Counsel and Chief Ethics & Compliance Officer, Hewlett-Packard Company (January 2011 - March 2015)

\* On February 21, 2018, Mr. Holston notified the Company that he will resign from his position with the Company, effective April 1, 2018.

#### PART II

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

The principal market for trading of the Company's Common Stock is the New York Stock Exchange (NYSE) under the symbol MRK. The Common Stock market price information set forth in the table below is based on historical NYSE market prices.

The following table also sets forth, for the calendar periods indicated, the cash dividends paid per common share and the high and low sales prices of the Company's Common Stock as reported by the NYSE.

#### **Cash Dividends Paid per Common Share**

	Year	4th Q	3rd Q	2nd Q	1st Q
2017	\$ 1.88	\$ 0.47	\$ 0.47	\$ 0.47	\$ 0.47
2016	\$ 1.84	\$ 0.46	\$ 0.46	\$ 0.46	\$ 0.46
Common Stock Market Prices 2017		 4th Q	 3rd Q	 2nd Q	 1st Q
High		64.90	66.41	66.40	66.80
		53.63	61.16	61.87	59.05

Low	53.63	61.16	61.87	 59.05
2016				
High	\$ 65.46	\$ 64.00	\$ 57.87	\$ 53.60
Low	\$ 58.29	\$ 57.18	\$ 52.44	\$ 47.97

As of January 31, 2018, there were approximately 121,125 shareholders of record of the Company's Common Stock.

Issuer purchases of equity securities for the three months ended December 31, 2017 were as follows:

#### **Issuer Purchases of Equity Securities**

			(\$ in millions)
Period	Total Number of Shares Purchased <sup>(1)</sup>	Average Price Paid Per Share	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs <sup>(1)</sup>
October 1 — October 31	2,172,335	\$63.38	\$2,605
November 1 — November 30	11,850,338	\$55.03	\$1,953
December 1 — December 31	16,285,000	\$56.05	\$11,040
Total	30,307,673	\$56.17	\$11,040

<sup>(1)</sup>All shares purchased during the period were made as part of a plan approved by the Board of Directors in March 2015 to purchase up to \$10 billion in Merck shares. In November 2017, the Board of Directors authorized additional purchases of up to \$10 billion of Merck's common stock for its treasury. Shares are approximated.

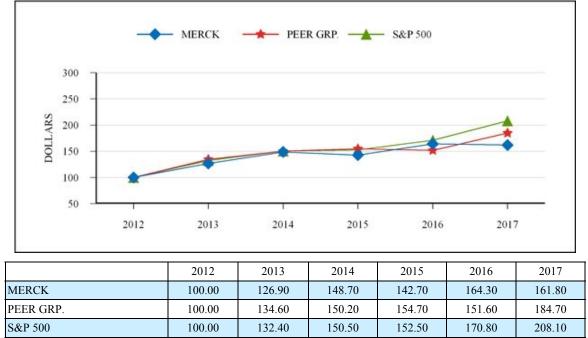
#### **Performance Graph**

The following graph assumes a \$100 investment on December 31, 2012, 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





\* Compound Annual Growth Rate

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

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

# Item 6. Selected Financial Data.

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

# Merck & Co., Inc. and Subsidiaries

(\$ in millions except per share amounts)

<b>2017</b> <sup>(1)</sup> 2016 <sup>(2)</sup>			2015 (3)		2014 (4)	2013			
\$	40,122	\$	39,807	\$	39,498	\$	42,237	\$	44,033
	12,775		13,891		14,934		16,768		16,954
	9,830		9,762		10,313		11,606		11,911
	10,208		10,124		6,704		7,180		7,503
	776		651		619		1,013		1,709
	12		720		1,527		(11,613)		411
	6,521		4,659		5,401		17,283		5,545
	4,103		718		942		5,349		1,028
	2,418		3,941		4,459		11,934		4,517
	24		21		17		14		113
	2,394		3,920		4,442		11,920		4,404
\$	0.88	\$	1.42	\$	1.58	\$	4.12	\$	1.49
\$	0.87	\$	1.41	\$	1.56	\$	4.07	\$	1.47
	5,177		5,135		5,115		5,156		5,132
\$	1.89	\$	1.85	\$	1.81	\$	1.77	\$	1.73
	1,888		1,614		1,283		1,317		1,548
	1,455		1,611		1,593		2,471		2,225
	2,730		2,766		2,816		2,894		2,963
	2,748		2,787		2,841		2,928		2,996
\$	6,152	\$	13,410	\$	10,550	\$	14,198	\$	17,461
	12,439		12,026		12,507		13,136		14,973
	87,872		95,377		101,677		98,096		105,370
	21,353		24,274		23,829		18,629		20,472
	34,569		40,308		44,767		48,791		52,326
	121,700		129,500		135,500		142,000		149,400
	69,000		68,000		68,000		70,000		77,000
	\$ \$ \$ \$	\$ 40,122 12,775 9,830 10,208 776 12 6,521 4,103 2,418 24 2,394 \$ 0.88 \$ 0.87 5,177 \$ 1.89 1,888 1,455 2,730 2,748 \$ \$ 6,152 12,439 87,872 21,353 34,569 121,700	\$       40,122       \$         12,775       9,830       1         9,830       10,208       7         776       12       6         12       6,521       4         4,103       2,418       24         2,394       \$       8         \$       0.88       \$         \$       0.88       \$         \$       0.88       \$         \$       0.87       \$         \$       0.87       \$         \$       1,455       2,730         2,748       \$       \$         \$       6,152       \$         \$       6,152       \$         \$       1,2,439       \$         \$       6,152       \$         \$       12,439       \$         \$       6,152       \$         \$       12,439       \$         \$       34,569       \$	\$       40,122       \$       39,807         12,775       13,891         9,830       9,762         10,208       10,124         776       651         12       720         6,521       4,659         4,103       718         2,418       3,941         24       21         2,394       3,920         \$       0.87       \$         1       5,177       5,135         \$       0.87       \$       1.41         5,177       5,135       \$       1.89         \$       0.87       \$       1.41         5,177       5,135       \$       1.85         \$       1.89       \$       1.85         \$       1.89       \$       1.85         \$       1.89       \$       1.85         \$       1.89       \$       1.85         \$       6,152       \$       13,410         \$       6,152       \$       13,410         \$       12,439       12,026       \$         \$       6,152       \$       13,410      12,026       \$7,872 <t< td=""><td>\$       40,122       \$       39,807       \$         12,775       13,891       9,830       9,762       10,208       10,124         776       651       12       720       13,891       10,124         776       651       12       720       13,891       14,12       12         6,521       4,659       4,659       4,103       718       14,12       14&lt;</td><td>\$       40,122       \$       39,807       \$       39,498         12,775       13,891       14,934         9,830       9,762       10,313         10,208       10,124       6,704         776       651       619         12       720       1,527         6,521       4,659       5,401         4,103       718       942         2,418       3,941       4,459         2,418       3,941       4,459         2,418       3,920       4,442         \$       0.88       \$       1.42       \$         2,394       3,920       4,442       \$       1.58         \$       0.87       \$       1.41       \$       1.56         5,177       5,135       5,115       \$       1.81         1,888       1,614       1,283       1,455       1,611       1,593         2,730       2,766       2,816       2,507       87,872       95,377       101,677         21,353  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17         14           2,394         3,920         4,442         11,920           5         0.88         \$         1.42         \$         1.58         \$         4.12           5         0.87         \$         1.41         \$         1.56         \$         4.07           5,177         5,135         5,115         5,156         \$         4.07           5,177         5,135         5,115         5,156         \$         4.07           1,455         1,611         1,593         2,471         2,730         2,766         2,816         2,894	\$       40,122       \$       39,807       \$       39,498       \$       42,237       \$         12,775       13,891       14,934       16,768         9,830       9,762       10,313       11,606         10,208       10,124       6,704       7,180         776       651       619       1,013         12       720       1,527       (11,613)         6,521       4,659       5,401       17,283         4,103       718       942       5,349         2,418       3,941       4,459       11,934         2,418       3,941       4,459       11,920         \$       0.88       \$       1.42       \$       1.58       \$       4.12       \$         \$       0.88       \$       1.42       \$       1.56       \$       4.07       \$         \$       0.87       \$       1.41       \$       1.56       \$       4.07       \$         \$       0.87       \$       1.41       \$       1.56       \$       4.07       \$         \$       0.87       \$       1.41       \$       1.56       \$       4.07       \$ </td

(1) 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.

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

<sup>(3)</sup>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.

<sup>(4)</sup>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.

# 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 segment is the only reportable segment.

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. 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. Beginning in 2017, Merck is 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 Company also has an Animal Health segment that discovers, develops, manufactures and markets animal health products, including vaccines, which the Company sells to veterinarians, distributors and animal producers. The Company's 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.

#### Overview

During 2017, Merck continued to bring innovation to patients and physicians, expanding its focus in oncology and advancing other programs in its latestage pipeline. Throughout 2017, *Keytruda*, the Company's anti-PD-1 (programmed death receptor-1) therapy, received approval for several additional indications globally, including U.S. Food and Drug Administration (FDA) approval in combination with pemetrexed and carboplatin, a commonly used chemotherapy regimen, for the first-line treatment of metastatic nonsquamous non-small-cell lung cancer (NSCLC), irrespective of PD-L1 expression. *Keytruda* is the only anti-PD-1 treatment approved in the first-line setting as both monotherapy and combination therapy for appropriate patients with metastatic NSCLC. In addition, Lynparza, an oral poly (ADP-ribose) polymerase (PARP) inhibitor, which is being developed in a collaboration, received FDA approval for the treatment of patients with germline BRCA-mutated, HER2-negative metastatic breast cancer who have been previously treated with chemotherapy. Additionally, in November 2017, the FDA approved *Prevymis* for prophylaxis (prevention) of cytomegalovirus (CMV) infection and disease, and in December 2017, the FDA approved *Steglatro, Steglujan* and *Segluromet* for the treatment of type 2 diabetes. In January 2018, *Prevymis* was also approved in the European Union (EU).

Worldwide sales were \$40.1 billion in 2017, an increase of 1% compared with 2016. Sales growth was driven primarily by the launches of *Keytruda*, *Zepatier* and *Bridion*, as well as positive performance from Merck's Animal Health business. In addition, revenue in 2017 benefited from the sale of vaccines in the markets that were previously part of the now-terminated SPMSD vaccines joint venture. Growth in these areas was largely offset by the effects of generic and biosimilar competition that resulted in sales declines for products including *Zetia*, *Vytorin*, *Cubicin* and *Remicade*.

Augmenting Merck's portfolio and pipeline with external innovation remains an important component of the Company's overall strategy. 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 PARP inhibitor currently approved for certain types of ovarian and breast cancer. The companies will develop and commercialize 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. 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 including thyroid cancer. In addition, in October 2017, Merck acquired Rigontec GmbH (Rigontec), a leader in accessing the retinoic acid-inducible gene I pathway, part of the innate immune system, as a novel and distinct approach in cancer immunotherapy to induce both immediate and long-term anti-tumor immunity. Also, in March 2017, Merck acquired a controlling interest in Vallée S.A. (Vallée), a leading privately held producer of animal health products in Brazil.

Merck continues to prioritize resources to maximize opportunities for ongoing and upcoming product launches. *Keytruda* is launching around the world in multiple indications. In 2017, Merck achieved multiple additional regulatory milestones for *Keytruda*, including approval from the FDA as combination therapy for appropriate patients with metastatic NSCLC as noted above, as well as monotherapy approval for the treatment of certain patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma; for the treatment of certain patients with locally advanced or metastatic urothelial carcinoma, a type of bladder cancer; for the treatment of adult and pediatric patients with classical Hodgkin lymphoma (cHL); and for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient solid tumors. During 2017, *Keytruda* also received approval in the EU for the treatment of certain patients with cHL and urothelial carcinoma.

Merck continues to evaluate its pipeline, focusing its research efforts on the opportunities it believes have the greatest potential to address unmet medical needs. In addition to the recent regulatory approvals discussed above, the Company has continued to advance other programs in its late-stage pipeline with several regulatory submissions. MK-1439, doravirine, an investigational, non-nucleoside reverse transcriptase inhibitor for the treatment of HIV-1 infection, and MK-1439A, doravirine with lamivudine and tenofovir disoproxil fumarate, are currently under review with the FDA. In addition, the FDA accepted for review a supplemental Biologics License Application (BLA) for *Keytruda* for the treatment of adult and pediatric patients with refractory primary mediastinal B-cell lymphoma (PMBCL) that is refractory to or has relapsed after two prior lines of therapy. Additionally, *Steglatro, Steglujan* and *Segluromet* are under review in the EU.

The Company's Phase 3 oncology programs include *Keytruda* in the therapeutic areas of breast, colorectal, esophageal, gastric, head and neck, hepatocellular, nasopharyngeal, renal and small-cell lung cancers; Lynparza for pancreatic and prostate cancer; and selumetinib for thyroid cancer. Additionally, the Company has candidates in Phase 3 clinical development in several other therapeutic areas (see "Research and Development" below).

The Company continues to support its innovation strategy by remaining disciplined and prioritizing resources wherever possible to not only fund investment in the many opportunities in Merck's pipeline that it believes can help drive long-term growth, but also fund near-term opportunities to grow revenue. *Research and development* expenses in 2017 reflect increased clinical development spending as the Company continues to invest in the pipeline.

In November 2017, Merck's Board of Directors raised the Company's quarterly dividend to \$0.48 per share from \$0.47 per share. During 2017, the Company returned \$9.2 billion to shareholders through dividends and share repurchases.

Earnings per common share assuming dilution attributable to common shareholders (EPS) for 2017 were \$0.87 compared with \$1.41 in 2016. EPS in both years reflect the impact of acquisition and divestiture-related costs, which in 2016 includes a charge related to the uprifosbuvir clinical development program, as well as restructuring costs and certain other items, which in 2017 include a provisional net tax charge related to the recent enactment of U.S. tax legislation and an aggregate charge related to the formation of a collaboration with AstraZeneca. Non-GAAP EPS, which exclude these items, were \$3.98 in 2017 and \$3.78 in 2016 (see "Non-GAAP Income and Non-GAAP EPS" below).

### 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. All of the Company's manufacturing sites are now operational, manufacturing active pharmaceutical ingredient (API), formulating, packaging and shipping product. The Company's external manufacturing was not impacted. Throughout this time, Merck continued to fulfill orders and ship product.

Due to the cyber-attack, as anticipated, 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 *Materials and production* costs, as well as expenses related to remediation efforts in *Marketing and administrative* expenses and *Research and development* expenses, which aggregated approximately \$285 million in 2017, net of insurance recoveries of approximately \$45 million. Due to a residual backlog of orders for certain products, the Company anticipates that in 2018 sales will be unfavorably affected in certain markets by approximately \$200 million from the cyber-attack. Merck does not expect a significant impairment to the value of intangible assets related to marketed products or inventories as a result of the cyber-attack.

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

Additionally, the temporary production shut-down from the cyber-attack contributed to the Company's inability to meet higher than expected demand for *Gardasil* 9, which resulted in Merck's decision to borrow doses of *Gardasil* 9 from the U.S. Centers for Disease Control and Prevention (CDC) Pediatric Vaccine Stockpile. The Company subsequently replenished a portion of the borrowed doses in 2017. The net effect of the borrowing and subsequent partial replenishment was a reduction in sales of \$125 million in 2017. The Company anticipates it will replenish the remaining borrowed doses in the second half of 2018.

### Hurricane Maria

In September 2017, Hurricane Maria made direct landfall on Puerto Rico. The Company has one plant in Puerto Rico that makes a limited number of its pharmaceutical products, and the Company also works with contract manufacturers on the island. Merck's plant did not sustain substantial damage, and production activities at the plant have resumed. While power has been restored to the facility, it is not yet fully reliable and the plant continues to be prepared to use alternative sources of power and water. The Company is making progress to fully restore normal operations despite the significant damage to the island's infrastructure. Supply chains within Puerto Rico are improving, but are not yet fully restored. There was an immaterial impact to sales in 2017 and the Company expects an immaterial impact to sales in 2018.

### **Operating Results**

#### Sales

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 recently launched products including *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 and Adempas, as well as 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 approaching the expiration of their marketing exclusivity or are no longer protected by patents in developed markets, including *Dulera* Inhalation Aerosol, 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 CDC Pediatric Vaccine Stockpile of doses of *Gardasil* 9 as discussed below. Also, as anticipated, 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.

Sales in the United States were \$17.4 billion in 2017, a decline of 6% compared with \$18.5 billion in 2016. The decrease was driven primarily by the effects of generic competition for *Zetia* and *Vytorin*, *Cubicin*, and declines of products within Diversified Brands including *Nasonex* and *Dulera* Inhalation Aerosol. Lower sales of *Januvia/Janumet*, *Gardasil/Gardasil* 9, *Isentress/Isentress HD* and *Zostavax*, also contributed to the U.S. sales decline in 2017.

These declines were partially offset by higher sales of Keytruda, Zepatier, Bridion, and Pneumovax 23, along with higher sales of animal health products.

International sales were \$22.7 billion in 2017, an increase of 6% compared with \$21.3 billion in 2016, primarily reflecting growth in *Keytruda* and *Zepatier*, and higher sales of vaccines due to the termination of the SPMSD joint venture, as well as higher sales of animal health products. Sales growth was partially offset by ongoing biosimilar competition for *Remicade*, as well as generic erosion for *Cancidas* and products within Diversified Brands. International sales represented 57% and 54% of total sales in 2017 and 2016, respectively.

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. 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. In addition, other austerity measures negatively affected the Company's revenue performance in 2017. The Company anticipates these pricing actions, including the biennial price reductions in Japan that will occur again in 2018, and other austerity measures will continue to negatively affect revenue performance in 2018.

Worldwide sales were \$39.8 billion in 2016, an increase of 1% compared with 2015. Foreign exchange unfavorably affected global sales performance by 2% in 2016, which includes a lower benefit from revenue hedging activities as compared with 2015. Revenue growth primarily reflects higher sales of *Keytruda*, the launch of the HCV treatment *Zepatier*, and growth in vaccine products, including *Gardasil/Gardasil* 9, *Varivax* and *Pneumovax* 23. Also contributing to sales growth in 2016 were higher sales of hospital acute care products including *Bridion* and *Noxafil*, growth within the diabetes franchise of *Januvia* and *Janumet*, as well as higher sales of animal health products, particularly *Bravecto*. These increases were largely offset by sales declines attributable to the ongoing effects of generic and biosimilar competition for certain products, including *Remicade* and *Nasonex*, along with other products within Diversified Brands. Declines in *Isentress* and *Dulera* Inhalation Aerosol also partially offset revenue growth in 2016. Sales performance in 2016 reflects a decline of approximately \$625 million due to reduced operations by the Company in Venezuela as a result of the economic conditions and volatility in that country.

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Sales of the Company's products were as follows:

(\$ in millions)		2017					20	016			2015	 
	U.S.	Int'l	Т	otal	U.8	š.	Ι	nt'l	Total	U.S.	Int'l	 Total
Primary Care and Women's Health												
Cardiovascular												
Zetia	\$ 352	\$ 992	\$	1,344	<b>\$</b> 1	1,588	\$	972	\$ 2,560	\$ 1,612	\$ 914	\$ 2,526
Vytorin	124	627		751		473		668	1,141	479	771	1,251
Atozet	_	225		225		1		146	146	2	34	36
Adempas	_	300		300		_		169	169	_	30	30
Diabetes												
Januvia	2,153	1,584		3,737	2	2,286		1,622	3,908	2,263	1,601	3,863
Janumet	863	1,296		2,158		984		1,217	2,201	976	1,175	2,151
General Medicine and Women's Health												
NuvaRing	564	197		761		576		202	777	515	216	732
Implanon/Nexplanon	496	191		686		420		186	606	367	221	588
Follistim AQ	123	174		298		157		197	355	160	223	383
Hospital and Specialty				2,0		107		1,7,7	555	100	220	505
Hepatitis												
Zepatier	771	888		1,660		488		67	555	_	_	_
HIV	//1	000		1,000		400		07	555			
Isentress/Isentress HD	565	639		1,204		721		666	1,387	797	714	1,511
Hospital Acute Care	505	057		1,204		721		000	1,507	1)1	/14	1,911
Bridion	220	465		704		77		405	492		252	252
Noxafil	239	465		704		77		405	482	-	353	353
Invanz	309	327		636		284		312	595	212	275	487
Cancidas	361	241		602		329		233	561	322	247	569
Cubicin <sup>(1)</sup>	20	402		422		25		533	558	24	548	573
Primaxin	189	193		382		906		181	1,087	1,030	97	1,127
Immunology	10	270		280		4		293	297	8	305	313
Remicade												
Simponi	—	837		837		—		1,268	1,268	—	1,794	1,794
Oncology	—	819		819		-		766	766	-	690	690
Keytruda												
Emend	2,309	1,500		3,809		792		610	1,402	393	173	566
Temodar	342	213		556		356		193	549	326	209	535
Diversified Brands	16	256		271		15		268	283	7	306	312
Respiratory												
Singulair	40	692		732		40		874	915	39	892	931
Nasonex	54	333		387		184		352	537	449	409	858
Dulera	261	26		287		412		24	436	515	21	536
Other												
Cozaar/Hyzaar	18	466		484		16		494	511	30	637	667
Arcoxia	_	363		363		—		450	450	_	471	471
Fosamax	6	235		241		5		279	284	12	347	359
Vaccines (2)												
Gardasil/Gardasil 9	1,565	743		2,308	1	1,780		393	2,173	1,520	388	1,908
ProQuad/M-M-R II /Varivax	1,374	303		1,676	1	1,362		279	1,640	1,290	214	1,505
Pneumovax 23	581	240		821		447		193	641	378	164	542
RotaTeq	481	204		686		482		169	652	447	163	610
Zostavax	422	246		668		518		168	685	592	157	749
Other pharmaceutical <sup>(3)</sup>	1,246	3,049		4,295	1	1,345		3,228	4,574	1,473	3,785	5,256
Total Pharmaceutical segment sales	15,854	19,536		35,390		7,073		18,077	35,151	16,238	18,544	34,782
Other segment sales (4)	1,486	2,785		4,272		1,374		2,489	3,862	1,213	2,454	3,667

Total segment sales	17,340	22,321	39,662	18,447	20,566	39,013	17,451	20,998	38,449
Other <sup>(5)</sup>	84	377	460	31	763	794	68	981	1,049
	\$ 17,424	\$ 22,698	\$ 40,122	\$ 18,478	\$ 21,329	\$ 39,807	\$ 17,519	\$ 21,979	\$ 39,498

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

(1) Sales of Cubicin in 2015 represent sales subsequent to the Cubist acquisition date.

(2) 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 2017 include sales in the European markets that were previously part of SPMSD. Amounts for 2016 and 2015 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 and 2015 do, however, include supply sales to SPMSD.

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

<sup>(4)</sup> Represents the non-reportable segments of Animal Health, Healthcare Services and Alliances.

(5) Other is primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, as well as third-party manufacturing sales. Other in 2017 and 2016 also includes \$85 million and \$170 million, respectively, related to the sale of the marketing rights to certain products.

# **Pharmaceutical Segment**

# Primary Care and Women's Health

### Cardiovascular

Combined global sales of Zetia (marketed in most countries outside the United States as *Ezetrol*), *Vytorin* (marketed outside the United States as *Inegy*), and *Atozet* (marketed in certain countries outside of the United States), medicines for lowering LDL cholesterol, were \$2.3 billion in 2017, a decline of 40% 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. By agreement, a generic manufacturer launched a generic version of *Zetia* in the United States in December 2016. The U.S. patent and exclusivity periods for *Zetia* and *Vytorin* otherwise expired in April 2017. Accordingly, the Company is experiencing rapid and substantial declines in U.S. *Zetia* and *Vytorin* sales and expects the declines to continue. The Company will lose market exclusivity in major European markets for *Ezetrol* in April 2018 and for *Inegy* in April 2019 and anticipates sales declines in these markets thereafter. Sales of *Ezetrol* and *Inegy* in these markets were \$552 million and \$457 million, respectively, in 2017. Combined worldwide sales of *Zetia*, *Vytorin* and *Atozet* were \$3.8 billion in 2016, growth of 1% compared with 2015, reflecting volume growth in Europe and higher pricing in the United States, largely offset by lower sales in Venezuela due to reduced operations by the Company in that country and lower volumes in the United States reflecting in part generic competition for *Zetia*.

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. Merck recorded sales for Adempas of \$300 million in 2017, \$169 million in 2016 and \$30 million in 2015, which 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.

### 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 2017, a decline of 3% compared with 2016 including a 1% favorable effect from foreign exchange. The sales decline was driven primarily by ongoing pricing pressure partially offset by continued volume growth globally. Combined global sales of *Januvia* and *Janumet* were \$6.1 billion in 2016, an increase of 2% compared with 2015. Sales growth was driven primarily by higher volumes in the United States, Europe and Canada, partially offset by pricing pressures in the United States and Europe, and lower sales in Venezuela due to the Company's reduced operations in that country.

In April 2017, Merck announced that the FDA issued a Complete Response Letter (CRL) regarding Merck's supplemental New Drug Applications (NDA) for *Janumet* and *Janumet XR* (sitagliptin and metformin HCl extended-release). With these applications, Merck is seeking to include data from TECOS (Trial Evaluating Cardiovascular Outcomes with Sitagliptin) in the prescribing information of sitagliptin-containing medicines. Merck is taking actions to respond to the CRL.

In December 2017, the FDA approved *Steglatro* (ertugliflozin) tablets, an oral sodium-glucose cotransporter 2 (SGLT2) inhibitor, and the fixed-dose combination *Steglujan* (ertugliflozin and sitagliptin) tablets, the only fixed-dose combination of an SGLT2 inhibitor and dipeptidyl peptidase-4 inhibitor *Januvia* (sitagliptin). The FDA also approved the fixed-dose combination *Segluromet* (ertugliflozin and metformin hydrochloride). *Steglatro*, *Steglujan* and *Segluromet* are indicated to improve glycemic control in adults with type 2 diabetes mellitus. These products are part of a worldwide (except Japan) collaboration between Merck and Pfizer Inc. (Pfizer) for the co-development and co-promotion of ertugliflozin. As a result of FDA approval, Merck will make a \$60 million payment to Pfizer, which was accrued for in the fourth quarter of 2017. The amount was capitalized and will be amortized over its estimated useful life, subject to impairment testing. Merck will exclusively promote *Steglatro* and the two fixed-dose combination products in the United States. Merck and Pfizer will share revenues and certain costs on a 60%/40% basis, with Merck having the 60% share, and Pfizer may be entitled to additional milestone payments. In January 2018, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending approval of ertugliflozin and the two fixed-dose combination products. The CHMP positive opinion will be considered by the European Commission (EC). If approval of any of the products in the EU is received, Merck will make an additional \$40 million milestone payment to Pfizer.

### General Medicine and Women's Health

Worldwide sales of *NuvaRing*, a vaginal contraceptive product, 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. Global sales of *NuvaRing* were \$777 million in 2016, an increase of 6% compared with 2015 including a 1% unfavorable effect from foreign exchange. Sales growth largely reflects higher pricing in the United States, partially offset by volume declines in Europe. The patent that provides U.S. market exclusivity for *NuvaRing* will expire in April 2018 and the Company anticipates a significant decline in U.S. *NuvaRing* sales thereafter.

Worldwide sales of *Implanon/Nexplanon*, single-rod subdermal contraceptive implants, grew to \$686 million in 2017, an increase of 13% compared with 2016, primarily reflecting higher pricing and volume growth in the United States. Global sales of *Implanon/Nexplanon* were \$606 million in 2016, an increase of 3% compared with 2015 including a 3% unfavorable effect from foreign exchange. Sales growth reflects higher demand in the United States, partially offset by declines in international markets, particularly in Venezuela.

# Hospital and Specialty

#### Hepatitis

Global sales of *Zepatier*, a treatment for chronic hepatitis C (HCV) infection, were \$1.7 billion in 2017 and \$555 million in 2016. Sales growth was driven primarily by higher sales in Europe, the United States and Japan following product launch in 2016. Merck has also launched *Zepatier* in other international markets. The Company is beginning to experience the unfavorable effects of increasing competition and declining patient volumes and anticipates that sales of *Zepatier* in the future will be materially adversely affected by these factors.

### HIV

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 \$1.2 billion in 2017, a decline of 13% compared with 2016. The sales decline primarily reflects lower demand in the United States and Europe due to competitive pressures. In May 2017, the FDA approved *Isentress HD*, a once-daily dose of *Isentress*. In July 2017, the EC granted marketing authorization for the once-daily dose of *Isentress* (where it will be marketed as *Isentress* 600 mg). Global sales of *Isentress* were \$1.4 billion in 2016, a decline of 8% compared with 2015 including a 2% unfavorable effect from foreign exchange. The sales decline was driven primarily by lower volumes in the United States, as well as lower demand and pricing in Europe due to competitive pressures, partially offset by a favorable adjustment to discount reserves in the United States.

### Hospital Acute Care

Global sales of *Bridion*, for the reversal of two types of neuromuscular blocking agents used during surgery, were \$704 million in 2017, growth of 46% compared with 2016, driven by strong global demand, particularly in the United States. Worldwide sales were \$482 million in 2016, growth of 37% compared with 2015 including a 2% favorable effect from foreign exchange. Sales growth reflects volume growth in most markets, including in the United States where it was approved by the FDA in December 2015, partially offset by a decline in Venezuela due to reduced operations by the Company in this country.

Worldwide sales of *Noxafil*, for the prevention of invasive fungal infections, 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. Global sales of *Noxafil* grew 22% in 2016 to \$595 million driven primarily by higher pricing in the United States, volume growth in Europe reflecting an ongoing positive impact from the approval of new formulations, and higher demand in the Asia Pacific region. Foreign exchange unfavorably affected global sales performance by 3% in 2016.

Global sales of *Invanz*, for the treatment of certain infections, 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. Worldwide sales of *Invanz* were \$561 million in 2016, a decline of 1% compared with 2015 including a 2% unfavorable effect from foreign exchange. Sales performance in 2016 reflects higher pricing in the United States, largely offset by a decline in Venezuela. The patent that provided U.S.

market exclusivity for Invanz expired in November 2017 and the Company anticipates a significant decline in U.S. Invanz sales in future periods.

Global sales of *Cancidas*, an anti-fungal product sold primarily outside of the United States, were \$422 million in 2017, a decline of 24% compared with 2016, 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. Worldwide sales of *Cancidas* were \$558 million in 2016, a decline of 3% compared with 2015, reflecting a 4% unfavorable effect from foreign exchange and pricing declines in Europe that were offset by higher volumes in China.

Global sales of *Cubicin*, an I.V. antibiotic for complicated skin and skin structure infections or bacteremia when caused by designated susceptible organisms, were \$382 million in 2017, a decline of 65% compared with 2016, and were \$1.1 billion in 2016, a decline of 4% compared with 2015. The U.S. composition patent for *Cubicin* expired in June 2016. Accordingly, the Company is experiencing a rapid and substantial decline in U.S. *Cubicin* sales as a result of generic competition and expects the decline to continue. The Company anticipates it will lose market exclusivity for *Cubicin* in some European markets in early 2018.

In November 2017, Merck announced that the FDA approved *Prevymis* (letermovir) for prophylaxis (prevention) of CMV infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant. As a result of FDA approval, Merck made a  $\in$ 105 million (\$125 million) milestone payment to AiCuris in 2017. This amount was capitalized and will be amortized over its estimated useful life, subject to impairment testing. In January 2018, *Prevymis* was approved by the EC and, as a result, Merck will make an additional  $\in$ 30 million milestone payment to AiCuris. Merck also has filed *Prevymis* for regulatory approval in other markets including Japan.

#### Immunology

Sales of *Remicade*, a treatment for inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were \$837 million in 2017, a decline of 34% compared with 2016, and were \$1.3 billion in 2016, a decline of 29% compared with 2015. Foreign exchange unfavorably affected sales performance by 1% in 2016. 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.

Sales of *Simponi*, a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were \$819 million in 2017, growth of 7% compared with 2016 including a 1% favorable effect from foreign exchange. Sales growth primarily reflects higher demand in Europe. Sales of *Simponi* were \$766 million in 2016, an increase of 11% compared with 2015 including a 3% unfavorable effect from foreign exchange. Sales growth was driven primarily by higher volumes in Europe reflecting in part an ongoing positive impact from the ulcerative colitis indication.

### Oncology

Sales of *Keytruda*, an anti-PD-1 therapy, were \$3.8 billion in 2017, \$1.4 billion in 2016 and \$566 million in 2015. The year-over-year increases were driven by volume growth in all markets, particularly in the United States, Europe and Japan as the Company continues to launch *Keytruda* with multiple new indications globally. U.S. sales of *Keytruda* were \$2.3 billion in 2017, \$792 million in 2016 and \$393 million in 2015. 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, including melanoma, head and neck cancer, and bladder cancer, also contributed to growth in 2017. Sales growth in international markets reflects positive performance in the melanoma indications, as well as a greater contribution from the treatment of patients with NSCLC as reimbursement is established in additional markets in the first- and second-line settings.

In March 2017, the FDA approved *Keytruda* for the treatment of adult and pediatric patients with cHL refractory to treatment, or who have relapsed after three or more prior lines of therapy. In May 2017, the EC approved *Keytruda* for the treatment of adult patients with relapsed or refractory cHL who have failed autologous stem cell transplant and brentuximab vedotin, or who are transplant-ineligible and have failed brentuximab vedotin.

In May 2017, the FDA approved *Keytruda* in combination with pemetrexed and carboplatin for the first-line treatment of metastatic nonsquamous NSCLC, irrespective of PD-L1 expression. *Keytruda* is the only anti-PD-1 treatment approved in the first-line setting as both monotherapy and combination therapy for appropriate patients with metastatic NSCLC. In October 2016, *Keytruda* was approved by the FDA as monotherapy in the first-line setting for patients with metastatic NSCLC whose tumors have high PD-L1 expression, with no EGFR or ALK genomic tumor aberrations. *Keytruda* as monotherapy is also indicated for the second-line or greater treatment setting for patients with metastatic NSCLC whose tumors express PD-L1, with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving *Keytruda*. Additionally, in January 2017, the EC approved *Keytruda* for the first-line treatment of metastatic NSCLC in adults whose tumors have high PD-L1 expression with no EGFR or ALK positive tumor mutations.

Also in May 2017, the FDA approved *Keytruda* for the treatment of certain patients with locally advanced or metastatic urothelial carcinoma, a type of bladder cancer. In the first-line setting, *Keytruda* is approved for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are ineligible for cisplatin-containing chemotherapy. In the second-line setting, *Keytruda* is approved for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are ineligible for cisplatin-containing chemotherapy. In the second-line setting, *Keytruda* is approved for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. In September 2017, the EC approved *Keytruda* for use as monotherapy for the treatment of locally advanced or metastatic urothelial carcinoma in adults who have received prior platinum-containing chemotherapy, as well as adults who are not eligible for cisplatin-containing chemotherapy.

Additionally in May 2017, the FDA approved *Keytruda* for a first-of-its-kind indication: the treatment of adult and pediatric patients with previously treated unresectable or metastatic MSI-H or mismatch repair deficient solid tumors. With this unique indication, *Keytruda* is the first cancer therapy approved for use based on a biomarker, regardless of tumor type.

In September 2017, the FDA approved *Keytruda* for the treatment of patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1. In December 2017, Merck announced that the pivotal Phase 3 KEYNOTE-061 trial investigating *Keytruda*, as a second-line treatment for patients with advanced gastric or gastroesophageal junction adenocarcinoma, did not meet its primary endpoint of overall survival (OS) in patients whose tumors expressed PD-L1. Additionally, progression free survival (PFS) in the PD-L1 positive population did not show statistical significance. The safety profile observed in KEYNOTE-061 was consistent with that observed in previously reported studies of *Keytruda*; no new safety signals were identified. The current indication remains unchanged and the Company continues to evaluate *Keytruda* for gastric or gastroesophageal junction adenocarcinoma through KEYNOTE-062, a Phase 3 clinical trial studying *Keytruda* as a monotherapy or in combination with chemotherapy as first-line treatment for patients with PD-L1 positive advanced gastric or gastroesophageal junction cancer, and with KEYNOTE-585, a Phase 3 trial studying *Keytruda* in combination with chemotherapy in a neoadjuvant/adjuvant setting.

In August 2016, Merck announced that the FDA approved *Keytruda* for the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) with disease progression on or after platinum-containing chemotherapy. In July 2017, Merck announced that the pivotal Phase 3 KEYNOTE-040 trial investigating *Keytruda* in previously treated patients with recurrent or metastatic HNSCC did not meet its pre-specified primary endpoint of OS. The safety profile observed in KEYNOTE-040 was consistent with that observed in previously reported studies of *Keytruda*; no new safety signals were identified. The current indication remains unchanged and clinical trials continue, including KEYNOTE-048, a Phase 3 clinical trial of *Keytruda* in the first-line treatment of recurrent or metastatic HNSCC.

As a result of the additional approvals received in 2017 as noted above, *Keytruda* is now approved in the United States and in the EU as monotherapy for the treatment of certain patients with NSCLC, melanoma, cHL and urothelial carcinoma. *Keytruda* is also approved in the United States as monotherapy for the treatment of certain patients with HNSCC, gastric or gastroesophageal junction adenocarcinoma and MSI-H or mismatch repair deficient cancer, and in combination with pemetrexed and carboplatin in certain patients with NSCLC. *Keytruda* is also approved in Japan for the treatment of radically unresectable melanoma, PD-L1-positive unresectable advanced or recurrent NSCLC,

relapsed or refractory cHL, and radically unresectable urothelial carcinoma. The Keytruda clinical development program includes studies across a broad range of cancer types (see "Research and Development" below).

In January 2017, Merck entered into a settlement and license agreement to resolve worldwide patent infringement litigation related to *Keytruda* (see Note 11 to the consolidated financial statements). 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.

Lynparza, an oral PARP inhibitor being developed as part of a collaboration formed in July 2017 with AstraZeneca (see Note 4 to the consolidated financial statements), is currently approved for certain types of ovarian and breast cancer. In January 2018, the FDA approved Lynparza for use in patients with BRCA-mutated, HER2-negative metastatic breast cancer who have been previously treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. As a result of this approval, Merck will make a \$70 million milestone payment to AstraZeneca (see Note 4 to the consolidated financial statements). Also in January 2018, the Japanese Ministry of Health, Labour and Welfare approved Lynparza for use as a maintenance therapy in patients for platinum-sensitive relapsed ovarian cancer, regardless of their BRCA mutation status, who responded to their last platinum-based chemotherapy. Lynparza is the first PARP inhibitor to be approved in Japan.

### Diversified Brands

Merck's diversified brands include human health pharmaceutical products that are approaching the expiration of their marketing exclusivity or are no longer protected by patents in developed markets, but continue to be a core part of the Company's offering in other markets around the world.

#### Respiratory

Worldwide sales of *Singulair*, a once-a-day oral medicine for the chronic treatment of asthma and for the relief of symptoms of allergic rhinitis, were \$732 million in 2017, a decline of 20% compared with 2016, and were \$915 million in 2016, a decrease of 2% compared with 2015. Foreign exchange unfavorably affected global sales performance by 1% in 2017 and favorably affected global sales performance by 2% in 2016. The sales declines were driven by lower volumes in Japan as a result of generic competition. The patents that provided market exclusivity for *Singulair* in Japan expired in 2016. As a result, the Company is experiencing a significant decline in *Singulair* sales in Japan and expects the decline to continue. The Company no longer has market exclusivity for *Singulair* in any major market.

Global sales of *Nasonex*, an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, were \$387 million in 2017, a decline of 28% compared with 2016, and were \$537 million in 2016, a decline of 37% compared with 2015. Foreign exchange favorably affected global sales performance by 1% in 2017. The Company is experiencing a substantial decline in U.S. *Nasonex* sales as a result of generic competition and expects the decline to continue. The decline in global *Nasonex* sales in 2016 was also driven by lower volumes and pricing in Europe from ongoing generic erosion and lower sales in Venezuela due to reduced operations by the Company in this country.

Global sales of *Dulera* Inhalation Aerosol, a combination medicine for the treatment of asthma, were \$287 million in 2017, a decline of 34% compared with 2016, driven by lower sales in the United States reflecting ongoing competitive pricing pressure, as well as lower demand. Worldwide sales of *Dulera* Inhalation Aerosol were \$436 million in 2016, a decline of 19% compared with 2015 including a 1% unfavorable effect from foreign exchange. The decline was driven by lower sales in the United Sales reflecting competitive pricing pressure that was partially offset by higher demand.

#### 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 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 are reflected in equity income from affiliates included in *Other (income) expense, net* (see Note 15 to the consolidated financial statements). 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 in 2017 were approximately \$400 million, of which approximately \$215 million relate to *Gardasil/Gardasil* 9.

Worldwide sales of Gardasil/Gardasil 9, vaccines to help prevent certain cancers and diseases caused by certain types of human papillomavirus (HPV), 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 Asia Pacific 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. In addition, 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, 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 nearly half 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 anticipates it will replenish the remaining borrowed doses in the second half of 2018, which will result in the recognition of sales and a reversal of the remaining liability. Additionally, in October 2016, the FDA approved a 2-dose vaccination regimen for Gardasil 9, for use in girls and boys 9 through 14 years of age, and the CDC's Advisory Committee on Immunization Practices (ACIP) voted to recommend the 2-dose vaccination regimen for certain 9 through 14 year olds. The Company is experiencing an impact from the transition from a 3-dose vaccine regimen to a 2-dose vaccination regimen; however, increased patient starts are helping to offset the negative effects of the transition. Merck's sales of Gardasil/Gardasil 9 were \$2.2 billion in 2016, growth of 14% compared with 2015. Sales growth was driven primarily by higher volumes and pricing in the United States, as well as higher demand in the Asia Pacific region, partially offset by a decline in government tenders in Brazil. The Company is a party to certain third-party license agreements with respect to Gardasil/Gardasil 9 (including a crosslicense and settlement agreement with GlaxoSmithKline). As a result of these agreements, the Company pays royalties on worldwide Gardasil/Gardasil 9 sales of 10% to 18% which vary by country and are included in Materials and production costs.

Global sales of *ProQuad*, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, were \$528 million in 2017, \$495 million in 2016 and \$454 million in 2015. The increase in 2017 as compared with 2016 was driven primarily by higher pricing and volumes in the United States, as well as volume growth in international markets, particularly in Europe. Sales growth in 2016 as compared with 2015 was driven primarily by higher demand and pricing in the United States.

Worldwide sales of *M-M-R* II, a vaccine to help protect against measles, mumps and rubella, were \$382 million in 2017, \$353 million in 2016 and \$365 million in 2015. Sales growth in 2017 as compared with 2016 was largely attributable to higher sales in Europe resulting from the termination of the SPMSD joint venture. Sales performance in 2016 as compared with 2015 was driven by higher demand in 2015 resulting from measles outbreaks in the United States.

Global sales of *Varivax*, a vaccine to help prevent chickenpox (varicella), were \$767 million in 2017, \$792 million in 2016 and \$686 million in 2015. The sales decline in 2017 as compared with 2016 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 partially offset by higher pricing. Higher sales in Europe resulting from the termination of the SPMSD joint venture partially offset the decline. Sales growth in 2016 as compared with 2015 was driven primarily by higher sales in the United States reflecting the effects of public sector purchasing and higher pricing that were partially offset by lower demand. Volume growth in Brazil reflecting the timing of government tenders also contributed to the sales increase in 2016 as compared with 2015.

Worldwide sales of *Pneumovax* 23, a vaccine to help prevent pneumococcal disease, 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. Merck's sales of *Pneumovax* 23 were \$641 million in 2016, an increase of 18% compared with 2015, driven primarily by higher volumes and pricing in the United States and higher demand in the Asia Pacific region. Foreign exchange unfavorably affected sales performance by 1% in 2017 and favorably affected sales performance by 1% in 2016.

Global sales of *RotaTeq*, a vaccine to help protect against rotavirus gastroenteritis in infants and children, 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. Merck's sales of *RotaTeq* were \$652 million in 2016, an increase of 7% compared with 2015 including a 3% unfavorable effect from foreign exchange. Sales performance was driven

primarily by the effects of public sector purchasing in the United States, as well as volume growth in several international markets.

Worldwide sales of *Zostavax*, a vaccine to help prevent shingles (herpes zoster) in adults 50 years of age and older, 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 competitor's vaccine that received a preferential recommendation from the ACIP in October 2017 for the prevention of shingles over *Zostavax*. The Company anticipates this competition will have a material adverse effect on sales of *Zostavax* in future periods. The U.S. sales decline was largely offset by growth in Europe resulting from the termination of the SPMSD joint venture and volume growth in the Asia Pacific region. Merck's sales of *Zostavax* were \$665 million in 2016, a decline of 9% compared with 2015 including a 1% unfavorable effect from foreign exchange. The decline was driven primarily by lower volumes in the United States, partially offset by higher pricing in the United States and higher demand in the Asia Pacific region.

## **Other Segments**

The Company's other segments are the Animal Health, Healthcare Services and Alliances segments, which are not material for separate reporting.

### Animal Health

Animal Health includes pharmaceutical and vaccine products for the prevention, treatment and control of disease in all major farm and companion animal species. Animal Health sales are affected by competition and the frequent introduction of generic products. Worldwide sales of Animal Health products were \$3.9 billion in 2017, \$3.5 billion in 2016 and \$3.3 billion in 2015. Global sales of Animal Health products grew 11% in 2017 compared with 2016 primarily reflecting higher sales of companion animal products, largely driven by growth in *Bravecto*, a line of products that kill fleas and ticks in dogs and cats for up to 12 weeks, reflecting both growth in the oral formulation and continued uptake in the topical formulation, which was launched in 2016. Animal Health sales growth was also driven by higher sales of ruminant, poultry and swine products. Worldwide sales of Animal Health products increased 4% in 2016 compared with 2015 including a 4% unfavorable effect from foreign exchange. Sales growth reflects volume growth across most species areas, particularly in products for companion animals, driven primarily by higher sales of *Bravecto*, as well as in poultry and swine products.

In March 2017, Merck acquired a controlling interest in Vallée, a leading privately held producer of animal health products in Brazil (see Note 3 to the consolidated financial statements).

# Costs, Expenses and Other

(\$ in millions)	2017	Change	2016	Change	2015
Materials and production	\$ 12,775	-8 %	\$ 13,891	-7 %	\$ 14,934
Marketing and administrative	9,830	1 %	9,762	-5 %	10,313
Research and development	10,208	1 %	10,124	51 %	6,704
Restructuring costs	776	19 %	651	5 %	619
Other (income) expense, net	12	-98 %	720	-53 %	1,527
	\$ 33,601	-4 %	\$ 35,148	3 %	\$ 34,097

## Materials and Production

Materials and production costs were \$12.8 billion in 2017, \$13.9 billion in 2016 and \$14.9 billion in 2015. Costs include expenses for the amortization of intangible assets recorded in connection with business acquisitions which totaled \$3.1 billion in 2017, \$3.7 billion in 2016 and \$4.7 billion in 2015. Costs in 2017, 2016 and 2015 also include intangible asset impairment charges of \$58 million, \$347 million and \$45 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. In addition, expenses for 2015 include \$105 million of amortization of purchase accounting adjustments to Cubist's

inventories. Also included in materials and production costs are expenses associated with restructuring activities which amounted to \$138 million , \$181 million and \$361 million in 2017 , 2016 and 2015 , 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 68.2% in 2017 compared with 65.1% in 2016 and 62.2% in 2015. The improvements in gross margin reflect a lower net impact from the amortization of intangible assets, intangible asset impairment charges and restructuring costs as noted above, which reduced gross margin by 8.2 percentage points in 2017, 10.6 percentage points in 2016 and 13.2 percentage points in 2015. 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. The improvement in 2016 as compared with 2015 was also driven by lower inventory write-offs and the favorable effects of foreign exchange.

### Marketing and Administrative

Marketing and administrative (M&A) expenses were \$9.8 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. M&A expenses were \$9.8 billion in 2016, a decline of 5% compared with 2015, driven largely by lower acquisition and divestiture-related costs, the favorable effects of foreign exchange, lower administrative expenses, such as legal defense costs, as well as lower selling costs. Higher promotional spending largely related to product launches and higher restructuring costs partially offset the decline. M&A expenses for 2017, 2016 and 2015 include restructuring costs of \$2 million , \$95 million and \$78 million , respectively, related primarily to accelerated depreciation for facilities to be closed or divested. Separation costs associated with sales force reductions have been incurred and are reflected in *Restructuring costs* as discussed below. M&A expenses also include acquisition and divestiture-related costs of \$44 million, \$78 million and \$436 million in 2017, 2016 and 2015, respectively, consisting of integration, transaction, and certain other costs related to business acquisitions and divestitures. Acquisition and divestiture-related costs in 2015 include costs related to the acquisition of Cubist (see Note 3 to the consolidated financial statements).

### Research and Development

Research and development (R&D) expenses were \$10.2 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 in-process research and development (IPR&D) impairment charges and lower restructuring costs. R&D expenses were \$10.1 billion in 2016 compared with \$6.7 billion in 2015. The increase was driven primarily by higher IPR&D impairment charges, increased clinical development spending, higher restructuring and licensing costs, partially offset by a reduction in expenses associated with a decrease in the estimated fair value measurement of liabilities for contingent consideration, as well as by the favorable effects of foreign exchange.

R&D expenses are comprised of the costs directly incurred by Merck Research Laboratories (MRL), the Company's research and development division that focuses on human health-related activities, which were \$4.6 billion in 2017, \$4.3 billion in 2016 and \$4.0 billion in 2015. 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 \$2.7 billion, \$2.5 billion and \$2.6 billion for 2017, 2016 and 2015, respectively. Additionally, R&D expenses in 2017 include a \$2.35 billion aggregate 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 \$483 million , \$3.6 billion and \$63 million in 2017 , 2016 and 2015 , respectively (see "Research and Development" below). 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 2017, the Company recorded charges of \$27 million to increase the estimated fair value of liabilities for contingent consideration. During 2016 and 2015, the Company recorded a reduction in expenses of \$402 million and \$24 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). R&D expenses in 2017, 2016 and 2015 also reflect \$11 million , \$142 million and \$52 million , respectively, of accelerated depreciation and asset abandonment costs associated with restructuring activities.

### Restructuring Costs

The Company incurs substantial costs for restructuring program activities related to Merck's productivity and cost reduction initiatives, as well as in connection with the integration of certain acquired businesses. 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 \$776 million , \$651 million and \$619 million in 2017 , 2016 and 2015 , respectively. In 2017 , 2016 and 2015 , separation costs of \$552 million , \$216 million and \$208 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 2,450 positions in 2017 , 2,625 positions in 2016 and 3,770 positions in 2015 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 *Materials and production*, *Marketing and administrative* and *Research and development* as discussed above. The Company recorded aggregate pretax costs of \$927 million in 2017, \$1.1 billion in 2016 and \$1.1 billion in 2015 related to restructuring program activities (see Note 5 to the consolidated financial statements). While the Company has substantially completed the actions under the programs, approximately \$500 million of additional pretax costs are expected to be incurred in 2018 relating to anticipated employee separations and remaining asset-related costs.

### Other (Income) Expense, Net

Other (income) expense, net was \$12 million of expense in 2017, \$720 million of expense in 2016 and \$1.5 billion of expense in 2015. For details on the components of *Other (income) expense, net*, see Note 15 to the consolidated financial statements.

Segment Profits			
(\$ in millions)	2017	2016	2015
Pharmaceutical segment profits	\$ 22,586 \$	22,180 \$	21,658
Other non-reportable segment profits	1,834	1,507	1,573
Other	(17,899)	(19,028)	(17,830)
Income before taxes	\$ 6,521 \$	4,659 \$	5,401

Segment profits are comprised of segment sales less standard costs, certain operating expenses directly incurred by the segment, components of equity income or loss from affiliates and certain depreciation and amortization expenses. For internal management reporting presented to the chief operating decision maker, Merck does not allocate materials and production costs, other than standard costs, the majority of research and development expenses 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, including the amortization of purchase accounting adjustments, intangible asset impairment charges and 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 loss on the extinguishment of debt in 2017, a charge related to the settlement of worldwide *Keytruda* patent litigation in 2016, gains on divestitures in 2016 and 2015, as well as a net charge related to the settlement of *Vioxx* shareholder class action litigation and foreign exchange losses related to the devaluation of the Company's net monetary assets in Venezuela in 2015, are reflected in "Other" in the above table. Also included in "Other" are miscellaneous corporate profits (losses), as well as operating profits (losses) related to third-party manufacturing sales.

Pharmaceutical segment profits grew 2% in 2017 compared with 2016 primarily reflecting higher sales and the favorable effects of product mix. Pharmaceutical segment profits grew 2% in 2016 compared with 2015 primarily reflecting higher sales.

#### Taxes on Income

The effective income tax rates of 62.9% in 2017, 15.4% in 2016 and 17.4% in 2015 reflect the impacts of acquisition and divestiture-related costs, which in 2016 include \$3.6 billion of IPR&D impairment charges, as well as restructuring costs and the beneficial impact of foreign earnings. In addition, the effective income tax rate for 2017 includes a provisional net charge of \$2.6 billion related to the enactment of U.S. tax legislation known as the Tax Cuts and Jobs Act (TCJA) (see Note 16 to the consolidated financial statements). The effective income tax rate for 2017 also reflects the unfavorable impact of a \$2.35 billion aggregate 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 benefit of \$234 million related to the settlement of certain federal income tax rate for 2015 reflects the favorable impact of a net benefit of \$410 million related to the settlement of a state income tax issues, the impact of a net charge related to the settlement of U.S. federal and state tax rates and the favorable impact of tax legislation enacted in the fourth quarter of 2015, as well as the unfavorable effect of non-tax deductible foreign exchange losses related to Venezuela (see Note 15 to the consolidated financial statements).

# Net Income and Earnings per Common Share

Net income attributable to Merck & Co., Inc. was \$2.4 billion in 2017, \$3.9 billion in 2016 and \$4.4 billion in 2015. EPS was \$0.87 in 2017, \$1.41 in 2016 and \$1.56 in 2015.

## 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).

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

(\$ in millions except per share amounts)	2017	2016	2015
Income before taxes as reported under GAAP	\$ 6,521	\$ 4,659	\$ 5,401
Increase (decrease) for excluded items:			
Acquisition and divestiture-related costs	3,760	7,312	5,398
Restructuring costs	927	1,069	1,110
Other items:			
Aggregate charge related to the formation of an oncology collaboration with AstraZeneca	2,350		_
Charge related to the settlement of worldwide Keytruda patent litigation	—	625	—
Foreign currency devaluation related to Venezuela			876
Net charge related to the settlement of Vioxx shareholder class action litigation	—	_	680
Gain on sale of certain migraine clinical development programs	—	—	(250)
Gain on divestiture of certain ophthalmic products	—	_	(147)
Other	(16)	(67)	(34)
Non-GAAP income before taxes	13,542	13,598	13,034
Taxes on income as reported under GAAP	4,103	718	942
Estimated tax benefit on excluded items <sup>(1)</sup>	785	2,321	1,470
Provisional net tax charge related to the enactment of the TCJA	(2,625)	—	_
Net tax benefits from the settlements of certain federal income tax issues	234	_	410
Tax benefit related to the settlement of a state income tax issue	88	—	—
Non-GAAP taxes on income	2,585	3,039	2,822
Non-GAAP net income	10,957	10,559	10,212
Less: Net income attributable to noncontrolling interests	24	21	17
Non-GAAP net income attributable to Merck & Co., Inc.	\$ 10,933	\$ 10,538	\$ 10,195
EPS assuming dilution as reported under GAAP	\$ 0.87	\$ 1.41	\$ 1.56
EPS difference <sup>(2)</sup>	3.11	2.37	2.03
Non-GAAP EPS assuming dilution	\$ 3.98	\$ 3.78	\$ 3.59

(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.

<sup>(2)</sup> 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 contingent consideration. Also excluded are integration, transaction, and certain other costs associated with business acquisitions and divestitures.

# Restructuring Costs

Non-GAAP income and non-GAAP EPS exclude costs related to restructuring actions (see Note 5 to the consolidated financial statements). These amounts include employee separation costs and accelerated depreciation associated with facilities to be closed or divested. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the asset, based upon the anticipated date the site will be closed or divested or the equipment disposed of, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. Restructuring costs also include asset abandonment, 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 2017 is an aggregate charge related to the formation of a collaboration with AstraZeneca (see Note 4 to the consolidated financial statements), a provisional net tax charge related to the enactment of the TCJA, a net benefit related to the settlement of certain federal income tax issues and a 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* (see Note 11 to the consolidated financial statements). Excluded from non-GAAP income and non-GAAP income and non-GAAP EPS in 2015 are foreign exchange losses related to the devaluation of the Company's net monetary assets in Venezuela (see Note 15 to the consolidated financial statements), a gain on the sale of certain migraine clinical development programs (see Note 3 to the consolidated financial statements), as well as a net tax benefit related to the settlement of certain federal income tax issues (see Note 16 to the consolidated financial statements), as well as a net tax benefit related to the settlement of certain federal income tax issues (see Note 16 to the consolidated financial statements), as well as a net tax benefit related to the settlement of certain federal income tax issues (see Note 16 to the consolidated financial statements), as well as a net tax benefit related to the settlement of certain federal income tax issues (see Note 16 to the consolidated financial statements), as well as a net tax benefit related to the settlement of certain federal income tax issues (see Not

# **Research and Development**

A chart reflecting the Company's current research pipeline as of February 23, 2018 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 December 2017, the FDA accepted for review a supplemental BLA for *Keytruda* for the treatment of adult and pediatric patients with refractory PMBCL, or who have relapsed after two or more prior lines of therapy. The FDA granted Priority Review status with a Prescription Drug User Fee Action (PDUFA), or target action, date of April 3, 2018.

Additionally, *Keytruda* has received Breakthrough Therapy designation from the FDA in combination with axitnib as a first-line treatment for patients with advanced or metastatic renal cell carcinoma; for the treatment of high-risk early-stage triple-negative breast cancer in combination with neoadjuvant chemotherapy; and for the treatment of Merkel cell carcinoma. Also, in January 2018, Merck and Eisai Co., Ltd. (Eisai) announced receipt of Breakthrough Therapy designation from the FDA for Eisai's multiple receptor tyrosine kinase inhibitor Lenvima (lenvatinib) in combination with *Keytruda* for the potential treatment of patients with advanced and/or metastatic renal cell carcinoma. The Lenvima and *Keytruda* combination therapy is being jointly developed by Eisai and Merck. This marks the 12 <sup>th</sup> Breakthrough Therapy designation granted to *Keytruda*. The FDA's Breakthrough Therapy designation is intended to expedite the development and review of a candidate that is planned for use, alone or in combination, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

In January 2018, Merck announced that the pivotal Phase 3 KEYNOTE-189 trial investigating *Keytruda* in combination with pemetrexed (Alimta) and cisplatin or carboplatin, for the first-line treatment of patients with metastatic non-squamous NSCLC, met its dual primary endpoints of OS and PFS. Based on an interim analysis conducted by the independent Data Monitoring Committee, treatment with *Keytruda* in combination with pemetrexed plus platinum chemotherapy resulted in significantly longer OS and PFS than pemetrexed plus platinum chemotherapy alone. Results from KEYNOTE-189 will be presented at an upcoming medical meeting and submitted to regulatory authorities.

In 2017, the FDA placed a full clinical hold on KEYNOTE-183 and KEYNOTE-185 and a partial clinical hold on Cohort 1 of KEYNOTE-023, three combination studies of *Keytruda* with lenalidomide or pomalidomide versus lenalidomide or pomalidomide alone in the blood cancer multiple myeloma. This decision followed a review of data by the Data Monitoring Committee in which more deaths were observed in the *Keytruda* arms of KEYNOTE-183 and

KEYNOTE-185. The FDA determined that the data available at the time indicated that the risks of *Keytruda* plus pomalidomide or lenalidomide outweighed any potential benefit for patients with multiple myeloma. All patients enrolled in KEYNOTE-183 and KEYNOTE-185 and those in the *Keytruda* /lenalidomide/dexamethasone cohort in KEYNOTE-023 have discontinued investigational treatment with *Keytruda*. This clinical hold does not apply to other studies with *Keytruda*.

The *Keytruda* clinical development program consists of more than 700 clinical trials, including more than 400 trials that combine *Keytruda* with other cancer treatments. These studies encompass more than 30 cancer types including: bladder, colorectal, esophageal, gastric, head and neck, hepatocellular, Hodgkin lymphoma, non-Hodgkin lymphoma, melanoma, 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.

MK-8835, ertugliflozin, an investigational oral SGLT-2 inhibitor in development to help improve glycemic control in adults with type 2 diabetes, and two fixed-dose combination products (MK-8835A, ertugliflozin and *Januvia*, and MK-8835B, ertugliflozin and metformin) are under review in the EU. In January 2018, the CHMP of the EMA adopted a positive opinion recommending approval of these medicines. The CHMP positive opinion will be considered by the EC. Ertugliflozin and the two fixed-dose combination products were approved by the FDA in December 2017.

MK-0431J is an investigational fixed-dose combination of sitagliptin and ipragliflozin under review with the Japan Pharmaceuticals and Medical Devices Agency. MK-0431 is being developed for commercialization in Japan in collaboration with Astellas Pharma Inc. (Astellas). Ipragliflozin, an SGLT2 inhibitor, co-developed by Astellas and Kotobuki Pharmaceutical Co., Ltd. (Kotobuki), is approved for use in Japan and is being co-promoted with Merck and Kotobuki.

MK-1439, doravirine, is an investigational, non-nucleoside reverse transcriptase inhibitor for the treatment of HIV-1 infection. In January 2018, Merck announced that the FDA accepted for review two NDAs for doravirine. The NDAs include data for doravirine as a once-daily tablet for use in combination with other antiretroviral agents, and for use of doravirine with lamivudine and tenofovir disoproxil fumarate in a once-daily fixed-dose combination single tablet as a complete regimen (MK-1439A). The PDUFA action date for both applications is October 23, 2018.

V419 is an investigational pediatric hexavalent combination vaccine, DTaP5-IPV-Hib-HepB, under review with the FDA that is being developed and, if approved, will be commercialized through a joint venture between Merck and Sanofi. This vaccine is designed to help protect against six important diseases - diphtheria, tetanus, pertussis (whooping cough), polio (poliovirus types 1, 2, and 3), invasive disease caused by *Haemophilus influenzae* type b (Hib), and hepatitis B. In 2015, the FDA issued a CRL with respect to the BLA for V419. Both companies are working to provide additional data requested by the FDA. V419 is being marketed as *Vaxelis* in the EU.

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-7655A is a combination of relebactam, an investigational beta-lactamase inhibitor, and imipenem/cilastatin (an approved carbapenem antibiotic). The FDA has 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.

MK-7339, Lynparza (olaparib), 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).

MK-5618, selumetinib, is an oral, potent, selective inhibitor of MEK, part of the mitogen-activated protein kinase (MAPK) pathway, currently being developed for multiple cancer types. Additionally, in February 2018, the FDA granted Orphan Drug designation for selumetinib for the treatment of neurofibromatosis type 1. The development of selumetinib is part of the global strategic oncology collaboration between Merck and AstraZeneca reference above.

V920 is an investigational rVSV-ZEBOV (Ebola) vaccine candidate being studied in large scale Phase 2/3 clinical trials. In November 2014, Merck and NewLink Genetics announced an exclusive licensing and collaboration agreement for the investigational Ebola vaccine. 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 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 December 2016, end of study results from the WHO ring vaccination trial were reported in Lancet supporting the July 2015 interim assessment that V920 offers substantial protection against Ebola virus disease, with no reported cases among vaccinated individuals from 10 days after vaccination in both randomized and non-randomized clusters. Results from other ongoing studies to be included in the first regulatory filing are anticipated in the first half of 2018.

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

V212 is an inactivated varicella zoster virus vaccine in development for the prevention of herpes zoster. The Company completed a Phase 3 trial in autologous hematopoietic cell transplant patients and another Phase 3 trial in patients with solid tumor malignancies undergoing chemotherapy and hematological malignancies. The study in autologous hematopoietic cell transplant patients met its primary endpoints and Merck presented the results from this study at the American Society for Blood and Marrow Transplantation Meetings in February 2017. The study in patients with solid tumor malignancies. Merck will present the results from this study at an upcoming scientific meeting. Due to the competitive environment, development of V212 is currently on hold.

MK-7264 is a selective, non-narcotic, orally-administered P2X3-receptor agonist being developed for the treatment of refractory, chronic cough. Merck plans to initiate a Phase 3 clinical trial in the first half of 2018. MK-7264 was originally developed by Afferent Pharmaceuticals (Afferent), which was acquired by the Company in 2016 (see Note 3 to the consolidated financial statements). Upon initiation of the Phase 3 clinical trial, Merck will make a \$175 million milestone payment, which was accrued for at estimated fair value at the time of acquisition.

The Company also discontinued certain drug candidates.

In February 2018, Merck announced that it will be stopping protocol 019, also known as the APECS study, a Phase 3 study evaluating verubecestat, MK-8931, an investigational small molecule inhibitor of the beta-site amyloid precursor protein cleaving enzyme 1 (BACE1), in people with prodromal Alzheimer's disease. The decision to stop the study follows a recommendation by the external Data Monitoring Committee (eDMC), which assessed overall benefit/risk during a recent interim safety analysis. The eDMC concluded that it was unlikely that positive benefit/risk could be established if the trial continued. As a result, the Company recorded an IPR&D impairment charge as discussed below.

In 2017, Merck announced that it will not submit applications for regulatory approval for MK-0859, anacetrapib, the Company's investigational cholesteryl ester transfer protein (CETP) inhibitor. The decision followed a thorough review of the clinical profile of anacetrapib, including discussions with external experts.

Also in 2017, Merck made a strategic decision to discontinue the development of the investigational combination regimens MK-3682B (grazoprevir/ruzasvir/uprifosbuvir) and MK-3682C (ruzasvir/uprifosbuvir) for the treatment of chronic 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 currently 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 as discussed below.

The Company maintains a number of long-term exploratory and fundamental research programs in biology and chemistry as well as research programs directed toward product development. The Company's research and development model is designed to increase productivity and improve the probability of success by prioritizing the Company's research and development resources on candidates the Company believes are capable of providing unambiguous, promotable advantages to patients and payers and delivering the maximum value of its approved medicines and vaccines through new indications and new formulations. Merck is pursuing emerging product

opportunities independent of therapeutic area or modality (small molecule, biologics and vaccines) and is building its biologics capabilities. The Company is committed to ensuring that externally sourced programs remain an important component of its pipeline strategy, with a focus on supplementing its internal research with a licensing and external alliance strategy focused on the entire spectrum of collaborations from early research to late-stage compounds, as well as access to new technologies.

The Company 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, 2017, the balance of IPR&D was \$1.2 billion.

During 2017, 2016 and 2015, \$14 million, \$8 million and \$280 million, respectively, of IPR&D projects received marketing approval in a major market and the Company began amortizing these assets based on their estimated useful lives.

All of 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 2017, the Company recorded \$483 million of IPR&D impairment charges within *Research and development* expenses. Of this amount, \$240 million resulted from a strategic decision to discontinue the development of the investigational combination regimens MK-3682B (grazoprevir/ruzasvir/uprifosbuvir) and MK-3682C (ruzasvir/uprifosbuvir) for the treatment of chronic 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 currently 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 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 relates 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 pretax impairment charge noted above. The IPR&D impairment charges in 2016 also include 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 relates 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 include \$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 relate 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 (see Note 6 to the consolidated financial statements).

During 2015, the Company recorded \$63 million of IPR&D impairment charges, of which \$50 million related to the surotomycin clinical development program. In 2015, the Company received unfavorable efficacy data from a clinical trial for surotomycin. The evaluation of this data, combined with an assessment of the commercial opportunity for surotomycin, resulted in the discontinuation of the program and the IPR&D impairment charge noted above.

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 February 2018, Merck and Viralytics Limited (Viralytics) announced a definitive agreement pursuant to which Merck will acquire Viralytics, an Australian publicly traded company focused on oncolytic immunotherapy treatments for a range of cancers, for AUD 1.75 per share. The proposed acquisition values the total issued shares in Viralytics at approximately AUD 502 million (\$394 million). Upon completion of the transaction, Merck will gain full rights to Cavatax (CVA21), Viralytics's investigational oncolytic immunotherapy. Cavatax 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. Cavatax 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 Cavatax combination in melanoma, prostate, lung and bladder cancers. The transaction remains subject to a Viralytics's shareholder vote and customary regulatory approvals. Merck anticipates the transaction will close in the second quarter of 2018.

In October 2017, Merck acquired 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, 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  $\notin$ 119 million (\$140 million) and may make additional contingent payments of up to  $\notin$ 349 million (of which  $\notin$ 184 million are related to the achievement of research milestones and regulatory approvals and  $\notin$ 165 million are related to the achievement of commercial targets). The transaction was accounted for as an acquisition of an asset and the upfront payment is reflected within *Research and development* expenses in 2017.

In July 2017, Merck and AstraZeneca entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza (olaparib) for multiple cancer types. Lynparza is an oral 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* (pembrolizumab) and Imfinzi (durvalumab). 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 including thyroid cancer. 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 will be 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 will fund all development to AstraZeneca of \$1.6 billion and is making payments of \$750 million over a multi-year period for certain license options (\$250 million was paid in December 2017, \$400 million will be paid in 2018 and \$100 million will 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 options payments. In addition, Merck will pay AstraZeneca up to an additional \$6.15 billion contingent upon successful achievement of future regulatory and sales-based milestones for total aggregate consideration of up to \$8.5 billion .

## **Capital Expenditures**

Capital expenditures were \$1.9 billion in 2017, \$1.6 billion in 2016 and \$1.3 billion in 2015. Expenditures in the United States were \$1.2 billion in 2017, \$1.0 billion in 2016 and \$879 million in 2015. Merck plans to invest approximately \$12.0 billion over five years in capital projects including approximately \$8.0 billion in the United States.

Depreciation expense was \$1.5 billion in 2017, \$1.6 billion in 2016 and \$1.6 billion in 2015 of which \$1.0 billion, \$1.0 billion and \$1.1 billion, respectively, applied to locations in the United States. Total depreciation expense in 2017, 2016 and 2015 included accelerated depreciation of \$60 million, \$227 million and \$174 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)	2017	2016	2015
Working capital	\$ 6,152 \$	13,410 \$	10,550
Total debt to total liabilities and equity	27.8%	26.0%	26.0%
Cash provided by operations to total debt	0.3:1	0.4:1	0.5:1

The decline in working capital in 2017 as 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 \$6.4 billion in 2017, \$10.4 billion in 2016 and \$12.5 billion in 2015. The decline in 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 settlement of worldwide *Keytruda* patent litigation (see Note 11 to the consolidated financial statements). Cash provided by operating activities in 2016 reflects a net payment of approximately \$680 million to fund the *Vioxx* shareholder class action litigation settlement not covered by insurance proceeds. 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 \$2.7 billion in 2017 compared with a use 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 investing activities was \$3.2 billion in 2016 compared with \$4.8 billion in 2015. The lower use of cash in 2016 was driven primarily by cash used in 2015 for the acquisition of Cubist, as well as lower purchases of securities and other investments in 2016 and the use of cash in 2016 for the acquisitions of Afferent and The StayWell Company LLC.

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. Cash used in financing activities was \$9.0 billion in 2016 compared with \$5.4 billion in 2015 driven primarily by lower proceeds from the issuance of debt, partially offset by a decrease in short-term borrowings in 2015, lower payments on debt, lower purchases of treasury stock and higher proceeds from the exercise of stock options.

During 2015, the Company recorded charges of \$876 million related to the devaluation of its net monetary assets in Venezuela, the large majority of which was cash (see Note 15 to the consolidated financial statements).

At December 31, 2017, the total of worldwide cash and investments was \$20.6 billion, including \$8.5 billion of cash, cash equivalents and short-term investments, and \$12.1 billion of long-term investments. A substantial majority of cash and investments are held by foreign subsidiaries that, prior to the enactment of the TCJA, would have been subject to significant tax payments if such cash and investments were repatriated in the form of dividends. In accordance with the TCJA, the Company has recorded a provisional amount for taxes on unremitted earnings through December 31, 2017 that were previously deemed to be indefinitely reinvested outside of the United States (see Note 16 to the consolidated financial statements). As a result of the TCJA, repatriation of foreign earnings in the future will have little to no incremental U.S. tax consequences.

The Company's contractual obligations as of December 31, 2017 are as follows:

### Payments Due by Period

(\$ in millions)	Total	2018	2019—2020	2021—2022	Thereafter
Purchase obligations <sup>(1)</sup>	\$ 2,226	\$ 715	\$ 892	\$ 478	\$ 141
Loans payable and current portion of long-term debt <sup>(2)</sup>	3,074	3,074	_	_	_
Long-term debt	21,400	_	3,200	4,589	13,611
Interest related to debt obligations	8,206	675	1,200	1,011	5,320
Unrecognized tax benefits <sup>(3)</sup>	67	67	_	_	_
Transition tax related to the enactment of the TCJA $^{(4)}$	5,057	545	853	1,194	2,465
Operating leases	852	255	301	158	138
	\$ 40,882	\$ 5,331	\$ 6,446	\$ 7,430	\$ 21,675

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

<sup>(2)</sup> In January 2018, \$1.0 billion of notes matured and were repaid.

<sup>(3)</sup> As of December 31, 2017, the Company's Consolidated Balance Sheet reflects liabilities for unrecognized tax benefits, interest and penalties of \$2.1 billion, including \$67 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 2018 cannot be made.

<sup>(4)</sup> 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, 2017, the Company has \$635 million of accrued milestone payments related to collaborations with Pfizer, Bayer and AstraZeneca (see Note 4 to the consolidated financial statements), as well as in connection with certain licensing arrangements, that are payable in 2018. In addition, at December 31, 2017, the Company has \$315 million of current liabilities for contingent consideration related to business acquisitions expected to be paid in 2018 (see Note 6 to the consolidated financial statements). Also excluded from research and development obligations are potential future funding commitments of up to approximately \$60 million for investments in research venture capital funds. Loans payable and current portion of long-term debt reflects \$73 million of long-dated notes that are subject to repayment at the option of the holders. Required funding obligations for 2018 relating to the Company's pension and other postretirement benefit plans are not expected to be material. However, the Company currently anticipates contributing

approximately \$60 million to its U.S. pension plans, \$150 million to its international pension plans and \$25 million to its other postretirement benefit plans during 2018.

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  $\notin 1.0$  billion principal amount of senior unsecured notes consisting of  $\notin 500$  million principal amount of 0.50% notes due 2024 and  $\notin 500$  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.

The Company has a \$6.0 billion, five-year credit facility that matures in June 2022. 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 December 2015, 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.

In February 2015, Merck issued \$8.0 billion aggregate principal amount of senior unsecured notes. The Company used a portion of the net proceeds of the offering of \$7.9 billion to repay commercial paper issued to substantially finance the Company's acquisition of Cubist. The remaining net proceeds were used for general corporate purposes, including for repurchases of the Company's common stock, and the repayment of outstanding commercial paper borrowings and debt maturities.

Also in February 2015, the Company redeemed \$1.9 billion of legacy Cubist debt acquired in the acquisition (see Note 3 to the consolidated financial statements).

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

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

In November 2017, the Board of Directors declared a quarterly dividend of \$0.48 per share on the Company's common stock that was paid in January 2018. In January 2018, the Board of Directors declared a quarterly dividend of \$0.48 per share on the Company's common stock for the second quarter of 2018 payable in April 2018.

In November 2017, Merck's board of directors authorized additional purchases of up to \$10 billion of Merck's common stock for its treasury. The treasury stock purchase authorization has no time limit and will be made over time in open-market transactions, block transactions, on or off an exchange, or in privately negotiated transactions. The Company purchased \$4.0 billion of its common stock (67 million shares) for its treasury during 2017. As of December 31, 2017, the Company's share repurchase authorization was \$11.0 billion, which includes \$1.0 billion in authorized repurchases remaining under a program announced in March 2015. The Company purchased \$3.4 billion and \$4.2 billion of its common stock during 2016 and 2015, respectively, under authorized share repurchase programs.

# **Financial Instruments Market Risk Disclosures**

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

A significant portion of the Company's revenues and earnings in foreign affiliates is exposed to changes in foreign exchange rates. The objectives 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.

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 \$400 million and \$538 million at December 31, 2017 and 2016, 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 rate and the cost of the hedging instrument. The cash flows from these contracts are reported as operating activities in the Consolidated Statements 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, 2017 and 2016, *Income before taxes* would have declined by approximately \$92 million and \$26 million in 2017 and 2016, 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.

Since January 2010, Venezuela has been designated hyperinflationary and, as a result, local foreign operations are remeasured in U.S. dollars with the impact recorded in results of operations. During 2015, upon evaluation of evolving economic conditions in Venezuela and volatility in the country, combined with a decline in transactions that were settled at the then official (CENCOEX) rate, the Company determined it was unlikely that all outstanding net monetary assets would be settled at the CENCOEX rate. Accordingly, during 2015, the Company recorded charges of \$876 million within *Other (income) expense, net* to devalue its net monetary assets in Venezuela to an amount that represented the Company's estimate of the U.S. dollar amount that would ultimately be collected and recorded additional exchange losses of \$138 million in the aggregate reflecting the ongoing effect of translating transactions and net monetary assets with these rates.

The Company may also use 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 and measures ineffectiveness based upon changes in spot foreign exchange rates that are recorded in *Other (income) expense, net*. The effective portion of the unrealized gains or losses on these contracts is recorded in foreign currency translation adjustment within *Other Comprehensive Income (OCI)*, and remains in *Accumulated Other Comprehensive Income (AOCI)* until either the sale or complete or substantially complete liquidation of the subsidiary. The cash flows from these contracts are reported as investing activities in the Consolidated Statement of Cash Flows.

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

### Interest Rate Risk Management

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

At December 31, 2017, the Company was a party to 26 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)	2017									
Debt Instrument	Par Valu	e of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount						
1.30% notes due 2018	\$	1,000	4	\$	1,000					
5.00% notes due 2019		1,250	3		550					
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 and offset by the 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 both December 31, 2017 and 2016 would have positively affected the net aggregate market value of these instruments by \$1.3 billion. A one percentage point decrease at December 31, 2017 and 2016 would have negatively affected the net aggregate market value by \$1.5 billion and \$1.6 billion, respectively. The fair value of Merck's debt was determined using pricing models reflecting one percentage point shifts in the appropriate yield curves. The fair values of Merck's investments were determined using a combination of pricing and duration models.

# **Critical Accounting Policies**

The Company's consolidated financial statements are prepared in conformity with GAAP and, accordingly, include certain amounts that are based on management's best estimates and judgments. Estimates are used when accounting for amounts recorded in connection with acquisitions, including initial fair value determinations of assets and liabilities, primarily IPR&D, other intangible assets and contingent consideration, as well as subsequent fair value

measurements. Additionally, estimates are used in determining such items as provisions for sales discounts and returns, depreciable and amortizable lives, recoverability of inventories, including those produced in preparation for product launches, amounts recorded for contingencies, environmental liabilities 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 recognized at fair value if fair value can reasonably be estimated. If the acquisition date fair value of an asset acquired or liability assumed that arises from a contingency 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 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

Revenues from sales of products are recognized when title and risk of loss passes to the customer, typically at time of delivery. Recognition of revenue also requires reasonable assurance of collection of sales proceeds and completion of all performance obligations. Domestically, 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 for customers for which collection of accounts receivable is expected to be in excess of one year.

The provision for aggregate customer discounts covers chargebacks and rebates. Chargebacks are discounts that occur when a contracted customer purchases directly through an intermediary wholesaler. The contracted customer generally purchases product at its contracted price plus a mark-up from the wholesaler. 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 is based on expected payments, which are driven by patient usage and contract performance by the benefit provider customers.

The Company uses historical customer segment mix, adjusted for other known events, 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 and other customers to the amounts accrued. Adjustments are recorded when trends or significant events indicate that a change in the estimated provision is appropriate.

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 2017, 2016 or 2015.

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

(\$ in millions)	2017	2016
Balance January 1	\$ 2,945 \$	2,798
Current provision	10,938	9,831
Adjustments to prior years	(223)	(169)
Payments	(11,109)	(9,515)
Balance December 31	\$ 2,551 \$	2,945

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 \$198 million and \$2.4 billion, respectively, at December 31, 2017 and were \$196 million and \$2.7 billion, respectively, at December 31, 2016.

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 additional 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 2.1% in 2017 , 1.4% in 2016 and 1.5% in 2015 .

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

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

### Inventories Produced in Preparation for Product Launches

The Company capitalizes inventories produced in preparation for product launches sufficient to support estimated initial market demand. Typically, capitalization of such inventory does not begin until the related product candidates are in Phase 3 clinical trials and are considered to have a high probability of regulatory approval. The Company monitors the status of each respective product within the regulatory approval process; however, the Company generally does not disclose specific timing for regulatory approval. If the Company is aware of any specific risks or contingencies other than the normal regulatory approval process or if there are any specific issues identified during the research process relating to safety, efficacy, manufacturing, marketing or labeling, the related inventory would generally not be capitalized. Expiry dates of the inventory are affected by the stage of completion. The Company manages the levels of inventory at each stage to optimize the shelf life of the inventory in relation to anticipated market demand in order to avoid product expiry issues. For inventories that are capitalized, anticipated future sales and shelf lives support the realization of the inventory value as the inventory shelf life is sufficient to meet initial product launch requirements. Inventories produced in preparation for product launches capitalized at both December 31, 2017 and 2016 were \$80 million .

### 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, 2017 and 2016 of approximately \$160 million and \$185 million , respectively, represents the Company's best estimate

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

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

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

The Company believes that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on the Company. Expenditures for remediation and environmental liabilities were \$11 million in 2017, and are estimated at \$56 million in the aggregate for the years 2018 through 2022. In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled \$82 million and \$83 million at December 31, 2017 and 2016, 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 \$63 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 \$312 million in 2017, \$300 million in 2016 and \$299 million in 2015. At December 31, 2017, there was \$469 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 \$201 million in 2017, \$144 million in 2016 and \$277 million in 2015. Net periodic benefit (credit) for other postretirement benefit plans was \$(60) million in 2017, \$(88) million in 2016 and \$(24) million in 2015. 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 (credit) for other postretirement benefit plans in 2017 and 2016 as compared with 2015 is largely attributable to changes in retiree medical benefit approved by the Company in December 2015, partially offset by lower returns on plan assets.

The Company reassesses its benefit plan assumptions on a regular basis. For both the pension and other postretirement benefit plans, the discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due. The discount rates for the Company's U.S. pension and other postretirement benefit plans ranged from 3.20% to 3.80% at December 31, 2017, compared with a range of 3.40% to 4.30% at December 31, 2016.

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 2018, the expected rate of return for the Company's U.S. pension and other postretirement benefit plans will range from 7.70% to 8.30%, compared to a range of 8.00% to 8.75% in 2017. 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 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 35% to 55% in U.S. equities, 20% to 35% in international equities, 20% to 35% 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 13%, 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 \$77 million favorable (unfavorable) impact on the Company's net periodic benefit cost in 2017. 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 \$44 million favorable (unfavorable) impact on Merck's net periodic benefit cost in 2017. Required funding obligations for 2018 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 *Accumulated Other Comprehensive Income (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 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. 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* 

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costs. Asset-related charges are reflected within Materials and production costs, Marketing 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 and is assigned to reporting units. The Company tests its goodwill for impairment on at least an annual basis, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. Some of the factors considered in the assessment include general macroeconomic conditions, conditions specific to the industry and market, cost factors which could have a significant effect on earnings or cash flows, the overall financial performance of the reporting unit, and whether there have been sustained declines in the Company's share price. Additionally, the Company evaluates the extent to which the fair value exceeded the carrying value of the reporting unit at the last date a valuation was performed. 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.

Other acquired intangible assets (excluding IPR&D) are initially recorded at fair value, assigned an estimated useful life, and are 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 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 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, including the duration and extent to which fair value is less than cost and, for equity securities, the Company's ability and intent to hold the investments. For debt securities, an other-than-temporary impairment has occurred if the Company does not expect to recover the entire amortized cost basis of the 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 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.

# Taxes on Income

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

# Item 8. Financial Statements and Supplementary Data.

# (a) Financial Statements

The consolidated balance sheet of Merck & Co., Inc. and subsidiaries as of December 31, 2017 and 2016, 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, 2017, the notes to consolidated financial statements, and the report dated February 27, 2018 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)

	2017	2016	2015
Sales	\$ 40,122	\$ 39,807	\$ 39,498
Costs, Expenses and Other			
Materials and production	12,775	13,891	14,934
Marketing and administrative	9,830	9,762	10,313
Research and development	10,208	10,124	6,704
Restructuring costs	776	651	619
Other (income) expense, net	12	720	1,527
	33,601	35,148	34,097
Income Before Taxes	6,521	4,659	5,401
Taxes on Income	4,103	718	942
Net Income	2,418	3,941	4,459
Less: Net Income Attributable to Noncontrolling Interests	24	21	17
Net Income Attributable to Merck & Co., Inc.	\$ 2,394	\$ 3,920	\$ 4,442
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	\$ 0.88	\$ 1.42	\$ 1.58
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	\$ 0.87	\$ 1.41	\$ 1.56

# Consolidated Statement of Comprehensive Income

Merck & Co., Inc. and Subsidiaries Years Ended December 31 (\$ in millions)

	2017	2016	2015
Net Income Attributable to Merck & Co., Inc.	\$ 2,394	\$ 3,920	\$ 4,442
Other Comprehensive Income (Loss) Net of Taxes:			
Net unrealized loss on derivatives, net of reclassifications	(446)	(66)	(126)
Net unrealized loss on investments, net of reclassifications	(58)	(44)	(70)
Benefit plan net gain (loss) and prior service credit (cost), net of amortization	419	(799)	579
Cumulative translation adjustment	401	(169)	(208)
	316	(1,078)	175
Comprehensive Income Attributable to Merck & Co., Inc.	\$ 2,710	\$ 2,842	\$ 4,617

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

## **Consolidated Balance Sheet**

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

	2017	2016
Assets		
Current Assets		
Cash and cash equivalents	\$ 6,092	\$ 6,515
Short-term investments	2,406	7,826
Accounts receivable (net of allowance for doubtful accounts of \$210 in 2017 and \$195 in 2016)	6,873	7,018
Inventories (excludes inventories of \$1,187 in 2017 and \$1,117 in 2016 classified in Other assets - see Note 7)	5,096	4,866
Other current assets	4,299	4,389
Total current assets	24,766	30,614
Investments	12,125	11,416
Property, Plant and Equipment (at cost)		
Land	365	412
Buildings	11,726	11,439
Machinery, equipment and office furnishings	14,649	14,053
Construction in progress	2,301	1,871
	29,041	27,775
Less: accumulated depreciation	16,602	15,749
	12,439	12,026
Goodwill	18,284	18,162
Other Intangibles, Net	14,183	17,305
Other Assets	6,075	5,854
	\$ 87,872	\$ 95,377
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	\$ 3,057	\$ 568
Trade accounts payable	3,102	2,807
Accrued and other current liabilities	10,427	10,274

Accrued and other current liabilities 10,427 10,274 Income taxes payable 708 2,239 Dividends payable 1,320 1,316 Total current liabilities 18,614 17,204 Long-Term Debt 21,353 24,274 Deferred Income Taxes 2,219 5,077 11,117 Other Noncurrent Liabilities 8,514

Merck & Co., Inc. Stockholders' Equity Common stock, \$0.50 par value Authorized - 6,500,000,000 shares Issued - 3,577,103,522 shares in 2017 and 2016 1,788 1,788 Other paid-in capital 39,902 39,939 Retained earnings 41,350 44,133 Accumulated other comprehensive loss (4,910) (5,226) 78,130 80,634 Less treasury stock, at cost: 880,491,914 shares in 2017 and 828,372,200 shares in 2016 43,794 40,546 Total Merck & Co., Inc. stockholders' equity 34,336 40,088 Noncontrolling Interests 233 220 Total equity 34,569 40,308 87,872 95,377 \$ \$

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



# **Consolidated Statement of Equity** Merck & Co., Inc. and Subsidiaries *Years Ended December 31*

(\$ in millions except per share amounts)

	Common Stock	Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock	Non- controlling Interests	Total
Balance January 1, 2015	\$1,788	\$ 40,423	\$ 46,021	\$ (4,323)	\$ (35,262)	\$ 144	\$ 48,791
Net income attributable to Merck & Co., Inc.	_	_	4,442	_	_	_	4,442
Other comprehensive income, net of taxes	_	_	_	175	_	_	175
Cash dividends declared on common stock (\$1.81 per share)	_	_	(5,115)	_	_	_	(5,115)
Treasury stock shares purchased	_	_	_	_	(4,186)	_	(4,186)
Changes in noncontrolling ownership interests	_	(20)	_	_	_	(55)	(75)
Net income attributable to noncontrolling interests	_	_	_	_	_	17	17
Distributions attributable to noncontrolling interests	_	_	_	_	_	(15)	(15)
Share-based compensation plans and other	_	(181)	_	_	914	_	733
Balance December 31, 2015	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)
Changes in noncontrolling ownership interests	_	_	_	_	_	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

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)

Cash Flows from Operating Activities	2017	2016	2015
Net income	\$ 2,418	¢ 2.041	\$ 4.450
Adjustments to reconcile net income to net cash provided by operating activities:	\$ 2,418	\$ 3,941	\$ 4,459
Depreciation and amortization	4,637	5,441	6,375
Intangible asset impairment charges	-,037	3,948	162
Provisional charge for one-time transition tax related to the enactment of U.S. tax legislation	5,347	5,740	102
Charge for future payments related to AstraZeneca collaboration license options	500		
Charge related to the settlement of worldwide <i>Keytruda</i> patent litigation	500	625	_
Foreign currency devaluation related to Venezuela			876
Net charge related to the settlement of <i>Vioxx</i> shareholder class action litigation		_	680
Equity income from affiliates	(42	) (86)	(205)
Dividends and distributions from equity method affiliates	2		50
Deferred income taxes	(2,621		(764)
Share-based compensation	312		299
Other	269	313	874
Net changes in assets and liabilities:	207	515	0/1
Accounts receivable	297	(619)	(480)
Inventories	(145		805
Trade accounts payable	254	278	(37)
Accrued and other current liabilities	(922		(8)
Income taxes payable	(3,291		(266)
Noncurrent liabilities	(123	, ,	(200)
Other	(1,091		(277)
Net Cash Provided by Operating Activities	6,447	10,376	12,538
Cash Flows from Investing Activities	0,777	10,570	12,556
Capital expenditures	(1,888	) (1,614)	(1,283)
Purchases of securities and other investments	(1,888)		(1,283)
Proceeds from sales of securities and other investments	15,664		20,413
Acquisition of Cubist Pharmaceuticals, Inc., net of cash acquired	15,004	14,555	(7,598)
Acquisitions of other businesses, net of cash acquired	(396	) (780)	(1,398)
Dispositions of businesses, net of cash divested	(370	) (780)	316
Other	38	482	
Net Cash Provided by (Used in) Investing Activities			221
Cash Flows from Financing Activities	2,679	(3,210)	(4,758)
Net change in short-term borrowings	(0)	<u>,</u>	(1.540)
Payments on debt	(26	-	(1,540)
Proceeds from issuance of debt	(1,103		(2,906)
Purchases of treasury stock		1,079	7,938
Dividends paid to stockholders	(4,014		(4,186)
Proceeds from exercise of stock options	(5,167		(5,117)
Other	499		485
Net Cash Used in Financing Activities	(195		(61)
	(10,006		(5,387)
Effect of Exchange Rate Changes on Cash and Cash Equivalents	457		(1,310)
Net (Decrease) Increase in Cash and Cash Equivalents	(423		1,083
Cash and Cash Equivalents at Beginning of Year	6,515		7,441
Cash and Cash Equivalents at End of Year	\$ 6,092	\$ 6,515	\$ 8,524

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

# Notes to Consolidated Financial Statements

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

# 1. Nature of Operations

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

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. 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. Beginning in 2017, Merck is 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 Company also has an Animal Health segment that discovers, develops, manufactures and markets animal health products, including vaccines, which the Company sells to veterinarians, distributors and animal producers. The Company's 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.

# 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 values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in the Company's consolidated financial statements after the date of the acquisition. If the Company determines the assets acquired do not meet the definition of a business under the acquisition method of accounting, the transaction will be accounted for as an acquisition of assets rather than a business combination and, therefore, no goodwill will be recorded.

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 market. The cost of a substantial majority of domestic 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 and equity securities classified as available-for-sale are reported at fair value. Fair values of the Company's investments 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)*. For declines in the fair value of equity securities that are considered other-than-temporary, impairment losses are charged to *Other (income) expense, net*. The Company considers available evidence in evaluating potential impairments of its investments, including the duration and extent to which fair value is less than cost and, for equity securities, the Company's ability and intent to hold the investments. For debt securities, an other-than-temporary impairment has occurred if the Company does not expect to recover the entire amortized cost basis of the 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 *Other (income) expense, net*.

*Revenue Recognition* — Revenues from sales of products are recognized when title and risk of loss passes to the customer, typically upon delivery. Recognition of revenue also requires reasonable assurance of collection of sales proceeds and completion of all performance obligations. Domestically, 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. Accruals for chargebacks are reflected as a direct reduction to accounts receivable and accruals for rebates are recorded as current liabilities. The accrued balances relative to the provisions for chargebacks and rebates included in *Accounts receivable* and *Accrued and other current liabilities* were \$198 million and \$2.4 billion , respectively, at December 31, 2017 and \$196 million and \$2.7 billion , respectively, at December 31, 2016 .

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.

*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 \$1.5 billion in 2017, \$1.6 billion in 2016 and \$1.6 billion in 2015.

Advertising and Promotion Costs — Advertising and promotion costs are expensed as incurred. The Company recorded advertising and promotion expenses of \$2.2 billion , \$2.1 billion and \$2.1 billion in 2017 , 2016 and 2015 , 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 \$449 million and \$452 million , net of accumulated amortization at December 31, 2017 and 2016, 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 a quantitative fair value test is performed.

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 are 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 in-process research and development (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 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 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 all periods. In addition, research and development expenses include restructuring fair value measurement of liabilities for contingent consideration.

*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. Cost reimbursements between the collaborative partners are recognized as incurred and included in *Materials and production* costs, *Marketing and administrative* expenses and *Research and development* expenses based on the underlying nature of the related activities subject to reimbursement. When Merck is the principal on sales transactions with third parties, the Company recognizes sales, materials and production costs and marketing and administrative expenses on a gross basis. The Company records profit sharing amounts received from its collaborative partners as alliance revenue (within *Sales*) and profit sharing amounts it pays to its collaborative partners within *Materials and production* costs. 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 guardee 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 *Materials and production* costs 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 *M* 

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

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

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

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

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 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 Issued Accounting Standards* — In May 2014, the Financial Accounting Standards Board (FASB) issued amended accounting guidance on revenue recognition that will be applied 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 will be effective as of January 1, 2018 and will be adopted using the modified retrospective method. The Company anticipates recording a cumulative-effect adjustment upon adoption increasing *Retained earnings* by \$5 million in 2018. The adoption of the new guidance will also result in some additional disclosures.

In January 2016, the FASB issued revised guidance for the accounting and reporting of financial instruments. 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 new guidance also simplifies the impairment testing of equity investments without readily determinable fair values and changes certain disclosure requirements. The new standard will be effective as of January 1, 2018 and will be adopted using a modified retrospective approach. The Company anticipates recording a cumulative-effect adjustment upon adoption increasing *Retained earnings* by \$8 million in 2018.

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 new standard is effective as of January 1, 2018 and will be adopted using a retrospective application. The Company does not anticipate any changes to the presentation of its Consolidated Statement of Cash Flows as a result of adopting the new standard.

In October 2016, the FASB issued guidance on the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. Under existing guidance, the recognition of current and deferred income taxes for an intra-entity asset transfer is prohibited until the asset has been sold to a third party. The new guidance will require 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. The new standard will be effective as of January 1, 2018 and will be adopted using a modified retrospective approach. The Company anticipates recording a cumulative-effect adjustment upon adoption increasing *Retained earnings* by approximately \$60 million in 2018 with a corresponding increase to deferred tax assets, subject to finalization.

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 is effective as of January 1, 2018 and will be adopted using a retrospective application. The adoption of the new guidance will not have a material effect on the Company's Consolidated Statement of Cash Flows.

In March 2017, the FASB amended the guidance 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. Entities must use a retrospective transition method to adopt the requirement for separate presentation in the income statement of service costs and other components and a prospective transition method to adopt the requirement to limit the capitalization of benefit costs to the service cost component. The Company will utilize 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. The new standard is effective as of January 1, 2018. Net periodic benefit cost (credit) other than service cost was approximately \$(510) million and \$(530) million for the years ended December 31, 2017 and 2016, respectively, (see Note 14). Upon adoption, these amounts will be reclassified to *Other (income) expense, net* from their current classification within *Materials and production* costs, *Marketing and administrative* expenses and *Research and development* costs.

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 new standard is effective as of January 1, 2018 and will be applied to future share-based payment award modifications should they occur.

In February 2016, the FASB issued new accounting guidance for the accounting and reporting of leases. 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 guidance will be effective for interim and annual periods beginning in 2019 and will be adopted using a modified retrospective approach which will require application of the new guidance at the beginning of the earliest comparative period presented. Early adoption is permitted. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In August 2017, the FASB issued new guidance on hedge accounting 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 new guidance is effective for interim and annual periods beginning in 2019 on a modified retrospective basis. Early application is permitted in any interim period. The Company intends to early adopt this guidance as of January 1, 2018 on a modified retrospective basis. The Company anticipates recording a cumulative-effect adjustment upon adoption decreasing *Retained earnings* by \$11 million in 2018. The adoption of the new guidance will result in some additional disclosures.

In February 2018, the FASB issued new guidance to address a narrow-scope financial reporting issue that arose as a consequence of the TCJA. 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 these amounts to retained earnings thereby eliminating these stranded tax effects. The new guidance is effective for interim and annual periods in 2019. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

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 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 new guidance is effective for interim and annual periods in 2020. Early adoption is permitted. The Company does not anticipate that the adoption of the new guidance will have a material effect on its consolidated financial statements.

#### 3. Acquisitions, Divestitures, Research Collaborations and License Agreements

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

#### **Recently Announced Transaction**

In February 2018, Merck and Viralytics Limited (Viralytics) announced a definitive agreement pursuant to which Merck will acquire Viralytics, an Australian publicly traded company focused on oncolytic immunotherapy treatments for a range of cancers, for AUD 1.75 per share. The proposed acquisition values the total issued shares in Viralytics at approximately AUD 502 million (\$394 million). Upon completion of the transaction, Merck will gain full rights to Cavatax (CVA21), Viralytics's investigational oncolytic immunotherapy. The transaction remains subject to a Viralytics's shareholder vote and customary regulatory approvals. Merck anticipates the transaction will close in the second quarter of 2018.

#### 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, 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  $\notin$ 119 million (\$140 million) and may make additional contingent payments of up to  $\notin$ 349 million (of which  $\notin$ 184 million are related to the achievement of research milestones and regulatory approvals and  $\notin$ 165 million are related to the achievement of commercial targets). The transaction was accounted for as an acquisition of an asset and the upfront payment is reflected within *Research and development* expenses in 2017.

In July 2017, Merck and AstraZeneca entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza (olaparib) 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 \$291 million related to currently marketed products, net deferred tax liabilities of \$93 million , other net assets of \$14 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 \$171 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

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years. In the fourth quarter of 2017, Merck acquired an additional 4.5% interest in Vallée for \$18 million , which reduced 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), is a selective, non-narcotic, orally-administered P2X3 antagonist being evaluated for the treatment of refractory, chronic cough. 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 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.

Also in July 2016, Merck, through its wholly owned subsidiary Healthcare Services & Solutions, LLC, acquired a majority ownership interest in The StayWell Company LLC (StayWell), a portfolio company of Vestar Capital Partners (Vestar). StayWell is a health engagement company that helps its clients engage and educate people to improve health and business results. Under the terms of the transaction, Merck paid \$150 million for a majority ownership interest. Additionally, Merck provided StayWell with a \$150 million intercompany loan to pay down preexisting third-party debt. Merck has an option to buy, and Vestar has an option to require Merck to buy, some or all of Vestar's remaining ownership interest at fair value beginning three years from the acquisition date. This transaction was accounted for as an acquisition of a business. Merck recognized intangible assets of \$238 million , deferred tax liabilities of \$84 million , other net liabilities of \$5 million and noncontrolling interest of \$124 million . The excess of the consideration transferred over the fair value of net assets acquired of \$275 million was recorded as goodwill and is largely attributable to anticipated synergies expected to arise after the acquisition. The goodwill was allocated to the Healthcare Services segment and is not deductible for tax purposes. The intangible assets recognized primarily relate to customer relationships, which are being amortized over a 10 -year useful life.

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.

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 provides 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 July 2017, Merck made a \$100 million payment as a result of the achievement of a clinical development milestone, which was accrued for at estimated fair value at the time of acquisition as noted above.

## 2015 Transactions

In December 2015, the Company divested its remaining ophthalmics portfolio in international markets to Mundipharma Ophthalmology Products Limited. Merck received consideration of approximately \$170 million and recognized a gain of \$147 million recorded in *Other (income) expense, net* in 2015.

In July 2015, Merck acquired cCAM Biotherapeutics Ltd. (cCAM), a privately held biopharmaceutical company focused on the discovery and development of novel cancer immunotherapies. Total purchase consideration in the transaction included an upfront payment of \$96 million in cash and potential future additional payments associated with the attainment of certain clinical development, regulatory and commercial milestones. The transaction was accounted for as an acquisition of a business. Merck recognized an intangible asset for IPR&D of \$180 million related to CM-24, a monoclonal antibody, as well as a liability for contingent consideration of \$105 million , goodwill of \$14 million and other net assets of \$7 million . During 2016, as a result of unfavorable efficacy data, the Company determined that it would discontinue development of the pipeline program. Accordingly, the Company recorded an IPR&D impairment charge of \$180 million related to CM-24 and reversed the related liability for contingent consideration, which had a fair value of \$116 million at the time of program discontinuation. Both the IPR&D impairment charge and the income related to the reduction in the liability for contingent consideration were recorded in *Research and development* expenses in 2016.

Also in July 2015, Merck and Allergan plc (Allergan) entered into an agreement pursuant to which Allergan acquired the exclusive worldwide rights to MK-1602 and MK-8031, Merck's investigational small molecule oral calcitonin gene-related peptide (CGRP) receptor antagonists, which are being developed for the treatment and prevention of migraine. Under the terms of the agreement, Allergan acquired these rights for upfront payments of \$250 million , of which \$125 million was paid in August 2015 upon closing of the transaction and the remaining \$125 million was paid in April of 2016. The Company recorded a gain of \$250 million within *Other (income) expense, net* in 2015 related to the transaction. Allergan is fully responsible for development of the CGRP programs, as well as manufacturing and commercialization upon approval and launch of the products. Under the agreement, Merck is entitled to receive potential development and commercial milestone payments and royalties at tiered double-digit rates based on commercialization of the programs. During 2016, Merck recognized gains of \$100 million within *Other (income) expense, net* resulting from payments by Allergan for the achievement of research and development milestones.

In February 2015, Merck and NGM Biopharmaceuticals, Inc. (NGM), a privately held biotechnology company, entered into a multi-year collaboration to research, discover, develop and commercialize novel biologic therapies across a wide range of therapeutic areas. Under the terms of the agreement, Merck made an upfront payment to NGM of \$94 million , which was included in *Research and development* expenses, and purchased a 15% equity stake in NGM for \$106 million . Merck committed up to \$250 million to fund all of NGM's efforts under the initial five -year term of the collaboration, with the potential for additional funding if certain conditions are met. Prior to Merck initiating a Phase 3 study for a licensed program, NGM may elect to either receive milestone and royalty payments or, in certain cases, to co-fund development and participate in a global cost and revenue share arrangement of up to 50% . The agreement also provides NGM with the option to participate in the co-promotion of any co-funded program in the United States. Merck has the option to extend the research agreement for two additional two -year terms.

In January 2015, Merck acquired Cubist Pharmaceuticals, Inc. (Cubist), a leader in the development of therapies to treat serious infections caused by a broad range of bacteria. Total consideration transferred of \$8.3 billion included cash paid for outstanding Cubist shares of \$7.8 billion, as well as share-based compensation payments to settle equity awards attributable to precombination service and cash paid for transaction costs on behalf of Cubist. Share-based compensation payments to settle non-vested equity awards attributable to postcombination service were

recognized as transaction expense in 2015. In addition, the Company assumed all of the outstanding convertible debt of Cubist, which had a fair value of approximately \$1.9 billion at the acquisition date. Merck redeemed this debt in February 2015. The transaction was accounted for as an acquisition of a business.

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

Estimated fair value at January 21, 2015

Cash and cash equivalents	\$ 733
Accounts receivable	123
Inventories	216
Other current assets	55
Property, plant and equipment	151
Identifiable intangible assets:	
Products and product rights (11 year weighted-average useful life)	6,923
IPR&D	50
Other noncurrent assets	184
Current liabilities <sup>(1)</sup>	(233)
Deferred income tax liabilities	(2,519)
Long-term debt	(1,900)
Other noncurrent liabilities <sup>(1)</sup>	(122)
Total identifiable net assets	3,661
Goodwill <sup>(2)</sup>	4,670
Consideration transferred	\$ 8,331

(1) Included in current liabilities and other noncurrent liabilities is contingent consideration of \$73 million and \$50 million, respectively.

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

The estimated fair values of identifiable intangible assets related to currently marketed products were determined using an income approach. The Company's estimates of projected net cash flows considered 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 extent and timing of potential new product introductions by the Company's competitors; and the life of each asset's underlying patent. The net cash flows were 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 were then discounted to present value utilizing a discount rate of 8%. Actual cash flows are likely to be different than those assumed.

The Company recorded the fair value of incomplete research project surotomycin (MK-4261) which, at the time of acquisition, had not reached technological feasibility and had no alternative future use. During the second quarter of 2015, the Company received unfavorable efficacy data from a clinical trial for surotomycin. The evaluation of this data, combined with an assessment of the commercial opportunity for surotomycin, resulted in the discontinuation of the program and an IPR&D impairment charge (see Note 8).

In connection with the Cubist acquisition, liabilities were recorded for potential future consideration that is contingent upon the achievement of future sales-based milestones. The fair value of contingent consideration liabilities was 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 a risk-adjusted discount rate of 8% used to present value the probability-weighted cash flows. Changes in the inputs could result in a different fair value measurement.

This transaction closed on January 21, 2015; accordingly, the results of operations of the acquired business have been included in the Company's results of operations beginning after that date. During 2015, the Company incurred

\$324 million of transaction costs directly related to the acquisition of Cubist including share-based compensation costs, severance costs, and legal and advisory fees which are reflected in *Marketing and administrative* expenses.

The following unaudited supplemental pro forma data presents consolidated information as if the acquisition of Cubist had been completed on January 1, 2014:

Years Ended December 31	2015
Sales	\$ 39,584
Net income attributable to Merck & Co., Inc.	4,640
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	1.65
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	1.63

The unaudited supplemental pro forma data reflects the historical information of Merck and Cubist adjusted to include additional amortization expense based on the fair value of assets acquired, additional interest expense that would have been incurred on borrowings used to fund the acquisition, transaction costs associated with the acquisition, and the related tax effects of these adjustments. The pro forma data should not be considered indicative of the results that would have occurred if the acquisition had been consummated on January 1, 2014, nor are they indicative of future results.

## 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 February 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 (olaparib) 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* (pembrolizumab) and Imfinzi (durvalumab). 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 including thyroid cancer. 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 will be 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 is recording its share of product sales of Lynparza, net of costs 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 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 is making payments of \$750 million over a multi-year period for certain license options (\$250 million was paid in December 2017, \$400 million will be paid in 2018 and \$100 million will 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 options payments. In addition, Merck will pay AstraZeneca up to an additional \$6.15 billion contingent upon successful achievement of future regulatory milestones of \$2.05 billion and sales-based milestones of \$4.1 billion for total aggregate consideration of up to \$8.5 billion .

During the fourth quarter of 2017, based on the performance of Lynparza since the formation of the collaboration, Merck determined it was probable that annual sales of Lynparza in the future would exceed \$250 million, which would trigger a \$100 million sales-based milestone payment from Merck to AstraZeneca upon achievement of the sales milestone. Accordingly, in the fourth quarter of 2017, Merck recorded a \$100 million liability and a corresponding intangible asset and also recognized \$4 million of cumulative amortization expense within *Materials and production* costs. The remaining intangible asset will be amortized over its remaining estimated useful life of 11 years, subject to impairment testing. The remaining \$4.0 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.

Also, in January 2018, Lynparza received approval in the United States for the treatment of certain patients with metastatic breast cancer, triggering a \$70 million milestone payment from Merck to AstraZeneca. This milestone payment will be capitalized and amortized over the remaining useful life of Lynparza.

Summarized information related to this collaboration is as follows:

Year Ended December 31	2017
Alliance revenues (net of commercialization costs)	\$ 20
Materials and production costs	4
Marketing and administrative expenses	1
Research and development expenses	2,419
Receivables from AstraZeneca	12
Payables to AstraZeneca	643

Expenses do not include all amounts attributed to activities related to the collaboration, rather only the amounts relating to payments between partners. Amounts in materials and production costs include amortization of related intangible assets.

## **Bayer AG**

In 2014, the Company entered into a worldwide clinical development collaboration with Bayer AG (Bayer) to market and develop soluble guanylate cyclase (sGC) modulators including Bayer's Adempas (riociguat), which is approved to treat pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension. The two companies equally share costs and profits from the collaboration and 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.

In 2016, the Company determined it was probable that annual sales of Adempas would exceed \$500 million triggering a \$350 million payment from Merck to Bayer. Accordingly, in 2016, the Company recorded a \$350 million liability and a corresponding intangible asset and also recognized \$50 million of cumulative amortization expense within *Materials and production* costs. The remaining intangible asset is being amortized over its then-

remaining estimated useful life, subject to impairment testing. In 2017, annual sales of Adempas exceeded \$500 million triggering the \$350 million milestone payment from Merck to Bayer, which will be paid in the first quarter of 2018. There are \$775 million of additional potential future sales-based milestone payments that have not yet been accrued as they are not deemed by the Company to be probable at this time.

Summarized information related to this collaboration is as follows:

Years Ended December 31	2	2017	2016	2015
Net product sales recorded by Merck	\$	149	\$ 88	\$ —
Merck's profit share of sales in Bayer's marketing territories		151	81	30
Total sales		300	169	30
Materials and production costs		99	133	67
Marketing and administrative expenses		27	26	3
Research and development expenses		96	45	3
Receivables from Bayer		33	—	
Payables to Bayer		352	353	

Expenses do not include all amounts attributed to activities related to the collaboration, rather only the amounts relating to payments between partners. Amounts in materials and production costs include amortization of related intangible assets.

## 5. Restructuring

The Company incurs substantial costs for restructuring program activities related to Merck's productivity and cost reduction initiatives, as well as in connection with the integration of certain acquired businesses. 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 \$927 million in 2017, \$1.1 billion in 2016 and \$1.1 billion in 2015 related to restructuring program activities. Since inception of the programs through December 31, 2017, Merck has recorded total pretax accumulated costs of approximately \$13.5 billion and eliminated approximately 43,350 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. While the Company has substantially completed the actions under these programs, approximately \$500 million of additional pretax costs are expected to be incurred in 2018 relating to anticipated employee separations and remaining asset-related costs.

For segment reporting, restructuring charges are unallocated expenses.

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

	Separation Costs	Accelerated Depreciation	Other	Total
Year Ended December 31, 2017				
Materials and production	\$ 	\$ 52	\$ 86	\$ 138
Marketing and administrative	_	2		2
Research and development	_	6	5	11
Restructuring costs	552	_	224	776
	\$ 552	\$ 60	\$ 315	\$ 927
Year Ended December 31, 2016				
Materials and production	\$ _	\$ 77	\$ 104	\$ 181
Marketing and administrative	_	8	87	95
Research and development		142	_	142
Restructuring costs	216	_	435	651
	\$ 216	\$ 227	\$ 626	\$ 1,069
Year Ended December 31, 2015				
Materials and production	\$ _	\$ 78	\$ 283	\$ 361
Marketing and administrative	_	59	19	78
Research and development	_	37	15	52
Restructuring costs	208	_	411	619
	\$ 208	\$ 174	\$ 728	\$ 1,110

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 2,450 in 2017, 2,625 in 2016 and 3,770 in 2015.

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 of 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 2017, 2016 and 2015 includes \$267 million, \$409 million and \$550 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 \$6 million in 2017, \$151 million in 2016 and \$117 million in 2015.

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

	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2016	\$ 592	\$ _	\$ 53	\$ 645
Expenses	216	227	626	1,069
(Payments) receipts, net	(413)	—	(347)	(760)
Non-cash activity	—	(227)	(186)	(413)
Restructuring reserves December 31, 2016	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 <sup>(1)</sup>	\$ 619	\$ _	\$ 128	\$ 747

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

## 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 effective portion of the unrealized gains or losses on these contracts is recorded in *AOCI* and reclassified into *Sales* when the hedged anticipated revenue is recognized. The hedge relationship is highly effective and hedge ineffectiveness has been *de minimis*. For those derivatives which are not designated as cash flow hedges, but serve as economic hedges of forecasted sales, unrealized gains or losses are recorded in *Sales* each period. The cash flows from both designated and non-designated contracts are reported as operating activities in the Consolidated Statement of Cash Flows. The Company does not enter into derivatives for trading or speculative purposes.

The Company manages operating activities and net asset positions at each local subsidiary in order to mitigate the effects of exchange on monetary assets and liabilities. The Company also uses a balance sheet risk management program to mitigate the exposure of net monetary assets that are denominated in a currency other than a subsidiary's



functional currency from the effects of volatility in foreign exchange. In these instances, Merck principally utilizes forward exchange contracts to offset the effects of exchange on exposures denominated in developed country currencies, primarily the euro and Japanese yen. For exposures in developing country currencies, the Company will enter into forward contracts to partially offset the effects of exchange on exposures when it is deemed economical to do so based on a cost-benefit analysis that considers the magnitude of the exposure, the volatility of the exchange rate and the cost of the hedging instrument. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

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

The Company may also use 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 and measures ineffectiveness based upon changes in spot foreign exchange rates that are recorded in *Other (income) expense, net*. The effective portion of the unrealized gains or losses on these contracts is recorded in foreign currency translation adjustment within *OCI*, and remains in *AOCI* until either the sale or complete or substantially complete liquidation of the subsidiary. 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*. Included in the cumulative translation adjustment are pretax losses of \$520 million in 2017, and pretax gains of \$193 million in 2016 and \$304 million in 2015 from the euro-denominated notes.

## Interest Rate Risk Management

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

At December 31, 2017, the Company was a party to 26 pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixedrate notes in which the notional amounts match the amount of the hedged fixed-rate notes as detailed in the table below.

	2017					
Debt Instrument	Par Value of Debt	Total Swap Notional Amount				
1.30% notes due 2018	\$ 1,000	4	\$ 1,000			
5.00% notes due 2019	1,250	3	550			
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 and offset by the 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.

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:

				2017			2016							
		 Fair Value of Derivative				U.S. Dollar		Fair ' Der	Valu ivati			U.S. Dollar		
	Balance Sheet Caption	Asset		Liability		Notional		Asset		Liability		Notional		
Derivatives Designated as Hedging Instruments														
Interest rate swap contracts	Other assets	\$ 2	\$	_	\$	550	\$	20	\$	_	\$	2,700		
Interest rate swap contracts	Accrued and other current liabilities	_		3		1,000		_		—		_		
Interest rate swap contracts	Other noncurrent liabilities	_		52		4,650				29		3,500		
Foreign exchange contracts	Other current assets	51		_		4,216		616		—		6,063		
Foreign exchange contracts	Other assets	38		_		1,936		129		_		2,075		
Foreign exchange contracts	Accrued and other current liabilities	_		71		2,014		_		1		48		
Foreign exchange contracts	Other noncurrent liabilities	_		1		20				1		12		
		\$ 91	\$	127	\$	14,386	\$	765	\$	31	\$	14,398		
Derivatives Not Designated as Hedging Instruments														
Foreign exchange contracts	Other current assets	\$ 39	\$	_	\$	3,778	\$	230	\$	—	\$	8,210		
Foreign exchange contracts	Accrued and other current liabilities	_		90		7,431		_		103		2,931		
		\$ 39	\$	90	\$	11,209	\$	230	\$	103	\$	11,141		
		\$ 130	\$	217	\$	25,595	\$	995	\$	134	\$	25,539		

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:

	2	2017			2	016	
	 Asset		Liability	Asset			Liability
Gross amounts recognized in the consolidated balance sheet	\$ 130	\$	217	\$	995	\$	134
Gross amount subject to offset in master netting arrangements not offset in the consolidated balance sheet	(94)		(94)		(131)		(131)
Cash collateral (received) posted	(3)		—		(529)		
Net amounts	\$ 33	\$	123	\$	335	\$	3

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The table below provides information on the location and pretax gain or loss amounts for derivatives that are: (i) designated in a fair value hedging relationship, (ii) designated in a foreign currency cash flow hedging relationship, (iii) designated in a foreign currency net investment hedging relationship and (iv) not designated in a hedging relationship:

Years Ended December 31	2017	2016		2015
Derivatives designated in a fair value hedging relationship				
Interest rate swap contracts				
Amount of loss (gain) recognized in Other (income) expense, net on derivatives (1)	\$ 43	\$	28	\$ (14)
Amount of (gain) loss recognized in Other (income) expense, net on hedged item (1)	(48)	(	29)	7
Derivatives designated in foreign currency cash flow hedging relationships				
Foreign exchange contracts				
Amount of gain reclassified from AOCI to Sales	(138)	(3	11)	(724)
Amount of loss (gain) recognized in OCI on derivatives	561	(2	10)	(526)
Derivatives designated in foreign currency net investment hedging relationships				
Foreign exchange contracts				
Amount of gain recognized in Other (income) expense, net on derivatives (2)	_		(1)	(4)
Amount of loss (gain) recognized in OCI on derivatives	_		2	(10)
Derivatives not designated in a hedging relationship				
Foreign exchange contracts				
Amount of loss (gain) recognized in Other (income) expense, net on derivatives (3)	110	1	32	(461)
Amount of gain recognized in Sales	(3)		_	(1)

(1) There was \$5 million , \$1 million and \$7 million of ineffectiveness on the hedge during 2017 , 2016 and 2015 , respectively.

<sup>(2)</sup> There was no ineffectiveness on the hedge. Represents the amount excluded from hedge effectiveness testing.

<sup>(3)</sup> 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.

At December 31, 2017, the Company estimates \$184 million of pretax net unrealized losses on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from *AOCI* to *Sales*. The amount ultimately reclassified to *Sales* may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.

# **Investments in Debt and Equity Securities**

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

	 2017								2016							
	 Fair				<b>Gross Unrealized</b>				Fair		Amontinad		Gross U	Gross Unrealize		
	Value	-	Amortized Cost		Gains		Losses		Fair Value		Amortized Cost		Gains	Ι	Losses	
Corporate notes and bonds	\$ 9,806	\$	9,837	\$	9	\$	(40)	\$	10,577	\$	10,601	\$	15	\$	(39)	
U.S. government and agency securities	2,042		2,059		_		(17)		2,232		2,244		1		(13)	
Asset-backed securities	1,542		1,548		1		(7)		1,376		1,380		1		(5)	
Foreign government bonds	733		739		_		(6)		519		521		_		(2)	
Mortgage-backed securities	626		634		1		(9)		796		801		1		(6)	
Commercial paper	159		159		_		_		4,330		4,330		_		_	
Equity securities	275		265		16		(6)		349		281		71		(3)	
	\$ 15,183	\$	15,241	\$	27	\$	(85)	\$	20,179	\$	20,158	\$	89	\$	(68)	

Available-for-sale debt securities included in *Short-term investments* totaled \$2.4 billion at December 31, 2017. Of the remaining debt securities, \$11.1 billion mature within five years. At December 31, 2017 and 2016, there were no debt securities pledged as collateral.

## **Fair Value Measurements**

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

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

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

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



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

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

		Fair Value Measu	rements 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)	Ob	gnificant Other servable Inputs Level 2)		Significant Unobservable Inputs (Level 3)		Total
		2017	,						2016	5			
Assets													
Investments													
Corporate notes and bonds		\$ 9,678	<b>S</b> -	- \$	9,678	\$	_	\$	10,389	\$	_	\$	10,389
U.S. government and agency securities	68	1,767	-	-	1,835		29		1,890		_		1,919
Asset-backed securities (1)	—	1,476	-	_	1,476		_		1,257		_		1,257
Foreign government bonds	_	732	-	_	732		_		518		_		518
Mortgage-backed securities (1)	_	547	-	_	547		_		628		_		628
Commercial paper	_	159	-	_	159		_		4,330		_		4,330
Equity securities	104	_	-	_	104		201		_		_		201
	172	14,359		_	14,531		230		19,012		_		19,242
Other assets (2)		1,005			11,001		200		19,012				17,212
U.S. government and agency securities	_	207		_	207		_		313		_		313
Corporate notes and bonds	_	128	-	_	128		_		188		_		188
Mortgage-backed securities (1)	_	79	-	_	79		_		168		_		168
Asset-backed securities (1)	_	66	_	_	66		_		119		_		119
Foreign government bonds	_	1	-	_	1		_		1		_		1
Equity securities	171	_	-	_	171		148		_		_		148
	171	481	-	_	652		148		789		_		937
Derivative assets <sup>(3)</sup>													
Purchased currency options	_	80	-	_	80		_		644		_		644
Forward exchange contracts	_	48		_	48		_		331		_		331
Interest rate swaps	_	2	-	_	2		_		20		_		20
	_	130		_	130		_		995		_		995
Total assets	343	\$ 14,970	<b>S</b> -	- \$	15,313	\$	378	\$	20,796	\$		\$	21,174
Liabilities													
Other liabilities													
Contingent consideration 5		s —	\$ 93	5 \$	935	\$	_	\$	_	\$	891	\$	891
Derivative liabilities (2)													
Forward exchange contracts	_	162	-	_	162		_		93		_		93
Interest rate swaps	_	55	-	_	55		_		29		_		29
Written currency options	_	_	-	_	_		_		12		_		12
		217	-	_	217		_		134		_		134
Total liabilities		\$ 217	\$ 93	5 S	1,152	\$		\$	134	\$	891	\$	1,025

<sup>(1)</sup> 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. Mortgage-backed securities represent AAA-rated securities issued or unconditionally guaranteed as to payment of principal and interest by U.S. government agencies.

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

<sup>(3)</sup> 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 2017. As of December 31, 2017, *Cash and cash equivalents* of \$6.1 billion include \$5.2 billion of cash equivalents (which would be considered Level 2 in the fair value hierarchy).

# Contingent Consideration

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

	2017	2016
Fair value January 1	\$ 891	\$ 590
Changes in estimated fair value <sup>(1)</sup>	141	(407)
Additions	3	733
Payments	(100)	(25)
Fair value December 31 <sup>(2)</sup>	\$ 935	\$ 891

(1) Recorded in Research and development expenses, Materials and production costs and Other (income) expense, net . Includes cumulative translation adjustments.

<sup>(2)</sup> Includes \$315 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 contingent consideration in 2017 primarily relate to changes 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 changes in the estimated fair value of contingent consideration in 2016 were largely attributable to the reversal of liabilities related to programs obtained in connection with the acquisitions of cCAM, OncoEthix and SmartCells (see Note 8). The additions to contingent consideration reflected in the table above in 2016 relate to the termination of the SPMSD joint venture (see Note 9) and the acquisitions of IOmet and Afferent (see Note 3). 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) and in 2016 relate to the first commercial sale of *Zerbaxa* in the European Union.

## 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, 2017, was \$25.6 billion compared with a carrying value of \$24.4 billion and at December 31, 2016, was \$25.7 billion compared with a carrying value of \$24.8 billion. Fair value was estimated using recent observable market prices and would be considered Level 2 in the fair value hierarchy.

# **Concentrations of Credit Risk**

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

The majority of the Company's accounts receivable arise from product sales in the 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. As of December 31, 2017, the Company's total net accounts receivable outstanding for more than one year were approximately \$130 million. The Company does not expect to have write-offs or adjustments to accounts receivable which would have a material adverse effect on its financial position, liquidity or results of operations.

The Company's customers with the largest accounts receivable balances are: McKesson Corporation, AmerisourceBergen Corporation, Cardinal Health, Inc. and Zuellig Pharma Ltd. (Asia Pacific), which represented, in aggregate, approximately 40% of total accounts receivable at December 31, 2017. 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. As of December 31, 2017 and 2016, the Company had received cash collateral of \$3 million and \$529 million, respectively, from various counterparties and the obligation to return such collateral is recorded in *Accrued and other current liabilities*. The Company had not advanced any cash collateral to counterparties as of December 31, 2017 or 2016.

# 7. Inventories

Inventories at December 31 consisted of:

	2017		2016
Finished goods	\$ 1,33	4 \$	1,304
Raw materials and work in process	4,70	3	4,222
Supplies	20	1	155
Total (approximates current cost)	6,23	8	5,681
Increase to LIFO costs	4	5	302
	\$ 6,28	3 \$	5,983
Recognized as:			
Inventories	\$ 5,09	6 \$	4,866
Other assets	1,18	7	1,117

Inventories valued under the LIFO method comprised approximately 2.2 billion and 2.3 billion of inventories at December 31, 2017 and 2016, respectively. Amounts recognized as *Other assets* are comprised almost entirely of raw materials and work in process inventories. At December 31, 2017 and 2016, these amounts included 1.1 billion and 1.0 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included 1.0 billion at both December 31, 2017 and 2016, of inventories produced in preparation for product launches.

# 8. Goodwill and Other Intangibles

The following table summarizes goodwill activity by segment:

	Pharmaceutical	All Other	Total
Balance January 1, 2016	\$ 15,862	\$ 1,861	\$ 17,723
Acquisitions	207	275	482
Impairments	—	(47)	(47)
Other <sup>(1)</sup>	6	(2)	4
Balance December 31, 2016 <sup>(2)</sup>	16,075	2,087	18,162
Acquisitions	—	177	177
Impairments	—	(38)	(38)
Other <sup>(1)</sup>	(9)	(8)	(17)
Balance December 31, 2017 <sup>(2)</sup>	\$ 16,066	\$ 2,218	\$ 18,284

(1) Other includes cumulative translation adjustments on goodwill balances and certain other adjustments.

<sup>(2)</sup> Accumulated goodwill impairment losses at December 31, 2017 and 2016 were \$225 million and \$187 million, respectively.

In 2016, the additions to goodwill in the Pharmaceutical segment resulted primarily from the acquisitions of Afferent and IOmet (see Note 3). The additions to goodwill within other non-reportable segments in 2017 primarily relate to the acquisition of Vallée, which is part of the Animal Health segment (see Note 3), and in 2016 relate to the acquisition of StayWell, which is part of the Healthcare Services segment (see Note 3). The impairments of goodwill within other non-reportable segments in 2017 and 2016 relate to certain businesses within the Healthcare Services segment.

Other intangibles at December 31 consisted of:

		2017			2016	
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Products and product rights	\$ 46,693	\$ 34,950	\$ 11,743	\$ 46,269	\$ 31,919	\$ 14,350
IPR&D	1,194	_	1,194	1,653	—	1,653
Tradenames	209	97	112	215	89	126
Other	2,035	901	1,134	1,947	771	1,176
	\$ 50,131	\$ 35,948	\$ 14,183	\$ 50,084	\$ 32,779	\$ 17,305

Acquired intangibles include products and product rights, tradenames and patents, which are initially recorded at fair value, assigned an estimated useful life, and are 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 product and product rights above) at December 31, 2017 include *Zerbaxa*, \$3.0 billion; *Sivextro*, \$879 million; *Zetia*, \$756 million; *Implanon/Nexplanon* \$529 million; *Jificid*, \$478 million; *Gardasil/Gardasil* 9, \$468 million; *Vytorin*, \$375 million; *Bridion*, \$320 million; and *Simponi*, \$226 million. The Company recognized an intangible asset related to Adempas as a result of a collaboration with Bayer (see Note 4) that had a carrying value of \$894 million at December 31, 2017 reflected in "Other" in the table above.

During 2017, 2016 and 2015, the Company recorded impairment charges related to marketed products and other intangibles of \$58 million, \$347 million and \$45 million, respectively, within *Material and production* costs. 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 of customer relationship, tradename and developed technology intangibles for certain businesses in the Healthcare Services segment. In 2016, the Company utilized market participant astrope. The Company utilized market participant astrope. The Company utilized market participant 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 *Zontivity* that, when compared with in-licensed products *Grastek* and *Ragwitek*, allergy immunotherapy tablets that, for business reasons, 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 impa

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. During 2017, 2016 and 2015, \$14 million, \$8 million and \$280 million, respectively, of IPR&D was reclassified to products and product rights upon receipt of marketing approval in a major market.

In 2017, the Company recorded \$483 million of IPR&D impairment charges within *Research and development* expenses. Of this amount, \$240 million resulted from a strategic decision to discontinue the development of the investigational combination regimens MK-3682B (grazoprevir/ruzasvir/uprifosbuvir) and MK-3682C (ruzasvir/uprifosbuvir) for the treatment of chronic hepatitis C virus (HCV) infection. This decision was made based on a review of available Phase 2 efficacy data and in consideration of the evolving marketplace and the growing number of treatment options available for patients with chronic HCV infection, including *Zepatier*, which is currently 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 writeoff 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 relates 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 pretax impairment charge noted above. The IPR&D impairment charges in 2016 also include charges of \$180 million and \$143 million related to the discontinuation of programs obtained in connection with the acquisitions of cCAM and OncoEthix, respectively, resulting from unfavorable efficacy data. An additional \$72 million relates 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 include \$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 relate 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 (see Note 6).

During 2015, the Company recorded \$63 million of IPR&D impairment charges, of which \$50 million related to the surotomycin clinical development program. In 2015, the Company received unfavorable efficacy data from a clinical trial for surotomycin. The evaluation of this data, combined with an assessment of the commercial opportunity for surotomycin, resulted in the discontinuation of the program and the IPR&D impairment charge noted above.

All of 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 *Materials and production* costs was \$3.2 billion in 2017, \$3.8 billion in 2016 and \$4.8 billion in 2015. The estimated aggregate amortization expense for each of the next five years is as follows: 2018, \$2.8 billion; 2019, \$1.5 billion; 2020, \$1.2 billion; 2021, \$1.1 billion; 2022, \$1.1 billion.

## 9. Joint Ventures and Other Equity Method Affiliates

Equity income from affiliates reflects the performance of the Company's joint ventures and other equity method affiliates including SPMSD (until termination on December 31, 2016) and certain investment funds. Equity income from affiliates was \$42 million in 2017, \$86 million in 2016 and \$205 million in 2015 and is included in *Other (income) expense, net* (see Note 15).

Investments in affiliates accounted for using the equity method totaled \$767 million at December 31, 2017 and \$715 million at December 31, 2016.

## 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 and \$923 million for 2015.

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 potential future sales of *Vaxelis* (a jointly developed investigational pediatric hexavalent combination vaccine that was approved by the European Commission in February 2016). 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 <sup>(1)</sup>	\$ 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 *Marketing 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.

## 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 is 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 will 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 \$232 million , \$98 million and \$182 million in 2017, 2016 and 2015, respectively, in *Other (income) expense, net* related to these amounts. The receivable from AstraZeneca was \$325 million at December 31, 2017.

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

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 holder. Loans payable at December 31, 2016 included \$300 million of notes due in 2017, \$267 million of long-dated notes that are subject to repayment at the option of the holders. The weighted-average interest rate of commercial paper borrowings was 0.85% and 0.40% for the years ended December 31, 2017 and 2016, respectively.



Long-term debt at December 31 consisted of:

	2017	2016
2.75% notes due 2025	\$ 2,488	\$ 2,487
3.70% notes due 2045	1,973	1,972
2.80% notes due 2023	1,744	1,743
5.00% notes due 2019	1,260	1,273
4.15% notes due 2043	1,237	1,236
1.85% notes due 2020	1,232	1,238
2.35% notes due 2022	1,220	1,228
1.125% euro-denominated notes due 2021	1,185	1,035
1.875% euro-denominated notes due 2026	1,178	1,028
3.875% notes due 2021	1,140	1,152
2.40% notes due 2022	993	1,003
6.50% notes due 2033	729	806
Floating-rate notes due 2020	699	698
0.50% euro-denominated notes due 2024	591	516
1.375% euro-denominated notes due 2036	587	512
2.50% euro-denominated notes due 2034	585	511
3.60% notes due 2042	489	489
6.55% notes due 2037	415	594
5.75% notes due 2036	338	369
5.95% debentures due 2028	306	355
5.85% notes due 2039	270	415
6.40% debentures due 2028	250	325
6.30% debentures due 2026	135	152
Floating-rate borrowing due 2018		999
1.10% notes due 2018	—	999
1.30% notes due 2018	—	985
Other	309	154
	\$ 21,353	\$ 24,274

Other (as presented in the table above) includes \$300 million and \$147 million at December 31, 2017 and 2016, respectively, of borrowings at variable rates that resulted in effective interest rates of 1.42% and 0.89% for 2017 and 2016, 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 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 financial covenants including a requirement that the Total Debt to Capitalization Ratio (as defined in the applicable agreements) not exceed 60%. At December 31, 2017, 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: 2018, \$3.0 billion; 2019, \$1.3 billion; 2020, \$1.9 billion; 2021, \$2.3 billion; 2022, \$2.2 billion.

The Company has a \$6.0 billion, five -year credit facility that matures in June 2022. 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 \$327 million in 2017, \$292 million in 2016 and \$303 million in 2015. The minimum aggregate rental commitments under noncancellable leases are as follows: 2018, \$255 million; 2019, \$175 million; 2020, \$126 million; 2021, \$90 million; 2022, \$68 million and thereafter, \$138 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, 2017, approximately 4,085 cases are filed and pending against Merck in either federal or state court. In approximately 15 of these actions, plaintiffs allege, among other things, that they have suffered osteonecrosis of the jaw (ONJ), generally subsequent to invasive dental procedures, such as tooth extraction or dental implants and/or delayed healing, in association with the use of *Fosamax*. In addition, plaintiffs in approximately 4,070 of these actions generally allege that they sustained femur fractures and/or other bone injuries (Femur Fractures) in association with the use of *Fosamax*.

## Cases Alleging ONJ and/or Other Jaw Related Injuries

In August 2006, the Judicial Panel on Multidistrict Litigation (JPML) ordered that certain *Fosamax* product liability cases pending in federal courts nationwide should be transferred and consolidated into one multidistrict litigation (*Fosamax* ONJ MDL) for coordinated pre-trial proceedings.

In December 2013, Merck reached an agreement in principle with the Plaintiffs' Steering Committee (PSC) in the *Fosamax* ONJ MDL to resolve pending ONJ cases not on appeal in the *Fosamax* ONJ MDL and in the state courts for an aggregate amount of \$27.7 million. Merck and the PSC subsequently formalized the terms of this agreement

in a Master Settlement Agreement (ONJ Master Settlement Agreement) that was executed in April 2014 and included over 1,200 plaintiffs. In July 2014, Merck elected to proceed with the ONJ Master Settlement Agreement at a reduced funding level of \$27.3 million since the participation level was approximately 95%. Merck has fully funded the ONJ Master Settlement Agreement and the escrow agent under the agreement has been making settlement payments to qualifying plaintiffs. The ONJ Master Settlement Agreement has no effect on the cases alleging Femur Fractures discussed below.

Discovery is currently ongoing in some of the approximately 15 remaining ONJ cases that are pending in various federal and state courts and the Company intends to defend against these lawsuits.

#### Cases Alleging Femur Fractures

In March 2011, Merck submitted a Motion to Transfer to the JPML seeking to have all federal cases alleging Femur Fractures consolidated into one multidistrict litigation for coordinated pre-trial proceedings. The Motion to Transfer was granted in May 2011, and 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. The *Glynn* decision was not appealed by plaintiff.

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). The Femur Fracture MDL court also dismissed without prejudice another approximately 510 cases pending plaintiffs' appeal of the preemption ruling to the Third Circuit. On March 22, 2017, the Third Circuit issued a decision reversing the Femur Fracture MDL court's preemption ruling and remanding the appealed cases back to the Femur Fracture MDL court. On April 5, 2017, Merck filed a petition seeking a rehearing on the Third Circuit's March 22, 2017 decision, which was denied on April 24, 2017. Merck filed a petition for a writ of certiorari to the U.S. Supreme Court on August 22, 2017, seeking review of the Third Circuit's decision. On December 4, 2017, the Supreme Court invited the Solicitor General to file a brief in the case expressing the views of the United States.

In addition, in June 2014, the Femur Fracture MDL court granted Merck summary judgment in the *Gaynor v. Merck* case and found that Merck's updates in January 2011 to the *Fosamax* label regarding atypical femur fractures were adequate as a matter of law and that Merck adequately communicated those changes. The plaintiffs in *Gaynor* did not appeal the Femur Fracture MDL court's findings with respect to the adequacy of the 2011 label change but did appeal the dismissal of their case based on preemption grounds, and the Third Circuit subsequently reversed that dismissal in its March 22, 2017 decision. In August 2014, Merck filed a motion requesting that the Femur Fracture MDL court enter a further order requiring all plaintiffs in the Femur Fracture MDL who claim that the 2011 *Fosamax* label is inadequate and the proximate cause of their alleged injuries to show cause why their cases should not be dismissed based on the court's preemption decision and its ruling in the *Gaynor* case. In November 2014, the court granted Merck's motion and entered the requested show cause order. No plaintiffs responded to or appealed the November 2014 show cause order.

As of December 31, 2017, approximately 530 cases were pending in the Femur Fracture MDL following the reinstatement of the cases that had been on appeal to the Third Circuit. The 510 cases dismissed without prejudice that were also pending the final resolution of the aforementioned appeal have not yet been reinstated.

As of December 31, 2017, approximately 2,750 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 during 2016 and 2017.

As of December 31, 2017, approximately 280 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. Oral argument on plaintiff's appeal in *Galper* was held in November 2016 and, on April 24, 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 five 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, 2017, Merck is aware of approximately 1,235 product user claims alleging generally that use of *Januvia* and/or *Janumet* caused the development of pancreatic cancer and other injuries. These complaints were filed in several different state and federal courts.

Most of the claims were filed in a consolidated multidistrict litigation proceeding in the U.S. District Court for the Southern District of California called "In re Incretin-Based Therapies Products Liability Litigation" (MDL). The MDL includes federal lawsuits alleging pancreatic cancer due to use of the following medicines: *Januvia, Janumet*, Byetta and Victoza, the latter two of which are products manufactured by other pharmaceutical companies. The majority of claims not filed in the MDL were filed in 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 preemption. Of the approximately 1,235 product user claims, these rulings resulted in the dismissal of approximately 1,100 product user claims.

Plaintiffs appealed the MDL and California State Court preemption rulings. On November 28, 2017, the U.S. Court of Appeals for the Ninth Circuit (Ninth Circuit) reversed the trial court's ruling in the MDL and remanded for further proceedings. The Ninth Circuit did not address the substance of defendants' preemption argument but instead ruled that the district court made various errors during discovery. Jurisdiction returned to U.S. District Court for the Southern District of California on January 2, 2018. The preemption appeal in the California state court litigation has been fully briefed, but the court has not yet scheduled oral argument.

As of December 31, 2017, seven product users have claims pending against Merck in state courts other than California state court, including four active product user claims pending in Illinois state court. On June 30, 2017, the Illinois trial court denied Merck's motion for summary judgment on grounds of preemption. Merck sought permission to appeal that order on an interlocutory basis and was granted a stay of proceedings in the trial court. On September 19, 2017, an intermediate appellate court in Illinois denied Merck's petition for interlocutory review. On October 20, 2017, Merck filed a petition with the Illinois Supreme Court, seeking leave to appeal the appellate court's denial. The Illinois Supreme Court denied Merck's petition for certain of the product users in Illinois have been delayed.

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.

## Propecia/Proscar

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Propecia* and/or *Proscar*. As of December 31, 2017, approximately 775 lawsuits have been filed by plaintiffs who allege that they have experienced persistent sexual side effects following cessation of treatment with *Propecia* and/or *Proscar*. Approximately 20 of the plaintiffs also allege that *Propecia* or *Proscar* has caused or can cause prostate cancer,

testicular cancer or male breast cancer. The lawsuits have been filed in various federal courts and in state court in New Jersey. The federal lawsuits have been 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 have been consolidated before Judge Hyland in Middlesex County. In addition, there is one matter pending in state court in California, one matter pending in state court in Ohio, and one matter on appeal in the Massachusetts Supreme Judicial Court. The Company intends to defend against these 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) on May 23, 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 has received a civil investigative demand from the U.S. Attorney's Office for the Southern District of New York that requests information relating to the Company's contracts with, services from and payments to pharmacy benefit managers with respect to *Maxalt* and Levitra from January 1, 2006 to the present. The Company is cooperating with the investigation.

As previously disclosed, the Company has received a subpoena from the Office of Inspector General of the U.S. Department of Health and Human Services on behalf of the U.S. Attorney's Office for the District of Maryland and the Civil Division of the U.S. Department of Justice that requests information relating to the Company's marketing of *Singulair* and *Dulera* Inhalation Aerosol and certain of its other marketing activities from January 1, 2006 to the present. 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.

## **Commercial and Other Litigation**

## K-DUR Antitrust Litigation

In June 1997 and January 1998, Schering-Plough Corporation (Schering-Plough) settled patent litigation with Upsher-Smith, Inc. (Upsher-Smith) and ESI Lederle, Inc. (Lederle), respectively, relating to generic versions of Schering-Plough's long-acting potassium chloride product supplement used by cardiac patients, for which Lederle and Upsher-Smith had filed abbreviated New DrugApplications (NDA). Putative class and non-class action suits were then

filed on behalf of direct and indirect purchasers of K-DUR against Schering-Plough, Upsher-Smith and Lederle and were consolidated in a multidistrict litigation in the U.S. District Court for the District of New Jersey. In February 2016, the court denied the Company's motion for summary judgment relating to all of the direct purchasers' claims concerning the settlement with Upsher-Smith and granted the Company's motion for summary judgment relating to all of the direct purchasers' claims concerning the settlement with Lederle.

As previously disclosed, in February 2017, Merck and Upsher-Smith reached a settlement in principle with the class of direct purchasers and the optouts to the class. Merck will contribute approximately \$80 million in the aggregate towards the overall settlement. On April 5, 2017, the claims of the opt-outs were dismissed with prejudice pursuant to a written settlement agreement with those parties. On May 15, 2017, Merck and the class executed a settlement agreement, which received preliminary approval from the court on May 23, 2017. On October 5, 2017, the court entered a Final Judgment and Order of Dismissal approving the settlement agreement with the direct purchaser class and dismissing the claims of the class with prejudice.

#### Zetia Antitrust Litigation

In May 2010, Schering Corporation (Schering) and MSP Singapore Company LLC (MSP) settled patent litigation with Glenmark Pharmaceuticals Inc., USA, and Glenmark Pharmaceuticals Ltd. (together, Glenmark) relating to a generic version of *Zetia*, a pharmaceutical product containing ezetimibe used by patients with high cholesterol, for which Glenmark had filed an abbreviated NDA. In January and February 2018, putative class action suits were filed on behalf of direct and indirect purchasers of *Zetia* against Merck, MSD, Schering-Plough, Schering, MSP, and Glenmark in the U.S. District Courts for the Eastern District of Virginia and the Eastern District of New York. These suits claim violations of federal and state antitrust laws, as well as other state statutory and common law causes of action. These suits seek unspecified damages.

#### 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. Plaintiffs sought and were granted leave to file an amended complaint. 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. On April 27, 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. As a result, the liability period will date back to April 2012, at the earliest. On April 29, 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 have opted-in to this action; the opt-in period has closed. On August 1, 2017, plaintiffs filed their motion for class certification. This motion seeks to certify a Title VII pay discrimination class and also seeks final collective action certification of plaintiffs' Equal Pay Act claim. The parties are currently e

#### Qui Tam Litigation

As previously disclosed, on June 21, 2012, the U.S. District Court for the Eastern District of Pennsylvania unsealed a complaint that has been filed against the Company under the federal False Claims Act by two former employees alleging, among other things, that the Company defrauded the U.S. government by falsifying data in connection with a clinical study conducted on the mumps component of the Company's M-M-R II vaccine. The complaint alleges the fraud took place between 1999 and 2001. The U.S. government had the right to participate in and take over the prosecution of this lawsuit, but notified the court that it declined to exercise that right. The two former employees are pursuing the lawsuit without the involvement of the U.S. government. In addition, as previously disclosed, two putative class action lawsuits on behalf of direct purchasers of the M-M-R II vaccine, which charge that the Company misrepresented the efficacy of the M-M-R II vaccine in violation of federal antitrust laws and various state consumer protection laws, are pending in the Eastern District of Pennsylvania. In September 2014, the court denied Merck's motion to dismiss the False Claims Act suit and granted in part and denied in part its motion to dismiss the then-pending

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antitrust suit. As a result, both the False Claims Act suit and the antitrust suits have proceeded into discovery. The Company intends to defend against these lawsuits.

#### Merck KGaA Litigation

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), 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, and India alleging breach of the parties' co-existence agreement, unfair competition and/or trademark infringement. 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. 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 no further appeal was pursued. 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 trade mark infringement, validity and the relief to which KGaA would be entitled.

#### **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. Certain products of the Company currently involved in such patent infringement litigation in the United States include *Noxafil* and *NuvaRing*. 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.

*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 has appealed this decision. 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 October 2017, the parties reached a settlement whereby Roxane can launch its generic version upon expiry of the patent, or earlier 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 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.

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.

*NuvaRing* — In December 2013, the Company filed a lawsuit against a subsidiary of Allergan plc 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 *NuvaRing*. The trial in this matter was held in January 2016. In August 2016, the district court ruled that the patent was invalid and the Company appealed this decision. In October 2017, the appellate court reversed the district court decision and found the patent to be valid. The case was remanded and the district court enjoined the defendant

from marketing its generic version of *NuvaRing* until the patent expires. In September 2015, the Company filed a lawsuit against Teva Pharma 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 *NuvaRing*. Based on its ruling in the Allergan plc matter, the district court dismissed the Company's lawsuit in December 2016. Following the appellate reversal in the Allergan plc matter, the defendant has agreed to be enjoined from marketing its generic version of *NuvaRing* until the patent expires.

# Anti-PD-1 Antibody Patent Oppositions and Litigation

As previously disclosed, Ono Pharmaceutical Co. (Ono) has a European patent (EP 1 537 878) ('878) that broadly claims the use of an anti-PD-1 antibody, such as the Company's immunotherapy, *Keytruda*, for the treatment of cancer. Ono has previously licensed its commercial rights to an anti-PD-1 antibody to Bristol-Myers Squibb (BMS) in certain markets. BMS and Ono also own European Patent EP 2 161 336 ('336) that, as granted, broadly claimed anti-PD-1 antibodies that could include *Keytruda*.

As previously disclosed, the Company and BMS and Ono were engaged in worldwide litigation, including in the United States, over the validity and infringement of the '878 patent, the '336 patent and their equivalents.

In January 2017, the Company announced that it had entered into a settlement and license agreement with BMS and Ono resolving the worldwide patent infringement litigation related to the use of an anti-PD-1 antibody for the treatment of cancer, such as *Keytruda*. Under the settlement and license agreement, the Company made a one-time payment of \$625 million (which was recorded as an expense in the Company's 2016 financial results) to BMS and will pay royalties on the worldwide sales of *Keytruda* for a non-exclusive license to market *Keytruda* in any market in which it is approved. For global net sales of *Keytruda*, the Company will pay royalties of 6.5% of net sales occurring from January 1, 2017 through and including December 31, 2023; and 2.5% of net sales occurring from January 1, 2024 through and including December 31, 2026. The parties also agreed to dismiss all claims worldwide in the relevant legal proceedings.

In October 2015, PDL Biopharma (PDL) filed a lawsuit in the United States against the Company alleging that the manufacture of *Keytruda* infringed US Patent No. 5,693,761 ('761 patent), which expired in December 2014. This patent claims platform technology used in the creation and manufacture of recombinant antibodies and PDL is seeking damages for pre-expiry infringement of the '761 patent. In April 2017, the parties reached a settlement pursuant to which, in exchange for a lump sum, PDL dismissed its lawsuit with prejudice and granted the Company a fully paid-up non-exclusive license to the '761 patent.

In July 2016, the Company filed a declaratory judgment action in the United States against Genentech and City of Hope seeking a ruling that US Patent No. 7,923,221 (Cabilly III patent), which claims platform technology used in the creation and manufacture of recombinant antibodies, is invalid and that *Keytruda* and bezlotoxumab do not infringe the Cabilly III patent. In July 2016, the Company also filed a petition in the USPTO for *Inter Partes* Review (IPR) of certain claims of US Patent No. 6,331,415 (Cabilly II patent), which claims platform technology used in the creation and manufacture of recombinant antibodies and is also owned by Genentech and City of Hope, as being invalid. In December 2016, the USPTO denied the petition but allowed the Company to join an IPR filed previously by another party. In May 2017, the parties reached a settlement pursuant to which the Company dismissed its lawsuit with prejudice and moved to terminate the IPR and Genentech and City of Hope granted the Company a fully paid-up non-exclusive license to the Cabilly II patent.

## **Gilead Patent Litigation and Opposition**

In August 2013, Gilead Sciences, Inc. (Gilead) filed a lawsuit in the U.S. District Court for the Northern District of California seeking a declaration that two Company patents were invalid and not infringed by the sale of their two sofosbuvir containing products, Solvadi and Harvoni. The Company filed a counterclaim that the sale of these products did infringe these two patents and sought a reasonable royalty for the past, present and future sales of these products. In March 2016, at the conclusion of a jury trial, the patents were found to be not invalid and infringed. The jury awarded the Company \$200 million as a royalty for sales of these products up to December 2015. After the conclusion of the jury trial, the court held a bench trial on the equitable defenses raised by Gilead. In June 2016, the court found for Gilead and determined that Merck could not collect the jury award and that the patents were unenforceable with respect to Gilead. The Company appealed the court's decision. Gilead also asked the court to overturn the jury's decision on validity. The court held a hearing on Gilead's motion in August 2016, and the court subsequently rejected

Gilead's request, which Gilead appealed. A hearing on the combined appeals for this case was held on February 4, 2018. The Company will pay 20%, net of legal fees, of damages or royalties, if any, that it receives to Ionis Pharmaceuticals, Inc.

The Company, through its Idenix Pharmaceuticals, Inc. subsidiary, has pending litigation against Gilead in the United States, the UK, Norway, Canada, Germany, France, and Australia based on different patent estates that would also be infringed by Gilead's sales of these two products. 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 will appeal this decision. In Australia, the Company was initially unsuccessful and the Full Federal Court affirmed the lower court decision. The Company has sought leave to appeal to the High Court of Australia for further review. In Canada, the Company was initially unsuccessful and the Federal Court of Appeals affirmed the lower court decision The Company sought leave to the Supreme Court of Canada for further review. In the UK and Norway, the patent was held invalid and no further appeal was filed. 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.

#### **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, 2017 and December 31, 2016 of approximately \$160 million and \$185 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 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. The Company intends to defend itself against any enforcement action that may result from this investigation.

In May 2015, the Environmental Protection Agency (EPA) conducted an air compliance evaluation of the Company's pharmaceutical manufacturing facility in Elkton, Virginia. As a result of the investigation, the Company was issued a Notice of Noncompliance and Show Cause Notification relating to certain federally enforceable requirements applicable to the Elkton facility. The Company has been advised by the EPA that enforcement action is no longer being pursued.

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 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 \$82 million and \$83 million at December 31, 2017 and 2016, 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 \$63 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:

	201	.7	201	6	2015					
	Common Stock	Treasury Stock	Common Stock	Treasury Stock	Common Stock	Treasury Stock				
Balance January 1	3,577	828	3,577	796	3,577	739				
Purchases of treasury stock	—	67	—	60	—	75				
Issuances <sup>(1)</sup>	—	(15)	—	(28)	—	(18)				
Balance December 31	3,577	880	3,577	828	3,577	796				

<sup>(1)</sup> Issuances primarily reflect activity under share-based compensation plans.

## 13. Share-Based Compensation Plans

The Company has share-based compensation plans under which the Company grants restricted stock units (RSUs) and performance share units (PSUs) to certain management level employees. In addition, employees and non-employee directors may be granted options to purchase shares of Company common stock at the fair market value at the time of grant. These plans were approved by the Company's shareholders.

At December 31, 2017, 118 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 onethird each year over a three -year period, with a contractual term of 7 - 10 years. RSUs are stock awards that are granted to employees and entitle the holder to shares of common stock as the awards vest. The fair value of the stock option and RSU awards is determined and fixed on the grant date based on the Company's stock price. PSUs are stock awards where the ultimate number of shares issued will be contingent on the Company's performance against a pre-set objective or set of objectives. The fair value of each PSU is determined on the date of grant based on the Company's stock price. For RSUs and PSUs, dividends declared during the vesting period are payable to the employees only upon vesting. Over the PSU performance period, the number of shares of stock that are expected to be issued will be adjusted based on the probability of achievement of a performance target and final compensation expense will be recognized based on the ultimate number of shares issued. RSU and PSU distributions will be in shares of Company stock after the end of the vesting or performance period, subject to the terms applicable to such awards. PSU awards generally vest after three years. Prior to 2018, RSU awards generally vested after three years; beginning with awards granted in 2018, RSU awards will vest one-third each year over a three -year period.

Total pretax share-based compensation cost recorded in 2017, 2016 and 2015 was \$312 million, \$300 million and \$299 million, respectively, with related income tax benefits of \$57 million, \$92 million and \$93 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 2017, 2016 and 2015 was \$63.88, \$54.63 and \$59.73 per option, respectively. The weighted average fair value of options granted in 2017, 2016 and 2015 was \$7.04, \$5.89 and \$6.46 per option, respectively, and were determined using the following assumptions:

Years Ended December 31	2017	2016	2015
Expected dividend yield	3.6%	3.8%	4.1%
Risk-free interest rate	2.0%	1.4%	1.7%
Expected volatility	17.8%	19.6%	19.9%
Expected life (years)	6.1	6.2	6.2

Summarized information relative to stock option plan activity (options in thousands) is as follows:

			Weighted	
		Weighted	Average	
		Average	Remaining	Aggregate
	Number	Exercise	Contractual	Intrinsic
	of Options	Price	Term (Years)	Value
Outstanding January 1, 2017	45,091	\$ 44.47		
Granted	4,232	63.88		
Exercised	(11,512)	43.38		
Forfeited	(1,537)	51.78		
Outstanding December 31, 2017	36,274	\$ 46.77	4.89	\$ 397
Exercisable December 31, 2017	26,778	\$ 42.54	3.64	\$ 384

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

Years Ended December 31	2017	201	,	2015
Total intrinsic value of stock options exercised	\$ 236	\$	444	\$ 332
Fair value of stock options vested	30		28	30
Cash received from the exercise of stock options	499		939	485

A summary of nonvested RSU and PSU activity (shares in thousands) is as follows:

		RSU	Js		PSU	S
	Number of Shares		Weighted Average Grant Date Fair Value	Number of Shares		Weighted Average Grant Date Fair Value
Nonvested January 1, 2017	13,266	\$	57.19	1,744	\$	59.24
Granted	5,014		63.85	1,008		63.62
Vested	(3,795)		58.13	(833)		62.71
Forfeited	(876)		58.22	(51)		60.24
Nonvested December 31, 2017	13,609	\$	59.32	1,868	\$	60.03

At December 31, 2017, there was \$469 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	Bene	efits								
		U.S.				Inte	ernational		 Other	Postr	etirement l	Benefi	its
Years Ended December 31	2017	2016	2015		2017		2016	2015	2017		2016		2015
Service cost	\$ 312	\$ 282	\$ 307	\$	252	\$	238	\$ 251	\$ 57	\$	54	\$	80
Interest cost	454	456	434		172		204	206	81		82		110
Expected return on plan assets	(862)	(831)	(819)		(393)		(382)	(379)	(78)		(107)		(143)
Amortization of unrecognized prior service cost	(53)	(55)	(56)		(11)		(11)	(14)	(98)		(106)		(64)
Net loss amortization	180	119	214		98		87	118	1		3		5
Termination benefits	44	23	22		4		4	1	8		4		7
Curtailments	3	5	(12)		(4)		(1)	(9)	(31)		(18)		(19)
Settlements	_	_	1		5		6	12	—		_		_
Net periodic benefit cost (credit)	\$ 78	\$ (1)	\$ 91	\$	123	\$	145	\$ 186	\$ (60)	\$	(88)	\$	(24)

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. The increase in net periodic benefit credit for other postretirement benefit plans in 2017 and 2016 as compared with 2015 is largely attributable to changes in retiree medical benefits approved by the Company in December 2015, partially offset by lower returns on plan assets.

In connection with restructuring actions (see Note 5), termination charges were recorded in 2017, 2016 and 2015 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.

# **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	Ben	efits				ther	
	U	J.S.		nal	Postret Ber	tiren nefits				
	2017		2016		2017		2016	 2017		2016
Fair value of plan assets January 1	\$ 9,766	\$	9,266	\$	7,794	\$	7,204	\$ 1,019	\$	1,913
Actual return on plan assets	1,723		941		677		898	161		138
Company contributions, net	58		63		226		424	(4)		68
Effects of exchange rate changes	_		_		843		(546)	_		_
Benefits paid	(651)		(504)		(198)		(193)	(62)		(108)
Settlements	_		_		(17)		(21)	_		_
Assets no longer restricted to the payment of postretirement benefits (1)	—		_		—		_	_		(992)
Other	_		_		14		28	_		_
Fair value of plan assets December 31	\$ 10,896	\$	9,766	\$	9,339	\$	7,794	\$ 1,114	\$	1,019
Benefit obligation January 1	\$ 10,849	\$	9,723	\$	8,372	\$	7,733	\$ 1,922	\$	1,810
Service cost	312		282		252		238	57		54
Interest cost	454		456		172		204	81		82
Actuarial losses (gains) (2)	881		854		(7)		938	(87)		77
Benefits paid	(651)		(504)		(198)		(193)	(62)		(108)
Effects of exchange rate changes	_		—		916		(576)	3		2
Plan amendments	—		—		(22)		—	—		—
Curtailments	15		15		(3)		(15)	—		1
Termination benefits	44		23		4		4	8		4
Settlements	—		—		(17)		(21)	_		—
Other	—		—		14		60	_		—
Benefit obligation December 31	\$ 11,904	\$	10,849	\$	9,483	\$	8,372	\$ 1,922	\$	1,922
Funded status December 31	\$ (1,008)	\$	(1,083)	\$	(144)	\$	(578)	\$ (808)	\$	(903)
Recognized as:										
Other assets	\$ —	\$	—	\$	828	\$	451	\$ —	\$	
Accrued and other current liabilities	(59)		(50)		(17)		(7)	(11)		(11)
Other noncurrent liabilities	(949)		(1,033)		(955)		(1,022)	(797)		(892)

<sup>(1)</sup> As a result of certain allowable administrative actions that occurred in June 2016, \$992 million of plan assets previously restricted for the payment of other postretirement benefits became available to fund certain other health and welfare benefits.

<sup>(2)</sup> Actuarial losses in 2017 and 2016 primarily reflect changes in discount rates.

At December 31, 2017 and 2016, the accumulated benefit obligation was \$20.5 billion and \$18.4 billion, respectively, for all pension plans, of which \$11.5 billion and \$10.5 billion, respectively, related to U.S. pension plans.

Information related to the funded status of selected pension plans at December 31 is as follows:

	U.S.					Interi	nation	al
		2017		2016		2017		2016
Pension plans with a projected benefit obligation in excess of plan assets								
Projected benefit obligation	\$	11,904	\$	10,849	\$	3,323	\$	5,486
Fair value of plan assets		10,896		9,766		2,352		4,457
Pension plans with an accumulated benefit obligation in excess of plan assets								
Accumulated benefit obligation	\$	676	\$	9,807	\$	2,120	\$	2,692
Fair value of plan assets		_		9,057		1,346		1,898

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, 2017 and 2016, \$488 million and \$435 million, respectively, or approximately 2% of the Company's pension investments were categorized as Level 3 assets.

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

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

				Quoted Prices Significant Quoted Prices Signific						air Value Measu	remei	its Using				
	l M Ider	oted Prices In Active larkets for ntical Assets (Level 1)	O Obs Ir	nificant Other ervable 1puts evel 2)	I	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
			2	017								2016				
U.S. Pension Plans																
Assets																
Cash and cash equivalents	\$	6	\$	_	\$	_	\$	6	\$	2	\$	2	\$	_	\$	2
Investment funds																
Developed markets equities		390		_		_		390		521		_		_		52
Emerging markets equities		138		_		_		138		104		_		_		104
Equity securities																
Developed markets		2,743		_		_		2,743		2,521		_		_		2,52
Fixed income securities								, -		3-						
Government and agency obligations		_		757		_		757		_		475		_		475
Corporate obligations		_		900		_		900		_		660		_		660
Mortgage and asset-backed securities		_		240		_		240		_		239		_		239
Other investments		_		_		15		15		_		_		18		18
Net assets in fair value hierarchy	\$	3,277	\$	1,897	\$	15		5,189	\$	3,148	\$	1,376	\$	18	\$	4,542
Investments measured at NAV (1)		5,217	φ	1,057	φ	13	φ	5,707	Ψ	5,140	Ψ	1,570	Ψ	10	Ψ	5,224
Plan assets at fair value							_									
							\$	10,896							\$	9,760
International Pension Plans																
Assets Cash and cash equivalents																
Investment funds	\$	54	\$	19	\$	_	\$	73	\$	42	\$	11	\$	—	\$	53
Developed markets equities																
Emerging markets equities		562		3,326		_		3,888		187		2,846		—		3,033
Government and agency obligations		62		176		_		238		24		148		—		172
Corporate obligations		249		2,095		_		2,344		123		1,904		—		2,027
		5		329		-		334		2		282		_		284
Fixed income obligations Real estate <sup>(2)</sup>		7		4		_		11		6		3		—		ç
		-		1		2		3		_		3		4		5
Equity securities																
Developed markets		660		-		-		660		565		-		—		565
Fixed income securities																
Government and agency obligations		2		266		-		268		2		235		-		237
Corporate obligations		1		118		_		119		_		92		_		92
Mortgage and asset-backed securities		_		55		-		55		_		50		_		50
Other investments																
Insurance contracts (3)		_		67		470		537		_		59		412		471
Other		_		6		1		7		1		4		1		e
Net assets in fair value hierarchy	\$	1,602	\$	6,462	\$	473	\$	8,537	\$	952	\$	5,637	\$	417	\$	7,006
Investments measured at NAV (1)								802								788

<sup>(1)</sup>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, 2017 and 2016.

(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:

		2017	7			2016							
	 Insurance Contracts	Real Estate		Other	Total		Insurance Contracts		Real Estate		Other		Total
U.S. Pension Plans													
Balance January 1	\$ _	\$ _	\$	18	\$ 18	\$	_	\$	_	\$	23	\$	23
Actual return on plan assets:													
Relating to assets still held at December 31	_			(2)	(2)		_		_		(3)		(3)
Relating to assets sold during the year	_	_		4	4		_		_		4		4
Purchases and sales, net	_	_		(5)	(5)		_		_		(6)		(6)
Balance December 31	\$ _	\$ 	\$	15	\$ 15	\$	_	\$	_	\$	18	\$	18
<b>International Pension Plans</b>													
Balance January 1	\$ 412	\$ 4	\$	1	\$ 417	\$	393	\$	5	\$	2	\$	400
Actual return on plan assets:													
Relating to assets still held at December 31	52	_		_	52		(9)		1		_		(8)
Purchases and sales, net	5	(2)			3		2		(2)		(1)		(1)
Transfers into Level 3	1	_		_	1		26		_		_		26
Balance December 31	\$ 470	\$ 2	\$	1	\$ 473	\$	412	\$	4	\$	1	\$	417

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

		1	Fair Value Measur	emen	ts 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)		Fotal		Quoted Prices In Active Markets for Identical Assets (Level 1)	ve Other for Observable .ssets Inputs			Significant Unobservable Inputs (Level 3)			Total
			2017								2016					
Assets																
Cash and cash equivalents	\$ 97	\$	_	\$	_	\$	97	\$	125	\$	_	\$		_	\$	125
Investment funds																
Developed markets equities	37		_		_		37		48		_			_		48
Emerging markets equities	13		_		_		13		10		_			_		10
Government and agency obligations	1		_		_		1		1		_			_		1
Equity securities																
Developed markets	256				_		256		231		_			_		231
Fixed income securities																
Government and agency obligations	_		71		_		71		_		43			_		43
Corporate obligations	_		84		_		84		_		60			_		60
Mortgage and asset-backed securities	_		23		_		23		_		22					22
Net assets in fair value hierarchy	\$ 404	\$	178	\$	_	\$	582	\$	415	\$	125	\$		_	\$	540
Investments measured at NAV (1)							532									479
Plan assets at fair value						\$	1,114								\$	1,019

<sup>(1)</sup>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, 2017 and 2016.

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

plan, given an acceptable level of risk. The target investment portfolio of the Company's U.S. pension and other postretirement benefit plans is allocated 35% to 55% in U.S. equities, 20% to 35% in international equities, 20% to 35% 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 13% , 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 2018 are approximately \$60 million for U.S. pension plans, approximately \$150 million for international pension plans and approximately \$25 million for other postretirement benefit plans.

#### Expected Benefit Payments

Expected benefit payments are as follows:

	U.S. Pen	sion Benefits	Inte	ernational Pension Benefits	Other Postretirement Benefits
2018	\$	609	\$	222	\$ 96
2019		638		205	101
2020		650		217	104
2021		663		225	109
2022		683		243	113
2023 — 2027		3,760		1,326	623

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* :

			Pensic	on Pla	ins						0	ther P	Postretiren	nent	
		U.S.			International					Benefit Plans					
Years Ended December 31	2017	2016	2015		2017		2016		2015		2017		2016		2015
Net (loss) gain arising during the period	\$ (19)	\$ (743)	\$ 73	\$	309	\$	(380)	\$	(66)	\$	170	\$	(45)	\$	209
Prior service (cost) credit arising during the period	(13)	(10)	(13)		22		(2)		(4)		(31)		(19)		511
	\$ (32)	\$ (753)	\$ 60	\$	331	\$	(382)	\$	(70)	\$	139	\$	(64)	\$	720
Net loss amortization included in benefit cost	\$ 180	\$ 119	\$ 214	\$	98	\$	87	\$	118	\$	1	\$	3	\$	5
Prior service (credit) cost amortization included in benefit cost	(53)	(55)	(56)		(11)		(11)		(14)		(98)		(106)		(64)
	\$ 127	\$ 64	\$ 158	\$	87	\$	76	\$	104	\$	(97)	\$	(103)	\$	(59)

The estimated net loss (gain) and prior service cost (credit) amounts that will be amortized from *AOCI* into net periodic benefit cost during 2018 are \$314 million and \$(64) million, respectively, for pension plans (of which \$230 million and \$(51) million, respectively, relates to U.S. pension plans) and \$1 million and \$(84) million, respectively, for other postretirement benefit plans.



#### 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:

		ension and Other ement Benefit Plar	Internati	3		
December 31	2017	2016	2015	2017	2016	2015
Net periodic benefit cost						
Discount rate	4.30%	4.70%	4.20%	2.20%	2.80%	2.70%
Expected rate of return on plan assets	8.70%	8.60%	8.50%	5.10%	5.60%	5.70%
Salary growth rate	4.30%	4.30%	4.40%	2.90%	2.90%	2.90%
Benefit obligation						
Discount rate	3.70%	4.30%	4.80%	2.10%	2.20%	2.80%
Salary growth rate	4.30%	4.30%	4.30%	2.90%	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 2018, the expected rate of return for the Company's U.S. pension and other postretirement benefit plans will range from 7.70% to 8.30%, as compared to a range of 8.00% to 8.75% in 2017. The decrease is primarily due to a modest shift in asset allocation. The increase in the weighted-average expected return on U.S. pension and other postretirement benefit plans' assets.

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

December 31	2017	2016
Health care cost trend rate assumed for next year	7.2%	7.4%
Rate to which the cost trend rate is assumed to decline	4.5%	4.5%
Year that the trend rate reaches the ultimate trend rate	2032	2032

A one percentage point change in the health care cost trend rate would have had the following effects:

	One Pe	rcenta	age Point
	 Increase		Decrease
Effect on total service and interest cost components	\$ 13	\$	(11)
Effect on benefit obligation	125		(104)

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 2017, 2016 and 2015 were \$131 million, \$126 million and \$125 million, respectively.



# 15. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

Years Ended December 31	2017	2016	2015
Interest income	\$ (385)	\$ (328)	\$ (289)
Interest expense	754	693	672
Exchange (gains) losses	(11)	174	1,277
Equity income from affiliates	(42)	(86)	(205)
Other, net	(304)	267	72
	\$ 12	\$ 720	\$ 1,527

The exchange losses in 2015 were related primarily to the Venezuelan Bolívar. During 2015, upon evaluation of evolving economic conditions in Venezuela and volatility in the country, combined with a decline in transactions that were settled at the then official (CENCOEX) rate, the Company determined it was unlikely that all outstanding net monetary assets would be settled at the CENCOEX rate. Accordingly, during 2015, the Company recorded charges of \$876 million to devalue its net monetary assets in Venezuela to amounts that represented the Company's estimate of the U.S. dollar amount that would ultimately be collected and recorded additional exchange losses of \$138 million in the aggregate during 2015 reflecting the ongoing effect of translating transactions and net monetary assets consistent with these rates. Since January 2010, Venezuela has been designated hyperinflationary and, as a result, local foreign operations are remeasured in U.S. dollars with the impact recorded in results of operations.

The decline in equity income from affiliates in 2017 as compared with 2016 was driven primarily by the termination of the SPMSD joint venture on December 31, 2016, partially offset by higher equity income from certain research investment funds. The decline in equity income from affiliates in 2016 as compared with 2015 was driven primarily by lower equity income from certain research investment funds.

Other, net (as presented in the table above) in 2017 includes gains of \$291 million on the sale of equity investments, income of \$232 million related to AstraZeneca's option exercise (see Note 9), and a \$191 million loss on extinguishment of debt (see Note 10).

Other, net in 2016 includes a charge of \$625 million to settle worldwide patent litigation related to *Keytruda* (see Note 11), 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 (see Note 3) and \$98 million of income related to AstraZeneca's option exercise.

Other, net in 2015 includes a \$680 million net charge related to the settlement of *Vioxx* shareholder class action litigation (which was paid in 2016) and an expense of \$78 million for a contribution of investments in equity securities to the Merck Foundation, partially offset by a \$250 million gain on the sale of certain migraine clinical development programs (see Note 3), a \$147 million gain on the divestiture of Merck's remaining ophthalmics business in international markets (see Note 3), and the recognition of \$182 million of income related to AstraZeneca's option exercise.

Interest paid was \$723 million in 2017, \$686 million in 2016 and \$653 million in 2015.

## 16. Taxes on Income

A reconciliation between the effective tax rate and the U.S. statutory rate is as follows:

			2017	20	16	20	015
	A	mount	Tax Rate	 Amount	Tax Rate	 Amount	Tax Rate
U.S. statutory rate applied to income before taxes	\$	2,282	35.0 %	\$ 1,631	35.0 %	\$ 1,890	35.0 %
Differential arising from:							
Provisional impact of the TCJA		2,625	40.3	_		_	
Impact of purchase accounting adjustments, including amortization	3	713	10.9	623	13.4	797	14.8
Valuation allowances		632	9.7	(5)	(0.1)	39	0.7
Restructuring		142	2.2	145	3.1	167	3.1
State taxes		77	1.2	173	3.7	159	2.9
U.S. health care reform legislation		74	1.1	68	1.4	66	1.2
Foreign currency devaluation related to Venezuela		_	_	—	_	321	5.9
Foreign earnings		(1,725)	(26.5)	(1,646)	(35.3)	(2,144)	(39.7)
Tax settlements		(356)	(5.5)	—	_	(417)	(7.7)
Unremitted foreign earnings		_	_	(30)	(0.6)	260	4.8
Other <sup>(1)</sup>		(361)	(5.5)	(241)	(5.2)	(196)	(3.6)
	\$	4,103	62.9 %	\$ 718	15.4 %	\$ 942	17.4 %

<sup>(1)</sup> Other includes the tax effect of contingency reserves, research credits, losses on foreign subsidiaries and miscellaneous items.

The Company's 2017 effective tax rate reflects 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 reduces 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 has reflected the impact of the TCJA in its financial statements as described below. However, application of certain provisions of the TCJA remains subject to further interpretation and in these instances the Company has made a reasonable estimate of the effects of the TCJA.

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 for its one-time transition tax liability of \$5.3 billion . Merck has not yet finalized its calculation of the total post-1986 undistributed E&P for these foreign subsidiaries. The transition tax is based in part on the amount of undistributed E&P held in cash and other specified assets; therefore, this amount may change when the Company finalizes its calculation of post-1986 undistributed foreign E&P and finalizes the amounts held in cash or other specified assets. 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. The Company anticipates that it will be able to utilize certain foreign tax credits to partially reduce the transition tax payment, resulting in a net transition tax payment of \$5.1 billion . As permitted under the TCJA, the Company has elected to pay the one-time transition tax over a period of eight years. The current portion of the transition tax liability of \$545 million is included as reduction to prepaid income taxes included in *Other Current Assets* and the remainder of \$4.5 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.

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. The deferred tax benefit calculation remains subject to certain clarifications, particularly related to executive compensation and benefits.

Beginning in 2018, the TCJA includes a tax on "global intangible low-taxed income" (GILTI) as defined in the TCJA. The Company is allowed to make an accounting policy election to account for the tax effects of the GILTI tax either in the income tax provision in future periods as the tax arises, or as a component of deferred taxes on the related investments in foreign subsidiaries. The Company is currently evaluating the GILTI provisions of the TCJA and the implications on its tax provision and has not finalized the accounting policy election; therefore, the Company has not recorded deferred taxes for GILTI as of December 31, 2017.

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 as compared with the 35% U.S. statutory rate. 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 as compared to the 35% U.S. statutory rate.

The Company's 2015 effective tax rate reflects the impact of the Protecting Americans From Tax Hikes Act, which was signed into law on December 18, 2015, extending the research credit permanently and the controlled foreign corporation look-through provisions for five years.

Income before taxes consisted of:

Years Ended December 31	2017	2016	2015
Domestic	\$ 3,483	\$ 518	\$ 2,247
Foreign	3,038	4,141	3,154
	\$ 6,521	\$ 4,659	\$ 5,401

Taxes on income consisted of:

Years Ended December 31	2017	2016	2015
Current provision			
Federal	\$ 5,585	\$ 1,166	\$ 732
Foreign	1,229	916	844
State	(90)	157	130
	6,724	2,239	1,706
Deferred provision			
Federal	(2,958)	(1,255)	(552)
Foreign	75	(225)	(163)
State	262	(41)	(49)
	(2,621)	(1,521)	(764)
	\$ 4,103	\$ 718	\$ 942

Deferred income taxes at December 31 consisted of:

	2	2017				2016					
	Assets		Liabilities		Assets		Liabilities				
Intangibles	\$ 307	\$	2,435	\$	86	\$	3,854				
Inventory related	29		499		30		660				
Accelerated depreciation	28		642		28		927				
Unremitted foreign earnings			33				2,044				
Pensions and other postretirement benefits	498		192		727		109				
Compensation related	314		—		438		_				
Unrecognized tax benefits	156		—		383		—				
Net operating losses and other tax credit carryforwards	654		—		437		_				
Other	1,088		19		1,248		46				
Subtotal	3,074		3,820		3,377		7,640				
Valuation allowance	(900)				(268)						
Total deferred taxes	\$ 2,174	\$	3,820	\$	3,109	\$	7,640				
Net deferred income taxes		\$	1,646			\$	4,531				
Recognized as:											
Other assets	\$ 573			\$	546						
Deferred income taxes		\$	2,219			\$	5,077				

The Company has net operating loss (NOL) carryforwards in several jurisdictions. As of December 31, 2017, \$630 million of deferred taxes on NOL carryforwards relate to foreign jurisdictions. Valuation allowances of \$900 million have been established on these foreign NOL carryforwards and other foreign deferred tax assets. In addition, the Company has \$24 million of deferred tax assets relating to various U.S. tax credit carryforwards and NOL carryforwards, all of which are expected to be fully utilized prior to expiry.

Income taxes paid in 2017, 2016 and 2015 were \$4.9 billion, \$1.8 billion and \$1.8 billion, respectively. Tax benefits relating to stock option exercises were \$73 million in 2017, \$147 million in 2016 and \$109 million in 2015.

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

	2017	2016	2015
Balance January 1	\$ 3,494	\$ 3,448	\$ 3,534
Additions related to current year positions	146	196	198
Additions related to prior year positions	520	75	53
Reductions for tax positions of prior years <sup>(1)</sup>	(1,038)	(90)	(59)
Settlements <sup>(1)</sup>	(1,388)	(92)	(184)
Lapse of statute of limitations	(11)	(43)	(94)
Balance December 31	\$ 1,723	\$ 3,494	\$ 3,448

(1) Amounts reflect the settlements with the IRS as discussed below.

If the Company were to recognize the unrecognized tax benefits of \$1.7 billion at December 31, 2017, the income tax provision would reflect a favorable net impact of \$1.6 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, 2017 could decrease by up to approximately \$165 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 \$183 million in 2017, \$134 million in 2016 and \$102 million in 2015. These amounts reflect the beneficial impacts of various tax

settlements, including those discussed below. Liabilities for accrued interest and penalties were \$341 million and \$886 million as of December 31, 2017 and 2016, respectively.

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.

Although the IRS's examination of the Company's 2002-2005 federal tax returns was concluded prior to 2015, one issue relating to a refund claim remained open. During 2015, this issue was resolved and the Company received a refund of approximately \$715 million, which exceeded the receivable previously recorded by the Company, resulting in a tax benefit of \$410 million.

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. For most of its other significant tax jurisdictions (both U.S. state and foreign), the Company's income tax returns are open for examination for the period 2003 through 2017.

# 17. Earnings per Share

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

Years Ended December 31	2017	2016	2015
Net income attributable to Merck & Co., Inc.	\$ 2,394	\$ 3,920	\$ 4,442
Average common shares outstanding	2,730	2,766	2,816
Common shares issuable <sup>(1)</sup>	18	21	25
Average common shares outstanding assuming dilution	2,748	2,787	2,841
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	\$ 0.88	\$ 1.42	\$ 1.58
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	\$ 0.87	\$ 1.41	\$ 1.56

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

In 2017, 2016 and 2015, 5 million, 13 million and 9 million, respectively, of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

# 18. Other Comprehensive Income (Loss)

Changes in AOCI by component are as follows:

	De	rivatives	Investments	Employee Benefit Plans	Cumulativ Translatio Adjustmer	n	Co	umulated Other omprehensive acome (Loss)
Balance January 1, 2015, net of taxes	\$	530	\$ 111	\$ (2,986)	\$ (1,9	978)	\$	(4,323)
Other comprehensive income (loss) before reclassification adjustments, pretax		526	(9)	710	(	158)		1,069
Tax		(177)	(13)	(272)		(28)		(490)
Other comprehensive income (loss) before reclassification adjustments, net of taxes		349	(22)	438	(	186)		579
Reclassification adjustments, pretax		(731) <sup>(1)</sup>	(73) (2)	203 (3)		(22)		(623)
Tax		256	25	(62)		_		219
Reclassification adjustments, net of taxes		(475)	(48)	141		(22)		(404)
Other comprehensive income (loss), net of taxes		(126)	(70)	579	(2	208)		175
Balance December 31, 2015, 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 <sup>(3)</sup>		—		(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) (4)	(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)	( <b>291</b> ) <sup>(2)</sup>	117 <sup>(3)</sup>		_		(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) <sup>(4)</sup>	\$ (1,	954)	\$	(4,910)

(1) Relates to foreign currency cash flow hedges that were reclassified from AOCI to Sales .

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

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

(4) Includes pension plan net loss of \$ 3.5 billion and \$3.9 billion at December 31, 2017 and 2016, respectively, and other postretirement benefit plan net (gain) loss of \$(16) million and \$115 million at December 31, 2017 and 2016, respectively, as well as pension plan prior service credit of \$326 million and \$361 million at December 31, 2017 and 2016, respectively, and other postretirement benefit plan prior service credit of \$383 million and \$466 million at December 31, 2017 and 2016, respectively.

## 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 segment is the only reportable segment.

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. 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 Company also has an Animal Health segment that discovers, develops, manufactures and markets animal health products, including vaccines, which the Company sells to veterinarians, distributors and animal producers. The Company's 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.

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Sales of the Company's products were as follows:

Years Ended December 31		2017		 2016			 2015					
	U.S.	Int'l	Total	 U.S.		Int'l	Total	 U.S.		Int'l		Total
Primary Care and Women's Health												
Cardiovascular												
Zetia	\$ 352	\$ 992	\$ 1,344	\$ 1,588	\$	972	\$ 2,560	\$ 1,612	\$	914	\$	2,526
Vytorin	124	627	751	473		668	1,141	479		771		1,251
Atozet	_	225	225	1		146	146	2		34		36
Adempas	_	300	300			169	169	_		30		30
Diabetes		500	500			107	105			50		50
Januvia	2 1 5 2	1,584	2 727	2 296		1,622	3,908	2,263		1,601		2 862
Janumet	2,153		3,737	2,286								3,863
General Medicine and Women's Health	863	1,296	2,158	984		1,217	2,201	976		1,175		2,151
NuvaRing												
Implanon/Nexplanon	564	197	761	576		202	777	515		216		732
Follistim AQ	496	191	686	420		186	606	367		221		588
-	123	174	298	157		197	355	160		223		383
Hospital and Specialty												
Hepatitis												
Zepatier	771	888	1,660	488		67	555	-		-		_
HIV												
Isentress/Isentress HD	565	639	1,204	721		666	1,387	797		714		1,511
Hospital Acute Care												
Bridion	239	465	704	77		405	482	_		353		353
Noxafil	309	327	636	284		312	595	212		275		487
Invanz	361	241	602	329		233	561	322		247		569
Cancidas	20	402	422	25		533	558	24		548		573
Cubicin <sup>(1)</sup>	189	193	382	906		181	1,087	1,030		97		1,127
Primaxin	10	270	280	4		293	297	8		305		313
Immunology							_,,					
Remicade	_	837	837	_		1,268	1,268	_		1,794		1,794
Simponi		819	819			766	766	_		690		690
Oncology	_	815	015			700	700	_		090		090
Keytruda	2 200	1 500	2 000	702		(10	1 402	202		172		
Emend	2,309	1,500	3,809	792		610	1,402	393		173		566
Temodar	342	213	556	356		193	549	326		209		535
Diversified Brands	16	256	271	15		268	283	7		306		312
Respiratory												
Singulair												
	40	692	732	40		874	915	39		892		931
Nasonex	54	333	387	184		352	537	449		409		858
Dulera	261	26	287	412		24	436	515		21		536
Other												
Cozaar/Hyzaar	18	466	484	16		494	511	30		637		667
Arcoxia	_	363	363	_		450	450	_		471		471
Fosamax	6	235	241	5		279	284	12		347		359
Vaccines <sup>(2)</sup>												
Gardasil/Gardasil 9	1,565	743	2,308	1,780		393	2,173	1,520		388		1,908
ProQuad/M-M-R II/Varivax	1,374	303	1,676	1,362		279	1,640	1,290		214		1,505
Pneumovax 23	581	240	821	447		193	641	378		164		542
RotaTeq	481	204	686	482		169	652	447		163		610
Zostavax	422	246	668	518		168	685	592		157		749
Other pharmaceutical <sup>(3)</sup>	1,246	3,049	4,295	1,345								
Total Pharmaceutical (3) Total Pharmaceutical segment sales						3,228	4,574	1,473		3,785		5,256
	15,854	19,536	35,390	17,073		18,077	35,151	16,238		18,544		34,782
Other segment sales (4)	 1,486	2,785	4,272	1,374		2,489	3,862	1,213		2,454		3,667

Total segment sales	17,340	22,321	39,662	18,447	20,566	39,013	17,451	20,998	38,449
Other <sup>(5)</sup>	84	377	460	31	763	794	68	981	1,049
	\$ 17,424	\$ 22,698	\$ 40,122	\$ 18,478	\$ 21,329	\$ 39,807	\$ 17,519	\$ 21,979	\$ 39,498

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

(1) Sales of Cubicin in 2015 represent sales subsequent to the Cubist acquisition date.

(2) 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 2017 include sales in the European markets that were previously part of SPMSD. Amounts for 2016 and 2015 do not include sales of vaccines sold through SPMSD, the results of which are reflected in equity income from affiliates include in Other (income) expense, net . Amounts for 2016 and 2015 do, however, include supply sales to SPMSD.

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

<sup>(4)</sup> Represents the non-reportable segments of Animal Health, Healthcare Services and Alliances.

(5) Other is primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, as well as third-party manufacturing sales. Other in 2017 and 2016 also includes \$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	2017	2016	2015
United States	\$ 17,424	\$ 18,478	\$ 17,519
Europe, Middle East and Africa	11,478	10,953	10,677
Asia Pacific	4,337	3,918	3,825
Japan	3,122	2,846	2,673
Latin America	2,339	2,155	2,825
Other	1,422	1,457	1,979
	\$ 40.122	\$ 39 807	\$ 39 498

A reconciliation of total segment profits to consolidated *Income before taxes* is as follows:

Years Ended December 31	2017	2016	2015
Segment profits:			
Pharmaceutical segment	\$ 22,586	\$ 22,180	\$ 21,658
Other segments	1,834	1,507	1,573
Total segment profits	24,420	23,687	23,231
Other profits	26	481	810
Unallocated:			
Interest income	385	328	289
Interest expense	(754)	(693)	(672)
Equity income from affiliates	49	(19)	135
Depreciation and amortization	(1,378)	(1,585)	(1,573)
Research and development	(9,355)	(9,084)	(5,871)
Amortization of purchase accounting adjustments	(3,056)	(3,692)	(4,816)
Restructuring costs	(776)	(651)	(619)
Loss on extinguishment of debt	(191)		
Gain on sale of certain migraine clinical development programs	—	100	250
Charge related to the settlement of worldwide Keytruda patent litigation	_	(625)	_
Gain on divestiture of certain ophthalmic products	—	—	147
Foreign currency devaluation related to Venezuela	—	—	(876)
Net charge related to the settlement of Vioxx shareholder class action litigation	—	—	(680)
Other unallocated, net	 (2,849)	 (3,588)	 (4,354)
	\$ 6,521	\$ 4,659	\$ 5,401

Segment profits are comprised of segment sales less standard costs and certain operating expenses directly incurred by the segments. For internal management reporting presented to the chief operating decision maker, Merck does not allocate materials and production costs, other than standard costs, the majority of research and development expenses or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. In addition, costs related to restructuring activities, as well as the amortization of purchase accounting adjustments are not allocated to segments.

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

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

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

	Pharmaceutical			All Other	Total	
Year Ended December 31, 2017						
Included in segment profits:						
Equity income from affiliates	\$	(7)	\$	—	\$	(7)
Depreciation and amortization		(125)		(87)		(212)
Year Ended December 31, 2016						
Included in segment profits:						
Equity income from affiliates	\$	105	\$	—	\$	105
Depreciation and amortization		(160)		(23)		(183)
Year Ended December 31, 2015						
Included in segment profits:						
Equity income from affiliates	y income from affiliates \$					70
Depreciation and amortization		(82)		(18)		(100)

Property, plant and equipment, net by geographic area where located is as follows:

December 31	2017	2016	2015	
United States	\$ 8,070	\$ 8,114	\$	8,467
Europe, Middle East and Africa	3,151	2,732		2,844
Asia Pacific	782	775		842
Latin America	271	234		182
Japan	158	164		164
Other	7	7		8
	\$ 12,439	\$ 12,026	\$	12,507

The Company does not disaggregate assets on a products and services basis for internal management reporting and, therefore, such information is not presented.

## **Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Shareholders 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 as of December 31, 2017 and 2016, 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, 2017, 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, 2017, 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, 2017 and 2016, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2017 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, 2017, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

#### **Basis for Opinions**

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

#### Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail,

accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

mewaterhouseloopers LLP

PricewaterhouseCoopers LLP Florham Park, New Jersey February 27, 2018

We have served as the Company's auditor since 2002

# (b) Supplementary Data

Selected quarterly financial data for 2017 and 2016 are contained in the Condensed Interim Financial Data table below.

# **Condensed Interim Financial Data (Unaudited)**

(\$ in millions except per share amounts)	4	th Q (1)	2	3rd Q (2)		2nd Q		1st Q
<b>2017</b> <sup>(3)</sup>								
Sales	\$	10,433	\$	10,325	\$	9,930	\$	9,434
Materials and production		3,406		3,274		3,080		3,015
Marketing and administrative		2,580		2,401		2,438		2,411
Research and development		2,281		4,383		1,749		1,796
Restructuring costs		306		153		166		151
Other (income) expense, net		(19)		(86)		58		58
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
2016 (3)								
Sales	\$	10,115	\$	10,536	\$	9,844	\$	9,312
Materials and production		3,332		3,409		3,578		3,572
Marketing and administrative		2,593		2,393		2,458		2,318
Research and development		4,650		1,664		2,151		1,659
Restructuring costs		265		161		134		91
Other (income) expense, net		631		22		19		48
(Loss) income before taxes		(1,356)		2,887		1,504		1,624
Net (loss) income attributable to Merck & Co., Inc.		(594)		2,184		1,205		1,125
Basic (loss) earnings per common share attributable to Merck & Co., Inc. common shareholders	\$	(0.22)	\$	0.79	\$	0.44	\$	0.41
(Loss) earnings per common share assuming dilution attributable to Merck & Co., Inc. common								
shareholders	\$	(0.22)	\$	0.78	\$	0.43	\$	0.40

<sup>(1)</sup> Amounts for 2017 include a provisional net tax charge related to the enactment of U.S. tax legislation (see Note 16). Amounts for 2016 include a charge to settle worldwide patent litigation related to Keytruda (see Note 11).

(2) Amounts for 2017 include an aggregate charge related to the formation of a collaboration with AstraZeneca (see Note 4).

<sup>(3)</sup> Amounts for 2017 and 2016 reflect acquisition and divestiture-related costs (see Note 8) and the impact of restructuring actions (see Note 5).

#### Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

#### Item 9A. Controls and Procedures.

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, 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 period covered by this report, 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, 2017. 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, which includes financial stewardship. This training reinforces the importance and understanding of internal controls by reviewing key corporate policies, procedures and systems. In addition, the Company has compliance programs, including an ethical business practices program to reinforce the Company's long-standing commitment to high ethical standards in the conduct of its business.

The financial statements and other financial information included in the Annual Report on Form 10-K fairly present, in all material respects, the Company's financial condition, results of operations and cash flows. Our formal certification to the Securities and Exchange Commission is included in this Form 10-K filing.

# Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control — Integrated Framework* issued

in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2017.

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, 2017, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

and C. J\_\_\_\_

Kenneth C. Frazier Chairman, President and Chief Executive Officer

Item 9B. Other Information.

None.

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Robert M. Davis Executive Vice President, Chief Financial Officer & Global Services

## 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 22, 2018. 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 22, 2018.

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 <u>www.merck.com/about/code of conduct.pdf</u>. 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. A printed copy will be sent, without charge, to any shareholder who requests it by writing to the Chief Ethics and Compliance Officer of Merck & Co., Inc., 2000 Galloping Hill Road, Kenilworth, NJ 07033.

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 22, 2018.

# 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 22, 2018.

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 22, 2018.

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 22, 2018.

# 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 22, 2018.

#### **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, 2017. 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)	36,274,481 <sup>(2)</sup>	\$ 46.77	117,820,468
Equity compensation plans not approved by security holders			_
Total	36,274,481	\$ 46.77	117,820,468

(i) 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 13,608,641 shares of restricted stock units and 1,867,526 performance share units (assuming maximum payouts) under the Merck Sharp & Dohme 2004, 2007 and 2010 Incentive Stock Plans. Also excludes 245,038 shares of phantom stock deferred under the MSD Employee Deferral Program and 551,358 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 22, 2018.

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 22, 2018.

## 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 2018 beginning with the caption "Pre-Approval Policy for Services of Independent Registered Public Accounting Firm" through "Fees for Services Provided by Independent Registered Public Accounting Firm" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 22, 2018.



# 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, 2017, 2016 and 2015

Consolidated statement of comprehensive income for the years ended December 31, 2017, 2016 and 2015

Consolidated balance sheet as of December 31, 2017 and 2016

Consolidated statement of equity for the years ended December 31, 2017, 2016 and 2015

Consolidated statement of cash flows for the years ended December 31, 2017, 2016 and 2015

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	_	<u>Third Supplemental Indenture to the 2003 Indenture (including Form of Note), dated September 17, 2007 — Incorporated by reference to</u> Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed September 17, 2007 (No. 1-6571)

Exhibit <u>Number</u>		Description
4.8		Fifth Supplemental Indenture to the 2003 Indenture, dated November 3, 2009 — Incorporated by reference to Exhibit 4.4 to Merck & Co.,
		Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
4.9	_	Indenture, dated as of January 6, 2010, between Merck & Co., Inc. and U.S. Bank Trust National Association, as Trustee — Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed December 10, 2010 (No. 1-6571)
4.10		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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10.12	_	Form of stock option terms for 2018 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan

Exhibit <u>Number</u>		Description
*10.13		Form of restricted stock unit terms for 2015 quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.22 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)
*10.14	_	Form of performance share unit terms for 2015 grants under the Merck & Co., Inc. 2010 Stock Incentive Plan — Incorporated by reference to to Exhibit 10.21 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)
*10.15	—	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)
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*10.20	—	Merck & Co., Inc. U.S. Separation Benefits Plan (amended and restated effective as of January 1, 2017) — Incorporated by reference to Exhibit 10.24 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)
*10.21	—	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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		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)
*10.23	—	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)
*10.24	—	Merck & Co., Inc. Plan for Deferred Payment of Directors' Compensation (effective as amended and restated as of January 1, 2018)
10.25	—	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) <sup>†</sup>
10.26		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) <sup>†</sup>
10.27	_	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)
12	_	Computation of Ratios of Earnings to Fixed Charges
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

# Table of Contents

Exhibit	
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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, 2017, 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.

<sup>\*</sup> Management contract or compensatory plan or arrangement.

# Item 16. Form 10-K Summary

Not applicable.

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.

#### 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, 2018

MERCK & CO., INC.

By: KENNETH C. FRAZIER

(Chairman, President and Chief Executive Officer)

By: /S/ MICHAEL J. HOLSTON Michael J. Holston (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, 2018
ROBERT M. DAVIS	Executive Vice President, Chief Financial Officer and Global Services; Principal Financial Officer	February 27, 2018
RITA A. KARACHUN	Senior Vice President Finance-Global Controller; Principal Accounting Officer	February 27, 2018
LESLIE A. BRUN	Director	February 27, 2018
THOMAS R. CECH	Director	February 27, 2018
PAMELA J. CRAIG	Director	February 27, 2018
THOMAS H. GLOCER	Director	February 27, 2018
ROCHELLE B. LAZARUS	Director	February 27, 2018
JOHN H. NOSEWORTHY	Director	February 27, 2018
CARLOS E. REPRESAS	Director	February 27, 2018
PAUL B. ROTHMAN	Director	February 27, 2018
PATRICIA F. RUSSO	Director	February 27, 2018
CRAIG B. THOMPSON	Director	February 27, 2018
WENDELL P. WEEKS	Director	February 27, 2018
PETER C. WENDELL	Director	February 27, 2018

Michael J. Holston, by signing his 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/ MICHAEL J. HOLSTON
	Michael J. Holston
	(Attorney-in-Fact)

# EXHIBIT INDEX

Exhibit		
<u>Number</u>		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	—	<u>Third Supplemental Indenture to the 2003 Indenture (including Form of Note), dated September 17, 2007 — Incorporated by reference to</u> Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed September 17, 2007 (No. 1-6571)
4.8	_	Fifth Supplemental Indenture to the 2003 Indenture, dated November 3, 2009 — Incorporated by reference to Exhibit 4.4 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
4.9		Indenture, dated as of January 6, 2010, between Merck & Co., Inc. and U.S. Bank Trust National Association, as Trustee — Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed December 10, 2010 (No. 1-6571)
4.10		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)
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32.1		Section 1350 Certification of Chief Executive Officer
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101		The following materials from Merck & Co., Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2017, 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

\* Management contract or compensatory plan or arrangement.

Cash Flows, and (vi) Notes to Consolidated Financial Statements.

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<sup>\*</sup> 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.

#### TERMS FOR 2018 NON-QUALIFIED STOCK OPTION (NQSO) GRANTS UNDER THE MERCK & CO., INC. 2010 INCENTIVE STOCK PLAN

This is a summary of the terms applicable to the stock option specified in this document. Different terms may apply to any prior or future stock option.

Grant Type:	NQSO
Option Price:	\$XX.XX
Grant Date:	May X, 2018
Expiration Date:	May X, 2028

Vesting Date	<b>Portion that Vests</b>
May X, 2019	First: 33.333%
May X, 2020	Second: 33.333%
May X, 2021	Balance

#### I. GENERAL INFORMATION

This stock option becomes exercisable in equal installments (subject to a rounding process) on the Vesting Dates indicated in the accompanying box. This stock option expires on its Expiration Date, which is the day before the tenth anniversary of the Grant Date. If your employment with the Company is terminated, your right to exercise this stock option will be determined according to the terms in Section II.

**Eligibility:** Eligibility for grants is determined under the Merck & Co., Inc. 2010 Incentive Stock Plan for employees of the Company, its subsidiaries, its affiliates or its joint ventures if designated by the Compensation and Benefits Committee of Merck's Board of Directors, or its delegate (the "Committee").

**Subject to Recoupment**: For employees in Band 600 and above, this Stock Option Award will be subject to recoupment in the event of certain violations of Company policy in accordance with the Company's policy for Recoupment of Compensation for Compliance Violations, as set forth in Appendix A (as may be amended from time to time).

#### II. TERMINATION OF EMPLOYMENT

Α. General Rule. If your employment is terminated for any reason other than those specified in the following paragraphs, the portion of this stock option that is unvested will expire on the date your employment ends; the portion of this stock option that is vested will expire unless exercised before the New York Stock Exchange closes (the "Close of Business") on the day before the same day of the third month ("Within Three Months") after the date of the termination (but in no event after the expiration of the Option Period). Close of Business for any day on which the New York Stock Exchange is not open means the close of business prior to that date when the Exchange is open. Where there is no corresponding day of a month, the last day of the month is deemed to be the same day as a later day (e.g., November 28, 29 and 30 all correspond to February 28 in non leap years). If you are rehired by the Company or JV, this option nevertheless will expire unless exercised Within Three Months, or the original Expiration Date if earlier.

**B. Retirement.** If you retire from service with the Company the portion of this stock option that would have become exercisable according to its original schedule within one year of the date

your employment terminates will vest and become exercisable on its applicable Vesting Date and the remainder will expire immediately. Whether already vested on the date your employment terminates or vested as a result of such retirement, this option will expire on the earlier of (a) the day before the fifth anniversary of the termination date or (b) its original Expiration Date. For grantees who are employed in the U.S., "retirement" means a termination of employment after attaining the earliest of (a) age 55 with at least 10 years of service (b) such age and service that provides eligibility for subsidized retiree medical coverage or (c) age 65 without regard to years of service. For other grantees, "retirement" is determined by the Company. If your employment is terminated as described in this paragraph and you are later rehired by the Company or JV, this option nevertheless will expire according to this paragraph notwithstanding such rehire.

**C. Involuntary Termination.** If your employment is terminated by the Company and the Company determines that such termination was involuntary, including the result of a restructuring or job elimination, but excluding non-performance of your duties and the reasons listed under paragraphs B or D through H, the portion of this stock option that is unvested will expire on the date your employment ends; the portion of this stock option that is vested will expire on the day before the one year anniversary of the date your employment ends, but in no event later than the original Expiration Date. If your employment is terminated as described in this paragraph and you are later rehired by the Company or JV, this option nevertheless will expire according to this paragraph notwithstanding such rehire.

D. Sale. If your employment is terminated and the Company determines that such termination resulted from the sale of your subsidiary, division or joint venture, the following portion of this stock option award will vest and become exercisable immediately upon such termination: one-third if employment terminates on or after the Grant Date but before the first anniversary thereof; and all if employment terminates on or after the first anniversary of the Grant Date. Whether already vested on the date your employment terminates or vested as a result of such sale, this stock option will expire the day before the first anniversary of the date your employment with the Company ends, but in no event later than the original Expiration Date. Notwithstanding the foregoing, the Committee may determine, for purposes of this stock option grant, whether employment with an entity that is established from the Company's spin off, split off, split up or distribution of equity securities in connection with that entity constitutes a termination of employment, and may make adjustments, if any, as it deems appropriate, at the time of the distribution of such equity securities, in the kind and/or number of shares subject to this option, and/or in the option price of such option. If your employment is terminated as described in this paragraph and you are later rehired by the Company or JV, this option nevertheless will expire according to this paragraph notwithstanding such rehire.

E. Misconduct. If your employment is terminated as a result of your deliberate, willful or gross misconduct, this stock option (whether vested or unvested) will expire immediately upon your receipt of notice of such termination.

**Death.** If your employment terminates as a result of your death, the F. portion of this stock option that is unvested will vest immediately upon your death. Whether already vested on the date of your death or vested as a result of your death, this stock option will expire on the day before the second anniversary of your death, even if such date is later than the Original Expiration date. This stock option will expire on such earlier date than otherwise specified in this paragraph as may be required under applicable non-U.S. law (e.g., in France, six months from the date of death). If you die while any portion of this stock option remains outstanding, but after your employment terminates for the reasons listed under paragraphs B, C, D, G or H of this section, the portion that remains outstanding after such employment termination will become immediately exercisable and will continue to be exercisable until the expiration date prescribed in paragraph B, C, D, G or H as applicable (and at least a year from your death in those jurisdictions where such extension is required by law).

**G. Disability.** If your employment is terminated and the Company determines that such termination resulted from your inability to perform the material duties of your role by reason of a physical or mental infirmity that is expected to last for at least six months or to result in your death, whether or not you are eligible for disability benefits from any applicable disability program, then this stock option will continue to become exercisable on applicable Vesting Dates and will expire on the earlier of (a) the day before the fifth anniversary of the day your employment terminates and (b) its original Expiration Date. If your employment is terminated as described in this paragraph and you are later rehired by the Company or JV, this option nevertheless will expire according to this paragraph notwithstanding such rehire.

Η. Change in Control. If the Company involuntarily terminates your employment without Cause before the second anniversary after the closing of a change in control, each unvested Stock Option that is outstanding immediately prior to the change in control will immediately become fully vested and exercisable. All options, including options vested prior to such time, will expire on the day before the fifth anniversary of the termination of your employment following a change in control (but not beyond the Expiration Date). This extended exercise period does not apply in the case of termination by reasons of retirement, involuntary termination, sale, misconduct, death or disability, as described in paragraphs B, D, E, F and G above or termination prior to a change in control. If this stock option does not remain outstanding following the change in control and is not converted into a successor stock option, then you will be entitled to receive cash for this option in an amount at least equal to the difference between the price paid to stockholders in the change in control and the Option Price of this stock option. A "change in control" has the same meaning that it has under the Merck & Co., Inc. Change in Control Separation Benefits Plan (excluding an MSD Change in Control).

I. Joint Venture. Employment with a joint venture or other entity in which the Company has determined that it has a significant business or ownership interest (a "JV") is not considered termination of employment for purposes of this

stock option. If you transfer employment from the Company to a JV or from a JV to the Company, such employment must be approved by, and contiguous with employment by, the Company or the JV. The terms set out in paragraphs A through H above apply to this stock option while the option holder is employed by the JV.

## III. TRANSFERABILITY

This stock option is not transferable and may not be assigned or otherwise transferred except, under specific terms, by executives who hold or who retired within the prior 12 months from a Section 16 officer position.

#### IV. ADMINISTRATION

The Committee is responsible for construing and interpreting this grant, including the right to construe disputed or doubtful plan provisions, and may establish, amend and construe such rules and regulations as it may deem necessary or desirable for the proper administration of this grant. Any decision or action taken or to be taken by the Committee, arising out of or in connection with the construction, administration, interpretation and effect of this grant shall, to the maximum extent permitted by applicable law, be within its absolute discretion (except as otherwise specifically provided herein) and shall be final, binding and conclusive upon the Company, all eligible employees and any person claiming under or through any eligible employee. All determinations by the Committee including, without limitation, determinations of the eligible employees, the form, amount and timing of incentives, the terms and provisions of incentives and the writings evidencing incentives, need not be uniform and may be made selectively among eligible employees who receive, or are eligible to receive, Incentives hereunder, whether or not such eligible employees are similarly situated.

#### V. GRANTS NOT PART OF EMPLOYMENT CONTRACT

Notwithstanding reference to grants of incentives in letters offering employment or in specific employment agreements, incentives do not constitute part of any employment contract between the Company or JV and the grantee, whether the employment contract arises as a matter of agreement or applicable law. The value of any grant or of the proceeds of any exercise of Incentives are not included in calculating compensation for purposes of pension payments, separation pay, termination indemnities or other similar payments due upon termination of employment.

This stock option is subject to the provisions of the 2010 Incentive Stock Plan. For further information regarding your stock options, you may access the Merck Global Long-Term Incentives homepage via <u>http://onemerck.com</u>

Unless you notify the Company in writing that you wish to refuse this grant within 60 days of the Grant Date, you will be deemed to acknowledge that you have read, understood and agree to all of the terms, conditions and provisions of this document and the Merck & Co., Inc. 2010 Incentive Stock Plan. If you wish to reject this grant, you must send your written notice of rejection to the Company at:

Attention: Global Executive Compensation and Benefits Merck & Co., Inc. 2000 Galloping Hill Road, Building K-1 Kenilworth, New Jersey, U.S.A. 07033

## Appendix A Recoupment of Compensation for Compliance Violations

## POLICIES AND PROCEDURES

#### Policy

It is the policy of the Compensation and Benefits Committee of the Board of Directors (the "Committee") that the Committee will exercise its discretion to determine whether to seek Recoupment of any bonus and/or other incentive compensation paid or awarded to an Affected Employee with respect to any performance period beginning after December 31, 2013, where it determines, in consultation with the Audit Committee, that: a) the Affected Employee engaged in misconduct, or failed to reasonably supervise an employee who engaged in misconduct, that resulted in a Material Policy Violation relating to the research, development, manufacturing, sales, or marketing of Company products; and b) the Committee concludes that the Material Policy Violation caused Significant Harm to the Company, as those terms are defined in this policy. The Committee's exercise of its discretion may take into account any considerations determined by the Committee to be relevant.

#### Definitions

1. "Recoupment" is defined to include any and all of the following actions to the extent permitted by law: (a) reducing the amount of a current or future bonus or other cash or non- cash incentive compensation award, (b) requiring reimbursement of a bonus or other cash-based incentive compensation award paid with respect to the most recently completed performance period, (c) cancelling all or a portion of a future-vesting equity award, (d) cancelling all or a portion of an equity award that vested within the previous twelve-month period, (e) requiring return of shares paid upon vesting and/or reimbursement of any proceeds received from the sale of an equity award, in each case that vested within the previous twelve-month period, and (f) any other method of reducing the total compensation paid to an employee for any prior twelve- month period or any current or future period.

2. A "Material Policy Violation" is defined as a material violation of a Company policy relating to the research, development, manufacturing, sales, or marketing of Company products.

3. An "Affected Employee" is an employee in Band 600 or higher who (i) engaged in misconduct that results in a Material Policy Violation; or (ii) failed in his or her supervisory responsibilities to reasonably manage or monitor the conduct of an employee who engaged in misconduct that results in a Material Policy Violation.

4. "Significant Harm" means a significant negative impact on the Company's financial operating results or reputation.

#### Procedures

1. The Committee, acting in consultation with the Audit Committee, shall administer this policy and have full discretion to interpret and to make any and all determinations under this policy, subject to the approval of the full Board of Directors in the case of a determination to seek or waive Recoupment from the Chief Executive Officer.

2. The General Counsel, in consultation with the Chief Ethics and Compliance Officer and the Executive Vice President, Human Resources, is responsible for determining whether to refer a matter to the Committee for review under this policy and for assisting the Committee with its review. The Committee may consult with other Board Committees and any external or internal advisors as it deems appropriate.

3. If the Committee, acting in consultation with the Audit Committee, determines that there is a basis for seeking Recoupment under this policy, the Committee shall exercise its discretion to determine for each Affected Employee, on an individual basis, whether, and to what extent and in which manner, to seek Recoupment.

4. In exercising its discretion, the Committee may take into consideration, as it deems appropriate, all of the facts and circumstances of the particular matter and the general interests of the Company.

#### **Delegation to Management for Certain Recoupment Decisions**

The Committee hereby delegates to the Chief Executive Officer (who may further delegate as he deems appropriate) the authority to administer this policy and to make any and all decisions under it regarding Affected Employees who are not Section 16 Officers of the Company. Section 16 Officers are employees of the Company who are subject to Section 16 of the Securities Exchange Act of 1934. Management shall report to the Committee on any affirmative decisions to seek Recoupment pursuant to this delegation.

#### **Disclosure of Recoupment Decisions**

The Company will comply with all applicable securities laws and regulations, including Securities and Exchange Commission disclosure requirements regarding executive compensation. The Company may also, but is not obligated to, provide additional disclosure beyond that required by law when the Company deems it to be appropriate and determines that such disclosure is in the best interest of the Company and its shareholders.

#### Miscellaneous

Nothing in this policy shall limit or otherwise affect any of the following: 1) management's ability to take any disciplinary action with respect to any Affected Employee; 2) the Committee's ability to use its negative discretion with respect to any incentive compensation performance target at any time; or

3) the Committee's or management's ability to reduce the amount (in whole or in part) of a current or future bonus or other cash or non-cash incentive compensation award to any executive or other employee for any reason as they may deem appropriate and to the extent permitted by law. Nothing in this policy shall replace or otherwise limit or affect the Clawback Policy for EIP Awards Upon Significant Restatement of Financial Results and/or the Clawback Policy for PSUs upon Significant Restatement of Financial Results.

#### TERMS FOR 2018 RESTRICTED STOCK UNIT GRANTS UNDER THE MERCK & CO., INC. 2010 INCENTIVE STOCK PLAN

# This is a summary of the terms applicable to the Restricted Stock Unit (RSU) Award specified in this document. Different terms may apply to any prior or future RSU Awards.

Grant Type:	RSU	
Grant Date:	May X, 2018	
Vesting Dates		<b>Portion that Vests</b>
May X, 2019		First: 33.333%
May X, 2020		Second: 33.333%
May X, 2021		Third: Balance

**Eligibility** : Eligibility for grants is determined under the Merck & Co., Inc. 2010 Incentive Stock Plan for employees of the Company, its subsidiaries, its affiliates or its joint ventures if designated by the Compensation and Benefits Committee of Merck's Board of Directors, or its delegate (the "Committee").

#### I. GENERAL INFORMATION

A. Restricted Period. The Restricted Period is the period during which this RSU Award is restricted and subject to forfeiture. The Restricted Period ends with respect to one-third of this RSU Award on each of the First, Second and Third anniversaries of the Grant Date as shown in the box above, unless ended earlier under Article II below. No voting rights apply to this RSU Award. No fractional shares will be awarded: all calculations are subject to rounding.

**B.** Dividend Equivalents. During the Restricted Period, dividend equivalents will be accrued for the holder ("you") if and to the extent dividends are paid by the Company on Merck Common Stock. Payment of such dividends will be made, without interest or earnings, at the time of distribution. If any portion of this RSU Award lapses, is forfeited or expires, no dividend equivalents will be credited or paid on such portion. Any payment of dividend equivalents will be reduced to the extent necessary for the Company to satisfy any tax or other withholding obligations.

**C. Distribution.** Upon the expiration of the Restricted Period if you are then employed, you will be entitled to receive a number of shares of Merck common stock equal to the number of RSUs that have become unrestricted and the dividend equivalents that accrued on that portion. Prior to distribution, you must deliver to the Company an amount the Company determines to be sufficient to satisfy any amount required to be withheld, including applicable taxes. The Company may, in its sole discretion, withhold from the RSU Award distribution a number of shares to pay applicable withholding (including taxes).

**D. 409A Compliance.** Anything to the contrary notwithstanding, no distribution of RSUs may be made unless in compliance with Section 409A of the Internal Revenue Code or any successor thereto. Specifically, distributions made due to a separation from service (as defined in Section 409A) to a "Specified Employee" as defined in Treas. Reg. Sec. 1.409A-1(i) or any successor thereto, to the extent required by Section 409A of the Code will not be made until administratively feasible following the first day of the sixth month following the separation from service, in the same form as they would have been made had this restriction not applied; provided further, that dividend equivalents that otherwise would have accrued will accrue during the period during which distribution is suspended.

E. Subject to Recoupment . For employees in Band 600 and above, this RSU Award will be subject to recoupment in the event of certain violations of Company policy in accordance with the Company's policy for Recoupment of Compensation for Compliance Violations, as set forth in Appendix A (as may be amended from time to time).

#### II. TERMINATION OF EMPLOYMENT

If your employment with the Company is terminated during the Restricted Period, your right to this RSU Award will be determined according to the terms in this Section II.

**A. General Rule.** If your employment is terminated during the Restricted Period for any reason other than those specified in the following paragraphs, the unvested portion of this RSU Award (and any accrued dividend equivalents) will be forfeited on the date your employment ends. If your employment is terminated as described in this paragraph and you are later rehired by the Company or JV, this grant nevertheless will expire according to this paragraph notwithstanding such rehire.

**B. Sale.** If your employment is terminated during the Restricted Period and the Company determines that such termination resulted from the sale of your subsidiary, division or joint venture, the following portion of your RSU Award and accrued dividend equivalents will be distributed to you at such time as it would have been paid if your employment had continued: one-third if employment terminates on or after the Grant Date but before the first anniversary thereof; and all if employment terminates on or after the first anniversary of the Grant Date. The remainder will be forfeited on the date your employment ends. If your employment is terminated as described in this paragraph and you are later rehired by the Company or JV, this grant nevertheless will expire according to this paragraph notwithstanding such rehire.

C. Involuntary Termination. If the company determines that your employment is involuntarily terminated during the Restricted Period but on or after the First Anniversary, a pro rata portion of your unvested RSU Award and accrued dividend equivalents will be distributed to you at such time as they would have been paid if your employment had continued. The pro rata portion will equal the full amount of this RSU Award (whether or not vested) times the number of completed months during the Restricted Period and prior to the date employment terminates, divided by 36; reduced by the number of RSUs that have vested pursuant to Paragraph A. The remainder and any accrued dividends will be forfeited on the date your employment ends. An "involuntary termination" includes termination of your employment by the Company as the result of a restructuring or job elimination, but excludes nonperformance of your duties and the reasons listed under paragraphs B, or D through H of this section. If your employment is terminated as described in this paragraph and you are later rehired by the Company or JV, this grant nevertheless will expire according to this paragraph notwithstanding such rehire.

**D. Retirement.** If your employment terminates by retirement during the Restricted Period, a pro rata portion of your unvested RSU Award and accrued dividend equivalents will be distributed to you at such time as they would have been paid if your employment had continued. The pro rata portion will equal the full amount of this RSU Award (whether or not vested) times the number of completed months during the Restricted Period and prior to the date employment terminates,

divided by 36; reduced by the number of RSUs that have vested pursuant to Paragraph A. The

remainder and any accrued dividends will be forfeited on the date your employment ends. For grantees who are employed in the U.S., "retirement" means a termination of employment after attaining the earliest of (a) age 55 with at least 10 years of service (b) such age and service that provides eligibility for subsidized retiree medical coverage or (c) age 65 without regard to years of service. For other grantees, "retirement" is determined by the Company. If your employment is terminated as described in this paragraph and you are later rehired by the Company or JV, this grant nevertheless will expire according to this paragraph notwithstanding such rehire.

E. Death. If your employment terminates due to your death during the Restricted Period, all of this RSU Award and accrued dividend equivalents will be distributed to your estate as soon as possible after your death. If you die during the Restricted Period but after your employment terminates for the reasons listed under paragraphs B, C, D, G or H of this section, the remaining, non-forfeited portion of this RSU Award and accrued dividend equivalents will be distributed to your estate as soon as possible after your death.

F. **Misconduct.** If your employment is terminated as a result of your deliberate, willful or gross misconduct, this RSU Award and accrued dividend equivalents will be forfeited immediately upon your receipt of notice of such termination.

**G. Disability.** If your employment is terminated during the Restricted Period and the Company determines that such termination resulted from inability to perform the material duties of your role by reason of a physical or mental infirmity that is expected to last for at least six months or to result in your death, whether or not you are eligible for disability benefits from any applicable disability program, then this RSU Award will continue and be distributable in accordance with its terms as if employment had continued and will be distributed at the time active RSU Grantees receive distributions with respect to this RSU Award.

Change in Control. If the Company involuntarily terminates your employment Н. during the Restricted Period without Cause before the second anniversary after the closing of any change in control, then this RSU Award will continue in accordance with its terms as if employment had continued and will be distributed at the time active RSU Grantees receive distributions with respect to this RSU Award. If this RSU does not remain outstanding following the change in control and is not converted into a successor RSU, then you will be entitled to receive cash for this RSU in an amount equal to the fair market value of the consideration paid to Merck stockholders for a share of Merck common stock in the change in control payable within 30 days of the closing of the change in control. On the second anniversary of the closing of the change in control, this paragraph shall expire. Change in control is defined in the Merck & Co., Inc. Change in Control Separation Benefits Plan (excluding an MSD Change in Control), but if RSUs are considered "deferred compensation" under Section 409A of the Internal Revenue Code, the definition of change in control will be modified to the extent necessary to comply with Section 409A.

I. Joint Venture. Employment with a joint venture or other entity in which the Company has a significant business or ownership interest is not considered termination of employment for purposes of this RSU Award. Such employment must be approved by, and contiguous with employment by, the Company. The terms set out in paragraphs A-H above apply to this RSU Award while you are employed by the joint venture or other entity.

#### III. TRANSFERABILITY

This RSU Award is not transferable and may not be assigned or otherwise transferred.

#### **IV. ADMINISTRATION**

The Committee is responsible for construing and interpreting this grant, including the right to construe disputed or doubtful plan provisions, and may establish, amend and construe such rules and regulations as it may deem necessary or desirable for the proper administration of this grant. Any decision or action taken or to be taken by the Committee, arising out of or in connection with the construction, administration, interpretation and effect of this grant shall, to the maximum extent permitted by applicable law, be within its absolute discretion (except as otherwise specifically provided herein) and shall be final, binding and conclusive upon the Company, all eligible employees and any person claiming under or through any eligible employee. All determinations by the Committee including, without limitation, determinations of the eligible employees, the form, amount and timing of incentives, the terms and provisions of incentives and the writings evidencing incentives, need not be uniform and may be made selectively among eligible employees who receive, or are eligible to receive, Incentives hereunder, whether or not such eligible employees are similarly situated.

#### V. GRANTS NOT PART OF EMPLOYMENT CONTRACT

Notwithstanding reference to grants of incentives in letters offering employment or in specific employment agreements, incentives do not constitute part of any employment contract between the Company or JV and the grantee, whether the employment contract arises as a matter of agreement or applicable law. The value of any grant or of the proceeds of any exercise of incentives are not included in calculating compensation for purposes of pension payments, separation pay, termination indemnities or other similar payments due upon termination of employment.

This RSU Award is subject to the provisions of the 2010 Incentive Stock Plan. For further information regarding your RSU Award, you may access the Merck Global Long-Term Incentives homepage via <u>http://onemerck.com</u>

Unless you notify the Company in writing that you wish to refuse this grant within 60 days of the Grant Date, you will be deemed to acknowledge that you have read, understood and agree to all of the terms, conditions and provisions of this document and the Merck & Co., Inc. 2010 Incentive Stock Plan.

If you wish to reject this grant, you must send your written notice of rejection to the Company at:

Attention: Global Executive Compensation and Benefits Merck & Co., Inc. 2000 Galloping Hill Road, Building K-1 Kenilworth, New Jersey, U.S.A. 07033

#### Appendix A Recoupment of Compensation for Compliance Violations

#### POLICIES AND PROCEDURES

#### Policy

It is the policy of the Compensation and Benefits Committee of the Board of Directors (the "Committee") that the Committee will exercise its discretion to determine whether to seek Recoupment of any bonus and/or other incentive compensation paid or awarded to an Affected Employee with respect to any performance period beginning after December 31, 2013, where it determines, in consultation with the Audit Committee, that: a) the Affected Employee engaged in misconduct, or failed to reasonably supervise an employee who engaged in misconduct, that resulted in a Material Policy Violation relating to the research, development, manufacturing, sales, or marketing of Company products; and b) the Committee concludes that the Material Policy Violation caused Significant Harm to the Company, as those terms are defined in this policy. The Committee's exercise of its discretion may take into account any considerations determined by the Committee to be relevant.

#### Definitions

1. "Recoupment" is defined to include any and all of the following actions to the extent permitted by law: (a) reducing the amount of a current or future bonus or other cash or non-cash incentive compensation award, (b) requiring reimbursement of a bonus or other cash-based incentive compensation award paid with respect to the most recently completed performance period, (c) cancelling all or a portion of a future-vesting equity award, (d) cancelling all or a portion of an equity award that vested within the previous twelve- month period, (e) requiring return of shares paid upon vesting and/or reimbursement of any proceeds received from the sale of an equity award, in each case that vested within the previous twelve-month period, and (f) any other method of reducing the total compensation paid to an employee for any prior twelve-month period or any current or future period.

2. A "Material Policy Violation" is defined as a material violation of a Company policy relating to the research, development, manufacturing, sales, or marketing of Company products.

3. An "Affected Employee" is an employee in Band 600 or higher who (i) engaged in misconduct that results in a Material Policy Violation; or (ii) failed in his or her supervisory responsibilities to reasonably manage or monitor the conduct of an employee who engaged in misconduct that results in a Material Policy Violation.

4. "Significant Harm" means a significant negative impact on the Company's financial operating results or reputation.

#### Procedures

1. The Committee, acting in consultation with the Audit Committee, shall administer this policy and have full discretion to interpret and to make any and all determinations under this policy, subject to the approval of the full Board of Directors in the case of a determination to seek or waive Recoupment from the Chief Executive Officer.

2. The General Counsel, in consultation with the Chief Ethics and Compliance Officer and the Executive Vice President, Human Resources, is responsible for determining whether to refer a matter to the Committee for review under this policy and for assisting the Committee with its review. The Committee may consult with other Board Committees and any external or internal advisors as it deems appropriate.

3. If the Committee, acting in consultation with the Audit Committee, determines that there is a basis for seeking Recoupment under this policy, the Committee shall exercise its discretion to determine for each Affected Employee, on an

individual basis, whether, and to what extent and in which manner, to seek Recoupment.

4. In exercising its discretion, the Committee may take into consideration, as it deems appropriate, all of the facts and circumstances of the particular matter and the general interests of the Company.

#### **Delegation to Management for Certain Recoupment Decisions**

The Committee hereby delegates to the Chief Executive Officer (who may further delegate as he deems appropriate) the authority to administer this policy and to make any and all decisions under it regarding Affected Employees who are not Section 16 Officers of the Company. Section 16 Officers are employees of the Company who are subject to Section 16 of the Securities Exchange Act of 1934. Management shall report to the Committee on any affirmative decisions to seek Recoupment pursuant to this delegation.

#### **Disclosure of Recoupment Decisions**

The Company will comply with all applicable securities laws and regulations, including Securities and Exchange Commission disclosure requirements regarding executive compensation. The Company may also, but is not obligated to, provide additional disclosure beyond that required by law when the Company deems it to be appropriate and determines that such disclosure is in the best interest of the Company and its shareholders.

#### Miscellaneous

Nothing in this policy shall limit or otherwise affect any of the following: 1) management's ability to take any disciplinary action with respect to any Affected Employee; 2) the Committee's ability to use its negative discretion with respect to any incentive compensation performance target at any time; or 3) the Committee's or management's ability to reduce the amount (in whole or in part) of a current or future bonus or other cash or non- cash incentive compensation award to any executive or other employee for any reason as they may deem appropriate and to the extent permitted by law. Nothing in this policy shall replace or otherwise limit or affect the Clawback Policy for EIP Awards Upon Significant Restatement of Financial Results.

MERCK & CO., INC.

# PLAN FOR DEFERRED PAYMENT OF

# DIRECTORS' COMPENSATION

(Effective as Amended and Restated January 1, 2018)

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## MERCK & CO., INC. PLAN FOR DEFERRED PAYMENT OF DIRECTORS' COMPENSATION

## I. PURPOSE

The Merck & Co., Inc. Plan for Deferred Payment of Directors' Compensation ("Plan") provides an unfunded arrangement for directors of Merck & Co., Inc., formerly known as Schering-Plough Corporation ("Merck" or the "Company") prior to the closing date ("Closing Date") of the Agreement and Plan of Merger dated as of March 8, 2009, as amended, by and among Merck & Co., Inc., Schering-Plough Corporation, SP Merger Subsidiary One, Inc. and SP Merger Subsidiary Two, Inc. (the "Transactions"), other than directors that are current employees of the Company or its subsidiaries, to value, account for and ultimately distribute amounts deferred (i) voluntarily in case of annual retainers and Board and committee meeting fees, if any, and (ii) mandatorily in certain other cases as described herein. Prior to the Closing Date, the predecessor to this Plan provided identical benefits to directors of Merck Sharp & Dohme Corp. (formerly Merck & Co, Inc. prior to the Closing Date) ("MSD").

# II. ELECTION OF DEFERRAL, INVESTMENT ALTERNATIVES AND DISTRIBUTION SCHEDULE

## A. <u>Election of Voluntary Deferral Amount</u>

- 1. Prior to December 31 of each year, each director may irrevocably elect (an "Initial Election") to defer, until termination of service as a director or later, 50% or 100% of each of the following (together, the "Voluntary Deferral Amount") with respect to the 12 months beginning April 1 of the next calendar year after such Initial Election:
  - (a) Board retainer
  - (b) Lead Director retainer
  - (c) Committee Chairperson retainer
  - (d) Audit Committee member retainer, and
  - (e) Board and committee meeting fees, if any.
- 2. Prior to commencement of duties as a director or within the first 30 days following commencement of services, a director newly elected or appointed to the Board during a calendar year may make an Initial Election for the portion of the Voluntary Deferral Amount applicable to such director's first year of service (or part thereof).
- 3. The Voluntary Deferral Amount shall be credited as follows: (1) Board and committee meeting fees, if any, that are deferred are credited as of the last business day of each calendar quarter; (2) if the Board retainer, Lead Director retainer, Committee Chairperson retainer and/or Audit Committee member retainer are deferred, a pro-rata share of the deferred retainer is credited as of the last business day of each calendar quarter. The dates as of which the Voluntary Deferral Amount, or parts thereof, are credited to the director's deferred account are hereinafter referred to as the Voluntary Deferral Dates.

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- 4. Once an Initial Election is made, including, effective December's 2008, elections made by directors of MSD prior to the Transactions, it shall continue to apply in successive years on the same terms and conditions until the director makes a new Initial Election.
- 5. Certain directors (the "Schering Directors") who were directors of Schering-Plough Corporation on the Closing Date of the Transactions continued service following the Closing Date. Anything in the Plan to the contrary notwithstanding, the Schering Directors were first eligible to elect Voluntary Deferrals by December 31 of the year that includes the Closing Date. That initial election may not apply earlier than January 1 of the following year and shall continue through April 1 of the second year following the Closing Date.

## B. Mandatory Deferral Amount

- 1. As of the Friday following the Company's Annual Meeting of Shareholders (the "Mandatory Deferral Date"), each director will be credited with an amount equivalent to the annual cash retainer for the 12 month period beginning on the April 1 preceding the Annual Meeting; provided, however, that effective for the 12-month period beginning April 1, 2018 and thereafter, such credit shall instead equal \$185,000 (the "Mandatory Deferral Amount"). The Mandatory Deferral Amount will be measured by the Merck Common Stock account.
- 2. A director newly elected or appointed to the Board after the Mandatory Deferral Date will be credited with a pro rata portion of the Mandatory Deferral Amount applicable to such director's first year of service (or part thereof). Such pro rata portion shall be credited to the director's account as of the first day of such director's service.
- 3. For purposes of the Mandatory Deferral Amount, the Schering Directors shall be treated as if newly elected or appointed to the Board as of the Closing Date.

## C. <u>Automatic Deferral of Executive Committee Fees</u>

Between June 2005, and April 2007, directors of MSD who served as either Chairperson or member of the Board's Executive Committee, in lieu of any cash payment for such service, were credited with an amount provided by way of retainer or meeting fees (the "Automatic Deferral Amount"). The Automatic Deferral Amount is measured by the Merck Common Stock account.

## D. <u>Election of Investment Alternatives</u>

Each Initial Election shall include an election as to the investment alternatives by which the value of amounts deferred will be measured in accordance with Article III, below. Investment alternatives available under this Plan shall be the same as the investment alternatives available from time to time under the Merck & Co., Inc. Deferral Program (the "Executive Deferral Program"); provided, however, that at all times there shall be a Merck Common Stock fund. All investment alternatives other than Merck Common Stock are referred to herein as "Other Investment Alternatives."

#### E. Initial Election of Distribution Schedule

An Initial Election shall include an election of the year during which the Distribution Date (as defined below) shall occur and shall apply to all Voluntary Deferral Amounts, Mandatory Deferral Amounts and Automatic Deferral Amounts credited during the same period. The Distribution Date shall be the 15th day of the month (or, if such day is not a business day, the next business day) of a calendar quarter following the Director's termination of service as a director or such number of years thereafter as would be permitted for distributions elected under the Executive Deferral Program.

## F. Changes to Distribution Schedule

If and to the extent that participants in the Executive Deferral Program are permitted to make re-deferral elections from time to time, participants in this Plan may elect to defer their Distribution Dates subject to the same restrictions applicable under the Executive Deferral Program; provided, however, that no re-deferral election may have the effect of accelerating a distribution prior to a director's termination of service or death.

## G. <u>Unforeseeable Emergency</u>

The Committee shall distribute a participant's deferred amounts if and to the extent a participant applies to receive a distribution due to an Unforeseeable Emergency as defined in Treas. Reg. Sec. 1.409A-3(i) or successor thereto. A participant wishing a hardship distribution must provide the Committee or its delegate with sufficient evidence to prove compliance with Treas. Reg. Sec. 1.409A-3(i). Such a participant's entire account balance may be distributed to satisfy such Unforeseeable Emergency without regard to whether it is invested wholly or partially in Merck Common Stock.

## III. VALUATION OF DEFERRED AMOUNTS

## A. Merck Common Stock

1. *Initial Crediting*. The annual Mandatory Deferral Amount shall be used to determine the number of full and partial shares of Merck Common Stock that such amount would purchase at the closing price of the Common Stock on the New York Stock Exchange ("NYSE") on the Mandatory Deferral Date.

The Automatic Deferral Amount is used to determine the number of full and partial shares of Merck Common Stock that such amount would have purchased at the closing price of the Common Stock on the NYSE.

That portion of the Voluntary Deferral Amount allocated to Merck Common Stock shall be used to determine the number of full and partial shares of Merck Common Stock that such amount would purchase at the closing price of the Common Stock on the NYSE on the applicable Voluntary Deferral Date.

This Plan is unfunded: at no time will any shares of Merck Common Stock be purchased or earmarked for such deferred amounts nor will any rights of a shareholder exist with respect to such amounts.

- 2. *Dividends*. Each director's account will be credited with the additional number of full and partial shares of Merck Common Stock that would have been purchasable with the dividends on shares previously credited to the account at the closing price of the Common Stock on the NYSE on the date each dividend was paid.
- 3. *Distributions.* Distributions from the Merck Common Stock account will be valued at the closing price of Merck Common Stock on the NYSE as of the Distribution Date.
- 4. For purposes of valuation of Merck Common Stock, if Merck Common Stock is no longer traded on the NYSE, but is publicly traded on any other exchange, references to NYSE shall mean such other exchange. If Merck Common Stock is not publicly traded and if the Governance, Public Policy and Corporate Responsibility Committee of the Board of Directors (formerly known as the Committee on Corporate Governance) determines that a measurement of Merck Common Stock on any Mandatory or Voluntary Deferral Date or Distribution Date would not constitute fair market value, then the Committee shall decide on the date and method to determine fair market value, which shall be in accord with any requirements set forth under Section 409A or any successor thereto.

## B. Other Investment Alternatives

1. *Initial Crediting.* The amount allocated to each Other Investment Alternative shall be used to determine the full and partial Other Investment Alternative shares that such amount would purchase at the closing net asset value of the Other Investment Alternative shares on the Mandatory or Voluntary Deferral Date, whichever is applicable. The director's account will be credited with the number of full and partial Other Investment Alternative shares so determined.

At no time will any Other Investment Alternative shares be purchased or earmarked for such deferred amounts nor will any rights of a shareholder exist with respect to such amounts.

- 2. *Dividends*. Each director's account will be credited with the additional number of full and partial Other Investment Alternative shares that would have been purchasable, at the closing net asset value of the Other Investment Alternative shares as of the date each dividend is paid on the Other Investment Alternative shares, with the dividends that would have been paid on the number of shares previously credited to such account (including pro rata dividends on any partial shares).
- 3. *Distributions*. Other Investment Alternative distributions will be valued based on the closing net asset value of the Other Investment Alternative shares as of the Distribution Date.



## C. Adjustments

In the event of a reorganization, recapitalization, stock split, stock dividend, combination of shares, merger, consolidation, rights offering or any other change in the corporate structure or shares of the Company or an Other Investment Alternative, the number and kind of shares or units shall be adjusted accordingly.

## IV. REDESIGNATION WITHIN A DEFERRAL ACCOUNT

## A. General

A director may redesignate how his or her account is invested among the Other Investment Alternatives (a "Redesignation"). A Redesignation affects only the Investment Alternatives; it does not affect the timing of distributions from the Plan. Except as provided in Section G. of Article II, amounts deferred using the Merck Common Stock method and any earnings attributable to such deferrals may not be redesignated prior to the first anniversary of the termination of the director's service. The change will be effective at the closing price as of (i) the day when the redesignation request is received pursuant to administrative guidelines established by the Human Resources Financial Services area provided the request is received prior to the close of the NYSE on such day or (ii) the next following business day if the request is received when the NYSE is closed.

## B. When Redesignation May Occur

- 1. *During Active Service*. There is no limit on the number of times a director may Redesignate the portion of his/her deferred account permitted to be Redesignated. Each such request shall be irrevocable and can be Redesignated in whole percentages or as a dollar amount.
- 2. *After Death* . Following the death of a director, the legal representative or beneficiary of such director may Redesignate subject to the same rules as for active directors set forth in Article IV, Section B.1.
- C. Valuation of Amounts to be Redesignated

The portion of the director's account to be Redesignated will be valued at its cash equivalent and such cash equivalent will be converted into shares or units of the Other Investment Alternatives. For purposes of such Redesignations, the cash equivalent of the value of the Other Investment Alternative shares shall be the closing net asset value of such Other Investment Alternative as of (i) the day when the Redesignation request is received pursuant to administrative guidelines established by the Human Resources Financial Services area of the Treasury department, provided the request is received prior to the close of the NYSE on such day or (ii) the next following business day if the request is received when the NYSE is closed.

## V. PAYMENT OF DEFERRED AMOUNTS

#### A. <u>Payment</u>

All payments to directors of amounts deferred will be in cash as of the Distribution Date. Distributions shall be pro rata by investment alternative. Distributions shall be paid as soon as administratively feasible after the Distribution Date.

## B. Forfeitures

A director's deferred amount attributable to the Mandatory Deferral Amount and earnings thereon shall be forfeited upon his or her removal as a director or upon a determination by the Governance, Public Policy and Corporate Responsibility Committee, in its sole discretion that, a director has:

- joined the Board of, managed, operated, participated in a material way in, entered employment with, performed consulting (or any other) services for, or otherwise been connected in any material manner with a company, corporation, enterprise, firm, limited partnership, partnership, person, sole proprietorship or any other business entity determined by the Governance, Public Policy and Corporate Responsibility Committee in its sole discretion to be competitive with the business of the Company, its subsidiaries or its affiliates (a "Competitor");
- (ii) directly or indirectly acquired an equity interest of 5 percent or greater in a Competitor; or
- (iii) disclosed any material trade secrets or other material confidential information, including customer lists, relating to the Company or to the business of the Company to others, including a Competitor.

## VI. DESIGNATION OF BENEFICIARY

In the event of the death of a director:

A. The deferred amount at the date of death shall be paid to the last named beneficiary or beneficiaries designated by the director, or, if no beneficiary has been designated, to the legal representative of the director's estate.

B. A lump sum distribution of any remaining account balance will be made to the director's beneficiary or estate's legal representative as soon as administratively feasible following such death, whether or not the director was in service at the time of death or has commenced to receive payments of his or her account balance. The Distribution Date of such a distribution shall be the 15th day of the month (or, if such day is not a business day, the next business day) of the calendar quarter following the date the Company learns of such death.

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## VII. PLAN AMENDMENT OR TERMINATION

The Governance Committee shall have the right to amend or terminate this Plan at any time for any reason.

## VIII. SECTION 409A COMPLIANCE

Anything in the Plan to the contrary notwithstanding, the Plan shall comply with Section 409A of the Internal Revenue Code of 1986, as amended (or any successor thereto) (the "Code") and shall be interpreted in accordance therewith. Any payment called for under the Plan as of or as soon as administratively feasible on or after a designated date shall be made no later than a date within the same tax year of a director, or by March 15 of the following year, if later (or such other time as permitted in Treas. Reg. Sec. 1.409A-3(d) or any successor thereto); provided further, that the director is not permitted to change the taxable year of payment, except in accordance with Article II, Section F and Section 409A of the Code. Where the Plan's obligation to pay is unclear, including a dispute about who is the proper beneficiary of a director who dies, payment shall be made as soon as administratively feasible after the Program's obligation becomes clear and at a time permitted by Treas. Reg. Sec. 1.409A-3(g)(4) or any successor thereto.

## IX. EFFECTIVE DATE.

This amendment and restatement of this plan shall be effective as of January 1, 2018.

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# MERCK & CO., INC. AND SUBSIDIARIES

## Computation of Ratios of Earnings to Fixed Charges

(\$ in millions except ratio data)

	Years Ended December 31,									
	2017		2016		2015		2014		2013	
Income Before Taxes	\$	6,521	\$	4,659	\$	5,401	\$	17,283	\$	5,545
Add (Subtract):										
One-third of rents		109		97		101		117		122
Interest expense, gross		754		693		672		732		801
Interest capitalized, net of amortization		2				(3)		(1)		(2)
Equity (income) loss from affiliates, net of distributions		(41)		(70)		(155)		(72)		(168)
Earnings as defined	\$	7,345	\$	5,379	\$	6,016	\$	18,059	\$	6,298
One-third of rents	\$	109	\$	97	\$	101	\$	117	\$	122
Interest expense, gross		754		693		672		732		801
Preferred stock dividends		—		—		—		86		147
Fixed Charges	\$	863	\$	790	\$	773	\$	935	\$	1,070
Ratio of Earnings to Fixed Charges		9		7		8		19		6

For purposes of computing these ratios, "earnings" consist of income before taxes, one-third of rents (deemed by the Company to be representative of the interest factor inherent in rents), interest expense, interest capitalized, net of amortization and equity (income) loss from affiliates, net of distributions. "Fixed charges" consist of one-third of rents, interest expense as reported in the consolidated financial statements and dividends on preferred stock. Interest expense does not include interest related to uncertain tax positions.

# MERCK & CO., INC. SUBSIDIARIES as of 12/31/2017

The following is a list of subsidiaries of the Company, doing business under the name stated.

Name	Country or State <u>of Incorporation</u>
7728026 Canada Inc.	Canada
Aacifar-Produtos Quimicos e Farmaceuticos, Sociedade Unipessoal, Lda	Portugal
Abmaxis Inc.	Delaware
Afferent Pharmaceuticals, Inc.	California
Animal Health Registration World Wide (Proprietary) Limited	South Africa
Aptus Health Holdings, Inc.	Delaware
Aptus Health International, Inc.	Delaware
Aptus Health, Inc.	Delaware
Aquaculture Holdings Limited	United Kingdom
Aquaculture Vaccines Limited	United Kingdom
Ark Products Limited	United Kingdom
AVL Holdings Limited	United Kingdom
Banyu Pharmaceutical Company, Ltd.	Japan
BRC Ltd.	Bermuda
Burgwedel Biotech GmbH	Germany
C3i (UK) Limited	United Kingdom
C3i Europe EOOD	Bulgaria
C3i Japan GK	Japan
C3i Services & Technology (Dalian) Co. Ltd.	China
C3i Support Services Private Limited	India
Canji, Inc.	Delaware
cCam Biotherapeutics Ltd.	Israel
Cherokee Pharmaceuticals LLC	Delaware
Comsort, Inc.	Delaware
Continuum Professional Services Limited	United Kingdom
Cooper Veterinary Products (Proprietary) Limited	South Africa
Coopers Animal Health Limited	United Kingdom
Cosmas B.V.	Netherlands
Cubist (UK) Ltd	United Kingdom
Cubist Pharmaceuticals (UK) Ltd.	United Kingdom
Cubist Pharmaceuticals GmbH	Switzerland
Cubist Pharmaceuticals LLC	Delaware
Dashtag	United Kingdom
Desarrollos Farmaceuticos Y Cosmeticos, S.A.	Spain
Dieckmann Arzneimittel GmbH	Germany
Diosynth France	France
Diosynth Holding B.V.	Netherlands
Diosynth Limited	United Kingdom
Diosynth Produtos Farmo-quimicos Ltda.	Brazil
Elastec S.R.L	Argentina
Essex Italia s.r.l.	Italy

Essex Pharmaceuticals, Inc. Essexfarm, S.A. European Insurance Risk Excess Designated Activity Company Farmacox-Companhia Farmaceutica, Sociedade Unipessoal, Lda Farmasix-Produtos Farmaceuticos, Sociedade Unipessoal, Lda Financiere MSD Fontelabor-Produtos Farmaceuticos, Sociedade Unipessoal, Lda. Frosst Laboratories, Inc. Frosst Portuguesa - Produtos Farmaceuticos, Sociedade Unipessoal, Lda. Fulford (India) Limited 1 Global Safety Surveillance LLC GlycoFi, Inc. Hangzhou MSD Pharmaceutical Co., Ltd.<sup>1</sup> Harrisvaccines, Inc. Hawk and Falcon L.L.C. Healthcare Services and Solutions, LLC Heptafarma - Companhia Farmacêutica, Sociedade Unipessoal, Lda. HMR Weight Management Services Corp. HSS Life-Science Holdings, LLC HSS Life-Science Solutions, LLC Hydrochemie GmbH Idenix GmbH Idenix Pharmaceuticals LLC Idenix SARL International Indemnity Ltd. Intervet (Ireland) Limited Intervet (Israel) Ltd. Intervet (M) Sdn. Bhd. Intervet (Proprietary) Limited Intervet (Thailand) Ltd. Intervet AB Intervet Agencies B.V. Intervet Animal Health Production B.V. Intervet Animal Health Taiwan Limited Intervet Argentina S.A. Intervet Australia Pty Limited Intervet Bulgaria EOOD Intervet Canada Corp. Intervet Central America S. de R.L. Intervet Colombia Ltda Intervet Deutschland GmbH Intervet Ecuador S.A. Intervet Egypt for Animal Health SAE Intervet GesmbH Intervet Hellas A.E. Intervet Holding B.V. Intervet Holdings France SAS Intervet Hungaria Ertékesitő Korlátolt Felelősségu Tarsaság Intervet Inc.

Philippines Ecuador Ireland Portugal Portugal France Portugal Delaware Portugal India Delaware Delaware China Iowa Delaware Delaware Portugal Delaware Delaware Delaware Germany Switzerland Delaware France Bermuda Ireland Israel Malaysia South Africa Thailand Sweden Netherlands Netherlands Taiwan (Republic of China) Argentina Australia Bulgaria Canada Panama Colombia Germany Ecuador Egypt Austria Greece Netherlands France Hungary Delaware



Intervet India Pvt Limited Intervet International B.V. Intervet International GmbH Intervet International Sarl Intervet K.K. Intervet LLC Intervet Maroc S.A. Intervet Mexico S.A. de C.V. Intervet Middle East Limited Intervet Nederland B.V. Intervet Oy Intervet Philippines, Inc. Intervet Productions S.A. Intervet Productions Srl Intervet Romania SRL Intervet S.A. Intervet SAS Intervet Schering-Plough Animal Health Pty Ltd Intervet South Africa (Proprietary) Limited Intervet Sp. z.o.o. Intervet UK Limited Intervet UK Production Limited Intervet Venezolana SA Intervet Veterinaria Chile Ltda Intervet Veteriner Ilaclari Pazarlama ve Ticaret Ltd. Sirketi Intervet, s.r.o. Interveterinaria SA de CV IOmet Pharma Ltd. Kirby-Warrick Pharmaceuticals Limited Laboratoires Merck Sharp & Dohme-Chibret Laboratorios Abello, S.A. Laboratorios Biopat, S.A. Laboratorios Chibret, S.A. Laboratorios Frosst, S.A. Laboratorios Quimico-Farmaceuticos Chibret, Sociedade Unipessoal, Lda. Livestock Nutrition Technologies Pty. Ltd. Maple Leaf Holdings GmbH Marketing Communications of North Carolina, LLC<sup>1</sup> Maya Tibbi Urunler Ticaret Limited Sirketi MCM Vaccine B.V.<sup>1</sup> MCM Vaccine Co.<sup>1</sup> Med Help International, Inc. Med-Nim (Proprietary) Limited Merck and Company, Incorporated Merck Canada Inc. Merck Capital Ventures, LLC<sup>1</sup> Merck Frosst Canada & Co. Merck Frosst Company Merck Global Health Innovation Fund, LLC

India Netherlands Germany France Japan Russian Federation Morocco Mexico Cyprus Netherlands Finland Philippines France Italy Romania Peru France Australia South Africa Poland United Kingdom United Kingdom Venezuela Chile Turkey Czech Republic Mexico United Kingdom United Kingdom France Spain Spain Spain Spain Portugal Australia Switzerland Delaware Turkey Netherlands Pennsylvania Delaware South Africa Delaware Canada Delaware Canada Canada Delaware



Merck Global Health Innovation, Private Equity, LLC Merck Global Research LLC Merck HDAC Research, LLC Merck Holdings II Corp. Merck Holdings III Corp. Merck Holdings IV Corp. Merck Holdings LLC Merck Lumira Biosciences Fund L.P.<sup>1</sup> Merck Registry Holdings, Inc. Merck SH Inc. Merck Sharp & Dohme (Argentina) Inc. Merck Sharp & Dohme (Asia) Limited Merck Sharp & Dohme (Australia) Pty. Limited Merck Sharp & Dohme (Chile) Ltda. Merck Sharp & Dohme (China) Limited Merck Sharp & Dohme (Enterprises) B.V. Merck Sharp & Dohme (Europe) Inc. Merck Sharp & Dohme (Holdings) Limited Merck Sharp & Dohme (Holdings) Pty Ltd Merck Sharp & Dohme (I.A.) LLC Merck Sharp & Dohme (International) Limited Merck Sharp & Dohme (Israel - 1996) Company Ltd. Merck Sharp & Dohme (Malaysia) SDN. BHD. Merck Sharp & Dohme (New Zealand) Limited Merck Sharp & Dohme (Sweden) A.B. Merck Sharp & Dohme (Switzerland) GmbH Merck Sharp & Dohme Animal Health, S.L. Merck Sharp & Dohme Asia Pacific Services Pte. Ltd. Merck Sharp & Dohme B.V. Merck Sharp & Dohme BH d.o.o. Merck Sharp & Dohme Bulgaria EOOD Merck Sharp & Dohme Colombia S.A.S. Merck Sharp & Dohme Comercializadora, S. de R.L. de C.V. Merck Sharp & Dohme Corp. Merck Sharp & Dohme Cyprus Limited Merck Sharp & Dohme d.o.o. Merck Sharp & Dohme d.o.o. Belgrade Merck Sharp & Dohme de Espana SAU Merck Sharp & Dohme Farmaceutica Ltda. Merck Sharp & Dohme Finance Europe Limited Merck Sharp & Dohme Gesellschaft m.b.H. Merck Sharp & Dohme IDEA AG Merck Sharp & Dohme inovativna zdravila d.o.o. Merck Sharp & Dohme International Services B.V. Merck Sharp & Dohme Ireland (Human Health) Ltd Merck Sharp & Dohme Limited Merck Sharp & Dohme Manufacturing Unlimited Company Merck Sharp & Dohme OU Merck Sharp & Dohme Peru SRL

Delaware Delaware Delaware Delaware Delaware Delaware Delaware Canada New Jersey Delaware Delaware Hong Kong Australia Chile Hong Kong Netherlands Delaware United Kingdom Australia Delaware Bermuda Israel Malaysia New Zealand Sweden Switzerland Spain Singapore Netherlands Bosnia Bulgaria Colombia Mexico New Jersey Cyprus Croatia Serbia Spain Brazil United Kingdom Austria Switzerland Slovenia Netherlands Ireland United Kingdom Ireland Estonia Peru



Merck Sharp & Dohme Pharmaceutical Industrial and Commercial Societe Anonyme Merck Sharp & Dohme Research GmbH Merck Sharp & Dohme Romania SRL Merck Sharp & Dohme S.A. Merck Sharp & Dohme s.r.o. Merck Sharp & Dohme Saude Animal Ltda. Merck Sharp & Dohme SIA Merck Sharp & Dohme Singapore Trading Pte. Ltd. Merck Sharp & Dohme Tunisie SARL Merck Sharp & Dohme, Lda. Merck Sharp & Dohme, S. de R.L. de C.V. Merck Sharp & Dohme, s.r.o. Merck Sharp Dohme Ilaclari Limited Sirketi ML Holdings (Canada) Inc. MMUSA Acquisition II Corp.<sup>1</sup> MRL Cambridge ESC, LLC MRL San Francisco, LLC MRL Ventures Fund LLC MSD (I.A.) B.V. MSD (L-SP) Unterstützungskasse GmbH MSD (Nippon Holdings) B.V. MSD (Norge) AS MSD (Proprietary) Limited MSD (Shanghai) Pharmaceuticals Consultancy Co., Ltd. MSD (Thailand) Ltd. MSD Access Sdn. Bhd. MSD Animal Health (Phils.), Inc MSD Animal Health (Shanghai) Trading Co., Ltd. MSD Animal Health A/S MSD Animal Health BVBA MSD Animal Health Danube Biotech GmbH MSD Animal Health FZ-LLC MSD Animal Health GmbH MSD Animal Health Innovation AS MSD Animal Health Innovation GmbH MSD Animal Health Innovation Pte. Ltd. MSD Animal Health Innovation SAS MSD Animal Health Korea Ltd. MSD Animal Health Limited MSD Animal Health Norge AS MSD Animal Health Pension Trustee Limited MSD Animal Health S.r.l. MSD Animal Health Vietnam Co. Ltd. MSD Animal Health, Lda. MSD Argentina Holdings B.V. MSD Argentina SRL MSD Asia Holdings Pte. Ltd. MSD Belgium BVBA/SPRL

Greece Switzerland Romania Morocco Czech Republic Brazil Latvia Singapore Tunisia Portugal Mexico Slovakia Turkey Canada Delaware Delaware Delaware Delaware Netherlands Germany Netherlands Norway South Africa China Thailand Malaysia Philippines China Denmark Belgium Austria United Arab Emirates Switzerland Norway Germany Singapore France Korea, Republic of United Kingdom Norway United Kingdom Italy Viet Nam Portugal Netherlands Argentina Singapore Belgium

MSD Biopharma B.V. MSD Brazil Investments B.V. MSD Central America Services S. de R.L. MSD China (Investments) B.V. MSD China B.V. MSD China Holding Co., Ltd. MSD Consumer Care Limited MSD Cubist Holdings Unlimited Company MSD Danmark ApS MSD Egypt LLC MSD EIC Unlimited Company MSD Eurofinance MSD Farmaceutica C.A. MSD FI BV MSD Finance 2 LLC MSD Finance B.V. MSD Finance Company MSD Finance Holding NL B.V. MSD Finance Holdings Unlimited Company MSD Finland Oy MSD France MSD Global Research GmbH MSD Holdings (Ireland) Unlimited Company MSD Holdings 2 G.K. MSD Holdings G.K. MSD Human Health Holding B.V. MSD IDEA Pharmaceuticals Nigeria Limited MSD IDEA Tunisie MSD Idenix Holdings Unlimited Company MSD International Finance B.V. MSD International Finance LLC MSD International GmbH MSD International Holdings 2 B.V. MSD International Holdings GmbH MSD International Investment Holdings Unlimited Company MSD International Manufacturing GmbH MSD Investment Holdings (Ireland) Unlimited Company MSD Investments (Holdings) GmbH MSD IT Global Innovation Center s.r.o. MSD Italia s.r.l. MSD K.K. MSD Korea Ltd. MSD Laboratories India LLC MSD Latin America Services S. de R.L. MSD Latin America Services S. de R.L. de C.V. MSD Limited MSD Luxembourg S.a.r.l. MSD Merck Sharp & Dohme AG MSD Mexico Investments B.V.

Netherlands Netherlands Panama Netherlands Netherlands China United Kingdom Ireland Denmark Egypt Ireland Bermuda Venezuela Netherlands Delaware Netherlands Bermuda Netherlands Ireland Finland France Switzerland Ireland Japan Japan Netherlands Nigeria Tunisia Ireland Netherlands Delaware Switzerland Netherlands Switzerland Ireland Switzerland Ireland Switzerland Czech Republic Italy Japan Korea Delaware Panama Mexico United Kingdom Luxembourg Switzerland Netherlands



MSD NL 2 B.V. MSD NL 4 B.V. MSD Oncology Holdings Limited MSD Overseas Manufacturing Co (Ireland) Unlimited Company MSD Panama International Services S. de R.L. MSD Participations B.V. MSD Pharma (Singapore) Pte. Ltd. MSD Pharma GmbH MSD Pharma Hungary Korlatolt Felelossegu Tarsasag MSD Pharmaceuticals MSD Pharmaceuticals Holdings Unlimited Company MSD Pharmaceuticals Investments 1 Unlimited Company MSD Pharmaceuticals Investments 3 Unlimited Company MSD Pharmaceuticals Ireland Unlimited Company MSD Pharmaceuticals Private Limited MSD Polska Dystrybucja Sp. z.o.o. MSD Polska Sp.z.o.o. MSD R&D (China) Co., Ltd. MSD R&D Innovation Centre Limited MSD RDC Costa Rica Sociedad de Responsabilidad Limitada MSD Regional Business Support Center GmbH MSD Registry Holdings, Inc. MSD Shared Business Services EMEA Limited MSD Sharp & Dohme Gesellschaft mit beschränkter Haftung MSD Switzerland Investments 1 Unlimited Company MSD Switzerland Investments 4 Unlimited Company MSD Switzerland Investments 5 Limited MSD Ukraine Limited Liability Company MSD Unterstutzungskasse GmbH MSD Vaccines (Ireland) Limited MSD Vaccines AG MSD Vaccines GmbH MSD Vaccines GmbH MSD Vaccines Limited MSD Vaccines S.A. MSD Vaccines S.p.A. MSD Vaccines Sweden A.B. MSD Vaccines, S.A. MSD Vaccins MSD Vaccins Holdings MSD Venezuela Holding GmbH MSD Ventures (Ireland) Unlinmited Company MSD Verwaltungs GmbH MSD Vietnam Company Limited MSD Vietnam Holdings B.V. MSD Vostok B.V. MSDRG LLC MSD-SP Ltd. MSD-SUN, LLC<sup>1</sup>

Netherlands Netherlands United Kingdom Ireland Panama Netherlands Singapore Germany Hungary Russian Federation Ireland Ireland Ireland Ireland India Poland Poland China United Kingdom Cost Rica Germany New Jersey Ireland Germany Ireland Ireland Ireland Ukraine Germany Ireland Switzerland Austria Germany United Kingdom Portugal Italy Sweden Spain France France Switzerland Ireland Germany Vietnam Netherlands Netherlands Delaware United Kingdom Delaware



MSP Singapore Company, LLC Multilan AG Mycofarm UK Limited N.V. Organon Nanjing Organon Pharmaceutical Co., Ltd. Nihon MSD G.K. Nourifarma - Produtos Químicos e Farmaceuticos, Sociedade Uniperssoal, Lda OBS Holdings B.V. Oncoethix GmbH Optimer Pharmaceuticals LLC Organon (India) Private Limited Organon (Ireland) Ltd Organon (Philippines) Inc. Organon Agencies B.V. Organon BioSciences International B.V. Organon BioSciences Ventures B.V. Organon China B.V. Organon Dominicana SA Organon Egypt Ltd Organon Laboratories Limited Organon Latin America S.A. Organon Middle East S.A.L. Organon Participations B.V. Organon Teknika Corporation LLC Organon USA Inc. P.T. Merck Sharp & Dohme Indonesia PI International PVT LTD. Pitman-Moore Saude Animal Comercio e Distribuicao de Produtos Veterinarios Plough (U.K.) Limited Preventice Solutions, Inc. Prondil S.A. PT Intervet Indonesia PT Merck Sharp Dohme Pharma Tbk<sup>1</sup> PT Organon Indonesia Rigontec GmbH Rigontec, Inc. Rosetta Biosoftware UK Limited Rosetta Inpharmatics LLC Schering-Plough Schering-Plough (India) Private Limited Schering-Plough (Ireland) Unlimited Company Schering-Plough Animal Health Limited Schering-Plough Bermuda Ltd. Schering-Plough Canada Inc. Schering-Plough Central East AG Schering-Plough Clinical Trials, S.E. Schering-Plough Corporation Schering-Plough Corporation, U.S.A. Schering-Plough del Ecuador, S.A.

Delaware Switzerland United Kingdom Netherlands China Japan Portugal Netherlands Switzerland Delaware India Ireland Philippines Netherlands Netherlands Netherlands Netherlands Dominican Republic Egypt United Kingdom Uruguay Lebanon Netherlands Delaware New Jersey Indonesia United Kingdom Brazil United Kingdom Delaware Uruguay Indonesia Indonesia Indonesia Germany Delaware United Kingdom Delaware France India Ireland New Zealand Bermuda Canada Switzerland United Kingdom Philippines Delaware Ecuador



Schering-Plough del Peru S.A. Schering-Plough Holdings Limited Schering-Plough Indústria Farmacêutica Ltda. Schering-Plough Int Limited Schering-Plough Labo NV Schering-Plough Limited Schering-Plough Limited Schering-Plough Maroc S.a.R.L. Schering-Plough S.A. Schering-Plough S.A. Schering-Plough S.A. Schering-Plough S.A. Schering-Plough S.A. de C.V. Schering-Plough Sante Animale Sentipharm AG Servicios Veterniarios Servet, Sociedad Anónima Shanghai MSD Pharmaceutical Trading Co., Ltd. ShareWIK, LLC 1 Sinova AG<sup>1</sup> Skyscape.Com India Private Limited SmartCells, Inc. SOL Limited S-P Ril Ltd. S-P Veterinary (UK) Limited S-P Veterinary Holdings Limited S-P Veterinary Limited S-P Veterinary Pensions Limited StayWell Health Management, LLC<sup>1</sup> StayWell Interactive, LLC<sup>1</sup> Supera Rx Medicamentos Ltda. 1 Tasman Vaccine Laboratory (UK) Ltd TELERx Marketing Inc. Teqqa, Inc. The StayWell Company, LLC<sup>1</sup> Theriak B.V. Tomorrow Networks, LLC Trius Therapeutics LLC UAB Merck Sharp & Dohme Undra, S.A. de C.V. Vallée S.A.<sup>1</sup> Venco Farmaceutica S.A. Venco Holding GmbH Vet Pharma Friesoythe GmbH Veterinaria Premium, Sociedad Anonima VetInvent, LLC Vetrex B.V. Vetrex Egypt L.L.C. Vetrex Limited Vilsan Veteriner Ilaclari Ticaret ve Sanayi Anonim Sirketi

Peru United Kingdom Brazil United Kingdom Belgium Taiwan (Republic of China) United Kingdom Morocco Panama Paraguay Spain Uruguay Mexico France Switzerland Costa Rica China Delaware Switzerland India Delaware Bermuda United Kingdom United Kingdom United Kingdom United Kingdom United Kingdom Delaware Delaware Brazil United Kingdom Pennsylvania Wyoming Delawarae Netherlands Delaware Delaware Lithuania Mexico Brazil Venezuela Switzerland Germany Guatemala Delaware Netherlands Egypt United Kingdom Turkey



Vree Health Italia S.r.l. Vree Health LLC Vree Health Ltd. Werthenstein Biopharma GmbH Zoöpharm B.V. Italy Delaware United Kingdom Switzerland Netherlands

<sup>1</sup> own less than 100%

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#### CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-208308, 333-208306 and 333-164482) and on Form S-8 (Nos. 333-173025, 333-173024, 333-162882, 333-162883, 333-162884, 333-162885, 333-162886, 333-134281 and 333-121089) of Merck & Co., Inc. of our report dated February 27, 2018 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

<u>/s/ PricewaterhouseCoopers LLP</u> PricewaterhouseCoopers LLP Florham Park, New Jersey February 27, 2018

## POWER OF ATTORNEY

Each of the undersigned does hereby appoint MICHAEL J. HOLSTON as his/her true and lawful attorney to execute on behalf of the undersigned (whether on behalf of the Company, or as an officer or director thereof, or by attesting the seal of the Company, or otherwise) the Annual Report on Form 10-K of Merck & Co., Inc. for the fiscal year ended December 31, 2017 under the Securities Exchange Act of 1934, including amendments thereto and all exhibits and other documents in connection therewith.

IN WITNESS WHEREOF, this instrument has been duly executed as of the 27 th day of February 2018.

MERCK & CO., Inc.

/s/ Kenneth C. Frazier Chairman, President and Chief Executive Officer (Principal Executive Officer; Director) Kenneth C. Frazier Executive Vice President, Chief Financial Officer /s/ Robert M. Davis and Global Services (Principal Financial Officer) Robert M. Davis /s/ Rita A. Karachun Senior Vice President Finance-Global Controller (Principal Accounting Officer) Rita A. Karachun DIRECTORS /s/ Leslie A. Brun /s/ Carlos E. Represas Leslie A. Brun Carlos E. Represas /s/ Thomas R. Cech /s/ Paul B. Rothman Paul B. Rothman Thomas R. Cech /s/ Patricia F. Russo /s/ Pamela J. Craig Patricia F. Russo Pamela J. Craig /s/ Thomas H. Glocer /s/ Craig B. Thompson Thomas H. Glocer Craig B. Thompson /s/ Rochelle B. Lazarus /s/ Wendell P. Weeks Rochelle B. Lazarus Wendell P. Weeks /s/ John H. Noseworthy /s/ Peter C. Wendell Peter C. Wendell John H. Noseworthy

I, Faye C. Brown, Senior Assistant Secretary of Merck & Co., Inc. (the "Company"), a corporation duly organized and existing under the laws of the State of New Jersey, do hereby certify that the following is a true copy of a resolution adopted by unanimous written consent of the Board of Directors of said Company on February 23, 2018 in accordance with the provisions of the By-Laws of said Company:

#### "Special Resolution No. 10-2018

RESOLVED, that the proposed form of the Annual Report on Form 10-K of the Company for the fiscal year ended December 31, 2017, attached hereto, is hereby approved with such changes as the proper officers of the Company, with the advice of counsel, deem appropriate; and

FURTHER RESOLVED, that each officer and director who may be required to execute the aforesaid Annual Report on Form 10-K or any amendments thereto (whether on behalf of the Company or as an officer or director thereof, or by attesting the seal of the Company, or otherwise) is hereby authorized to execute a power of attorney appointing Michael J. Holston as his/her true and lawful attorney to execute in his/her name, place and stead (in any such capacity) such Annual Report on Form 10-K and any and all amendments thereto and any and all exhibits and other documents necessary or incidental in connection therewith and to file the same with the Securities and Exchange Commission, the attorney to have power to act and to have full power and authority to do and perform in the name and on behalf of each of said officers and directors, or both, as the case may be, every act whatsoever necessary or advisable to be done in the premises as fully and to all intents and purposes as any such officer or director might or could do in person; and

FURTHER RESOLVED that an executed copy of the Action by Unanimous Written Consent be filed with the minutes of the meetings of the Board of Directors of the Company."

IN WITNESS WHEREOF, I have hereunto subscribed my signature and affixed the seal of the Company this 27 th day of February 2018.

[Corporate Seal]

/s/ Faye C. Brown

Faye C. Brown Senior Assistant Secretary

#### CERTIFICATION

I, Kenneth C. Frazier, certify that:

1. I have reviewed this annual report on Form 10-K of Merck & Co., Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2018

By: /s/ Kenneth C. Frazier

KENNETH C. FRAZIER Chairman, President and Chief Executive Officer

#### CERTIFICATION

I, Robert M. Davis, certify that:

1. I have reviewed this annual report on Form 10-K of Merck & Co., Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2018

By: /s/ Robert M. Davis

ROBERT M. DAVIS Executive Vice President, Chief Financial Officer & Global Services

## Section 1350 Certification of Chief Executive Officer

Pursuant to 18 U.S.C. Section 1350, the undersigned officer of Merck & Co., Inc. (the "Company"), hereby certifies that the Company's Annual Report on Form 10-K for the year ended December 31, 2017 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 27, 2018

/s/ Kenneth C. Frazier

Name: KENNETH C. FRAZIER Title: Chairman, President and Chief Executive Officer

## Section 1350 Certification of Chief Financial Officer

Pursuant to 18 U.S.C. Section 1350, the undersigned officer of Merck & Co., Inc. (the "Company"), hereby certifies that the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 27, 2018

/s/ Robert M. Davis

Name: ROBERT M. DAVIS Title: Executive Vice President, Chief Financial Officer & Global Services