As filed with the Securities and Exchange Commission on February 26, 2016

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, 2015

or

☐ **Transition Report Pursuant to Section 13 or 15(d)**
of the Securities Exchange Act of 1934
For the transition period from _____ to _____

Commission File No. 1-6571

Merck & Co., Inc.

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

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

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

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

Number of shares of Common Stock ($0.50 par value) outstanding as of January 31, 2016: 2,775,258,591.

Aggregate market value of Common Stock ($0.50 par value) held by non-affiliates on June 30, 2015 based on closing price on June 30, 2015: $160,710,000,000.

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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 (§ 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** ☒ **No** ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐
(Do not check if a smaller reporting company)

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

Documents Incorporated by Reference:

Document	*Part of Form 10-K*
Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2016, to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this report	Part III

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PART I

Item 1. Business.

Merck & Co., Inc. (Merck or the Company) is a global health care company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies and animal health products, which it markets directly and through its joint ventures. The Company's operations are principally managed on a products basis and are comprised of four operating segments, the Pharmaceutical, Animal Health, Alliances and Healthcare Services segments. The Pharmaceutical segment is the only reportable segment. The Pharmaceutical segment includes human health pharmaceutical and vaccine products marketed either directly by the Company or through joint ventures. 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 animal health operations that discover, develop, manufacture and market animal health products, including vaccines, which the Company sells to veterinarians, distributors and animal producers. Merck's Alliances segment primarily includes results from the Company's relationship with AstraZeneca LP until the termination of that relationship on June 30, 2014. 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. On October 1, 2014, the Company divested its Consumer Care segment that developed, manufactured and marketed over-the-counter, foot care and sun care products. 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

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

($ in millions)	**2015**	2014	2013
Total Sales	**$ 39,498**	$ 42,237	$ 44,033
Pharmaceutical	**34,782**	36,042	37,437
Januvia	**3,863**	3,931	4,004
Zetia	**2,526**	2,650	2,658
Janumet	**2,151**	2,071	1,829
Gardasil/Gardasil 9	**1,908**	1,738	1,831
Remicade	**1,794**	2,372	2,271
Isentress	**1,511**	1,673	1,643
ProQuad/M-M-R II/*Varivax*	**1,505**	1,394	1,306
Vytorin	**1,251**	1,516	1,643
Cubicin	**1,127**	25	24
Singulair	**931**	1,092	1,196
Animal Health	**3,324**	3,454	3,362
Consumer Care[1]	**3**	1,547	1,894
Other Revenues[2]	**1,389**	1,194	1,340

[1] *On October 1, 2014, the Company divested its Consumer Care segment that developed, manufactured and marketed over-the-counter, foot care and sun care products.*

[2] *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); and *Vytorin* (ezetimibe/simvastatin) (marketed as *Inegy* outside the United States), cholesterol modifying medicines.

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; *Dulera* Inhalation Aerosol (mometasone furoate/formoterol fumarate dihydrate), a combination medicine for the treatment of asthma; 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), approved by the U.S. Food and Drug Administration (FDA) in January 2016, for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype (GT) 1 or GT4 infection, with or without ribavirin; and *PegIntron* (peginterferon alpha-2b) and *Victrelis* (boceprevir), medicines for the treatment of chronic HCV.

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

Hospital Acute Care: *Cubicin (*daptomycin for injection), an I.V. antibiotic for complicated skin and skin structure infections or bacteremia, when caused by designated susceptible organisms; *Cancidas* (caspofungin acetate), an anti-fungal product; *Invanz* (ertapenem sodium) for the treatment of certain infections; *Noxafil* (posaconazole) for the prevention of invasive fungal infections; *Bridion* (sugammadex) Injection, a medication for the reversal of two types of neuromuscular blocking agents used during surgery; 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) for the treatment of advanced melanoma and metastatic non-small-cell lung cancer (NSCLC) in patients whose tumors express PD-L1 with disease progression following other therapies; *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 *Clarinex* (desloratadine), a non-sedating antihistamine.

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; *Fosamax* (alendronate sodium) (marketed as *Fosamac* in Japan) for the treatment and prevention of osteoporosis; *Zocor* (simvastatin), a statin for modifying cholesterol; and *Propecia* (finasteride), a product for the treatment of male pattern hair loss.

Vaccines

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

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* antibiotic range for use in cattle and swine; *Bovilis*/*Vista* vaccine lines for infectious diseases in cattle; *Banamine* bovine and swine anti-inflammatory; *Estrumate* for the treatment of fertility disorders in cattle; *Matrix* fertility management for swine; *Resflor, a* combination broad-spectrum antibiotic and non-steroidal anti-inflammatory drug for bovine respiratory disease; *Zuprevo* for bovine respiratory disease; *Zilmax* and *Revalor* to improve production efficiencies in beef cattle; *Safe-Guard* de-wormer for cattle; *M+Pac* swine pneumonia vaccine; and *Porcilis* and *Circumvent* vaccine lines for infectious diseases in swine.

Poultry Products: *Nobilis*/*Innovax,* vaccine lines for poultry; and *Paracox* and *Coccivac* coccidiosis vaccines.

Companion Animal Products: *Bravecto*, a chewable tablet that kills fleas and ticks in dogs for up to 12 weeks; *Nobivac* vaccine lines for flexible dog and cat vaccination; *Otomax*/*Mometamax*/*Posatex* ear ointments for acute and chronic otitis; *Caninsulin*/*Vetsulin* diabetes mellitus treatment for dogs and cats; *Panacur*/*Safeguard* broad-spectrum anthelmintic (de-wormer) for use in many animals; *Regumate* fertility management for horses; *Prestige* vaccine line for horses; and *Activyl/Scalibor/Exspot* for protecting against bites from fleas, ticks, mosquitoes and sandflies.

Aquaculture Products: *Slice* parasiticide for sea lice in salmon; *Aquavac*/*Norvax* vaccines against bacterial and viral disease in fish; *Compact PD* vaccine for salmon; and *Aquaflor* 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.

Product Approvals

In January 2016, Merck announced that the FDA approved *Zepatier* for the treatment of adult patients with chronic HCV GT1 or GT4 infection, with or without ribavirin.

In December 2015, Merck announced that the FDA approved an expanded age indication for *Gardasil* 9, Merck's 9-valent HPV vaccine, to include use in males 16 through 26 years of age for the prevention of anal cancers, precancerous or dysplastic lesions and genital warts caused by certain HPV types. *Gardasil* 9 includes the greatest number of HPV types in any available HPV vaccine.

Also, in December 2015, the Company announced that the FDA approved an expanded indication for *Keytruda*, an anti-PD-1 (programmed death receptor-1) therapy, to include the first-line treatment of patients with unresectable or metastatic melanoma. Additionally, the FDA approved an update to the product labeling for *Keytruda* for the treatment of patients with ipilimumab-refractory advanced melanoma.

In October 2015, the FDA granted accelerated approval of *Keytruda* at a dose of 2mg/kg every three weeks for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 as determined by an FDA-approved test and who have 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*. In addition to approving *Keytruda* for NSCLC, the FDA approved the first companion diagnostic that will enable physicians to determine the level of PD-L1 expression in a patient's tumor.

In September 2015, Merck announced that the Japanese Pharmaceuticals and Medical Devices Agency approved *Marizev* (omarigliptin) 25 mg and 12.5 mg tablets, an oral, once-weekly dipeptidyl peptidase-4 (DPP-4) inhibitor indicated for the treatment of adults with type 2 diabetes. Japan is the first country to have approved omarigliptin.

Joint Ventures

Sanofi Pasteur MSD

In 1994, Merck and Pasteur Mérieux Connaught (now Sanofi Pasteur S.A.) formed a joint venture to market human vaccines in Europe and to collaborate in the development of combination vaccines for distribution in the then-existing European Union (EU) and the European Free Trade Association. Merck and Sanofi Pasteur contributed, among other things, their European vaccine businesses for equal shares in the joint venture, known as Pasteur Mérieux MSD, S.N.C. (now Sanofi Pasteur MSD, S.N.C.) (SPMSD). The joint venture maintains a presence, directly or through affiliates or branches, in Belgium, Italy, Germany, Spain, France, Austria, Ireland, Sweden, Portugal, the Netherlands, Switzerland and the United Kingdom (UK) and through distributors in the rest of its territory.

Licenses

In 1998, a subsidiary of Schering-Plough Corporation (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. In 2007, Schering-Plough and Centocor revised their distribution agreement regarding the development, commercialization and distribution of both *Remicade* and *Simponi*, extending the Company's rights to exclusively market *Remicade* to match the duration of the Company's exclusive marketing rights for *Simponi*. In addition, Schering-Plough and Centocor agreed to share certain development costs relating to *Simponi*'s auto-injector delivery system. In 2009, the European Commission (EC) approved *Simponi* as a treatment for rheumatoid arthritis and other immune system disorders in two presentations — a novel auto-injector and a prefilled syringe. As a result, the Company's marketing rights for both products extend for 15 years from the first commercial sale of *Simponi* in the EU following the receipt of pricing and reimbursement approval within the EU. *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.

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 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 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), which began to be implemented in 2010. Various insurance market reforms have advanced and state and federal insurance exchanges were launched in 2014. By the end of the decade, the law is expected to expand access to health care to about 32 million Americans who did not previously have insurance coverage. 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 $550 million, $430 million and $280 million was recorded by Merck as a reduction to revenue in 2015, 2014 and 2013, respectively, related to the donut hole provision. Also, pharmaceutical manufacturers are now required to pay an annual non-tax deductible health care reform fee. The total annual industry fee was $3.0 billion in 2015 and will remain $3.0 billion in 2016. 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 $173 million, $390 million and $151 million of costs within *Marketing and administrative* expenses in 2015, 2014 and 2013, respectively, for the annual health care reform fee. The higher expenses in 2014 reflect final regulations on the annual health care reform fee issued by the Internal Revenue Service (IRS) on July 28, 2014. The final IRS regulations accelerated the recognition criteria for the fee obligation by one year to the year in which the underlying sales used to allocate the fee occurred rather than the year in which the fee was paid. As a result of this change, Merck recorded an additional year of expense of $193 million in 2014. On January 21, 2016, the Centers for Medicare & Medicaid Services issued the Medicaid Rebate Final Rule that implements provisions of the Patient Protection and Affordable Care Act 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. Merck is still evaluating the rule to determine whether it will have a material impact on Merck's Medicaid rebate liability.

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 Patient Protection and Affordable Care Act. 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.

Efforts toward health care cost containment remain intense in several European countries. Many countries have continued to announce and execute austerity measures, which include the implementation of pricing actions to reduce prices of generic and patented drugs and mandatory switches to generic drugs. While the Company is taking steps to mitigate the impact in these countries, the austerity measures continued to negatively affect the Company's revenue performance in 2015 and the Company anticipates the austerity measures will continue to negatively affect revenue performance in 2016. In addition, a majority of countries 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 2016. 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, 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.

The Company's focus on emerging markets has increased. 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 2016 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 appears to have accelerated the regulatory review process for medicines with this designation.

The EU has adopted directives and other legislation concerning the classification, labeling, advertising, wholesale distribution, integrity of the supply chain, enhanced pharmacovigilance monitoring and approval for marketing of medicinal products for human use. These provide mandatory standards throughout the EU, which may be supplemented or implemented with additional regulations by the EU member states. 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 efficiently 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 four percent 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 the Asia Pacific Economic Cooperation Cross-Border Privacy Rules System and is under regulatory review in the EU.

In October 2015, the Court of Justice of the EU invalidated a 2000 decision of the EC, which had held that the U.S.-EU Safe Harbor Framework (Safe Harbor) provided adequate protection for transfers of personal data from the European Economic Area to the United States. Merck had annually self-certified adherence to the Safe Harbor since 2001 and relied on the Safe Harbor for a significant number of data transfers across its business. Since November 2014, Merck has been working toward regulatory recognition of its global privacy program as meeting the EU's binding corporate rules requirements, an alternative legal mechanism for internal company transfers. At the end of January 2016, EU review for the Company's binding corporate rules application was completed for the 21 EU member states that participate in the EU mutual recognition process. Completion of the final EU cooperation review phase is expected in the first quarter of 2016. Binding corporate rules approval in the EU is expected to reduce the operational impact of the Safe Harbor invalidation on our global business. Cross-border data transfers to third parties that support the Company's business will not be directly facilitated by its binding corporate rules, once approved. However, the Company anticipates that the standards its global privacy program has met through its binding corporate rules review will support its ability to comply with the new EU-U.S. Privacy Shield, a transatlantic data transfer agreement to replace the Safe Harbor, which was announced on February 2, 2016, as well as to continue to implement other data transfer mechanisms as necessary to support its business.

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 in 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 under Patent Term Restoration for periods when the patented product was under regulatory review by the FDA.

Patent portfolios developed for products introduced by the Company normally provide market exclusivity. The Company has the following key U.S. patent protection (including the potential for Patent Term Restoration and Pediatric Exclusivity where indicated) for the following marketed products:

Product	**Year of Expiration (in the U.S.)**[1]
Invanz	2016 (compound)/2017 (composition)
Cubicin[2]	2016 (composition)
Zostavax	2016 (use)
Dulera	2017 (formulation)/2020 (combination)
Zetia[3]*/Vytorin*	2017
Asmanex	2018 (formulation)
Nasonex[4]	2018 (formulation)
NuvaRing	2018 (delivery system)
Emend for Injection[5]	2019
Noxafil[5]	2019
RotaTeq	2019
Intron A	2020
Recombivax	2020 (method of making/vectors)
Januvia[5]*/Janumet*[5]*/Janumet XR*[5]	2022
Isentress[5]	2023
Bridion[5]	2026 (with pending Patent Term Restoration)
Nexplanon	2026 (device)/2027 (device with applicator)
Grastek	2026 (use)
Ragwitek	2026 (use)
Bravecto	2027 (with pending Patent Term Restoration)
Zontivity[5]	2027 (with pending Patent Term Restoration)
Gardasil/Gardasil 9	2028
Keytruda	2028
Zerbaxa[5]	2028 (with pending Patent Term Restoration)
Sivextro[5]	2028 (with pending Patent Term Restoration)
Belsomra[5]	2029
Zepatier[5]	2031

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

(2) *In a December 2014 decision of a district court action against Hospira, Inc. (Hospira), the June 2016 patent was found to be valid and infringed. Later patents for* Cubicin*, expiring in September 2019 and November 2020, were found to be invalid. In November 2015, the U.S. Court of Appeals for the Federal Circuit (CAFC) affirmed the lower court decision. Hospira's application to the FDA will not be approved until at least June 2016. An earlier district court action against Teva resulted in a settlement whereby Teva can launch a generic version of* Cubicin *at the latest in December 2017, or earlier under certain conditions, but in no event before June 2016.*

(3) *By agreement, a generic manufacturer may launch a generic version of* Zetia *in the United States in December 2016.*

(4) *A district court decision (upheld on appeal to the CAFC) found that a proposed generic product by Apotex, a generic manufacturer, would not infringe on Merck's* Nasonex *formulation patent. Thus, if Apotex's application is approved by the FDA, it can enter the market in the United States with a generic version of* Nasonex.

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

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 Review	Currently Anticipated Year of Expiration (in the U.S.)
V419 (pediatric hexavalent combination vaccine)	2020 (method of making/vectors)
MK-6072 (bezlotoxumab)	2025

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

Phase 3 Drug Candidate	Currently Anticipated Year of Expiration (in the U.S.)
V212 (inactivated varicella zoster virus (VZV) vaccine)	2016 (use)
V920 (ebola vaccine)	2023
MK-0822 (odanacatib)	2024
MK-8228 (letermovir)	2025
MK-8237 (allergy, house dust mites)	2026 (use)
MK-0859 (anacetrapib)	2027
MK-7655A (relebactam + imipenem/cilastatin)	2029
MK-3102 (omarigliptin)	2030
MK-8931 (verubecestat)	2030
MK-8835 (ertugliflozin)	2030
MK-8835A (ertugliflozin + sitagliptin)	2030
MK-8835B (ertugliflozin + metformin)	2030
MK-1439 (doravirine)	2031
MK-8342B (contraception, next generation ring)	2034

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 10. "Contingencies and Environmental Liabilities" below.

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

Royalty income in 2015 on patent and know-how licenses and other rights amounted to $221 million. Merck also incurred royalty expenses amounting to $1.2 billion in 2015 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. Approximately 11,900 people are employed in the Company's research activities. Research and development expenses were $6.7 billion in 2015, $7.2 billion in 2014 and

$7.5 billion in 2013 (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 making externally sourced programs a greater component of its pipeline strategy, with a renewed 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 which 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 atherosclerosis, cancer, cardiovascular diseases, diabetes, infectious diseases, inflammatory/autoimmune diseases, neurodegenerative diseases, osteoporosis, respiratory diseases and women's health.

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

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

filings with the appropriate regulatory agencies. Also during this stage, the proposed manufacturing facility undergoes a pre-approval inspection during which production of the vaccine as it is in progress is examined in detail.

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 or internationally.

Keytruda is an FDA-approved anti-PD-1 therapy in clinical development for expanded indications in different cancer types. *Keytruda* is currently approved for the treatment of melanoma, advanced melanoma and NSCLC.

In December 2015, Merck announced results from the pivotal KEYNOTE-010 study to evaluate the potential of an immunotherapy compared to chemotherapy based on prospective measurement of PD-L1 expression in patients with advanced NSCLC. In the Phase 2/3 study, *Keytruda* significantly improved overall survival compared to chemotherapy in patients with any level of PD-L1 expression. Based on these data, Merck has submitted a supplemental BLA to the FDA and has filed an MAA with the EMA.

In November 2015, Merck announced that the FDA granted Breakthrough Therapy designation to *Keytruda* for the treatment of patients with microsatellite instability high metastatic colorectal cancer. *Keytruda* was previously granted Breakthrough Therapy status for advanced melanoma and advanced NSCLC.

The *Keytruda* clinical development program consists of more than 200 clinical trials, including over 100 trials that combine *Keytruda* with other cancer treatments. These studies encompass more than 30 cancer types including: bladder, colorectal, esophageal, gastric, head and neck, melanoma, multiple myeloma, non-small-cell lung, and triple negative breast, several of which are currently in Phase 3 clinical development.

MK-6072, bezlotoxumab, is an investigational antitoxin for the prevention of *Clostridium difficile (C. difficile)* infection recurrence currently under review with the FDA and EMA. In January 2016, Merck announced that the FDA accepted for review the BLA for bezlotoxumab and granted Priority Review with a PDUFA action date of July 23, 2016. In September 2015, Merck announced that the two pivotal Phase 3 clinical studies for bezlotoxumab met their primary efficacy endpoint: the reduction in *C. difficile* recurrence through week 12 compared to placebo, when used in conjunction with standard of care antibiotics for the treatment of *C. difficile*. The Company is also seeking approval in the EU and intends to file in Canada in 2016. Currently, there are no therapies approved for the prevention of recurrent disease caused by *C. difficile*.

MK-1293 is an insulin glargine candidate for the treatment of patients with type 1 and type 2 diabetes being developed in collaboration with Samsung Bioepis. In December 2015, the Company submitted an application for regulatory approval in the EU and plans to submit MK-1293 to the FDA in 2016.

MK-5172A, *Zepatier*, currently under review in the EU for the treatment of chronic HCV, is a once-daily, fixed-dose combination tablet containing the NS5A inhibitor elbasvir (50 mg) and the NS3/4A protease inhibitor grazoprevir (100 mg). *Zepatier* was approved by the FDA in January 2016 for the treatment of adult patients with chronic HCV GT1 or GT4 infection, with or without ribavirin.

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 partnership of Merck and Sanofi Pasteur. 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. On November 2, 2015, the FDA issued a CRL with respect to the BLA for V419. Both companies are reviewing the CRL and plan to have further communication with the FDA. In February 2016, the EC granted marketing authorization for V419 for prophylaxis against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis, and invasive disease caused by Hib, in infants and toddlers from the age of 6 weeks. V419 will be marketed as *Vaxelis* in the EU through SPMSD, the Company's joint venture with Sanofi Pasteur.

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. The Company anticipates filing applications for regulatory approval with the FDA with respect to certain of these candidates in 2016, including MK-1293 as noted above.

MK-0822, odanacatib, is an oral, once-weekly investigational treatment for patients with osteoporosis. Osteoporosis is a disease that reduces bone density and strength and results in an increased risk of bone fractures.

Odanacatib is a cathepsin K inhibitor that selectively inhibits the cathepsin K enzyme. Cathepsin K is known to play a central role in the function of osteoclasts, which are cells that break down existing bone tissue, particularly the protein components of bone. Inhibition of cathepsin K is a novel approach to the treatment of osteoporosis. In September 2014, Merck announced data from the pivotal Phase 3 fracture outcomes study for odanacatib in postmenopausal women with osteoporosis. In the Long-Term Odanacatib Fracture Trial (LOFT), odanacatib met its primary endpoints and significantly reduced the risk of three types of osteoporotic fractures (radiographically-assessed vertebral, clinical hip, and clinical non-vertebral) compared to placebo and also reduced the risk of the secondary endpoint of clinical vertebral fractures. In addition, treatment with odanacatib led to progressive increases over five years in bone mineral density at the lumbar spine and total hip. The rates of adverse events overall in LOFT were generally balanced between patients taking odanacatib and placebo. Adjudicated events of morphea-like skin lesions and atypical femoral fractures occurred more often in the odanacatib group than in the placebo group. Adjudicated major adverse cardiovascular events were generally balanced overall between the treatment groups. There were numerically more adjudicated stroke events with odanacatib than with placebo. Adjudicated atrial fibrillation was reported more often in the odanacatib group than in the placebo group. A numeric imbalance in mortality was observed; this numeric difference does not appear to be related to a particular reported cause or causes of death. Merck continues to collect data from the blinded extension study and is planning additional analyses of data from the trial, including an independent re-adjudication of major adverse cardiovascular events (MACE), in support of regulatory submissions. Merck plans to submit an NDA to the FDA for odanacatib in 2016 following completion of the independent adjudication and analysis of MACE. Merck also plans to submit applications to the EMA and the Ministry of Health, Labour, and Welfare in Japan.

MK-3102, omarigliptin, is an investigational once-weekly DPP-4 inhibitor in development for the treatment of adults with type 2 diabetes. In September 2015, the Company announced that omarigliptin achieved its primary efficacy endpoint in a Phase 3 study. Omarigliptin was found to be non-inferior to *Januvia*, at reducing patients' A1C (an estimate of a person's blood glucose over a two-to three-month period) levels from baseline, with similar A1C reductions achieved in both groups. The head-to-head study was designed to evaluate once-weekly treatment with omarigliptin 25 mg compared to 100 mg of *Januvia* once daily. Results were presented during an oral session at the 51st European Association for the Study of Diabetes Annual Meeting. Also, in September 2015, Merck announced that the Japanese Pharmaceuticals and Medical Devices Agency approved *Marizev* (omarigliptin) 25 mg and 12.5 mg tablets. Japan is the first country to have approved omarigliptin. Merck plans to submit omarigliptin for regulatory approval in the United States in 2016. Other worldwide regulatory submissions will follow.

MK-8835, ertugliflozin, is an investigational oral sodium glucose cotransporter-2 (SGLT2) inhibitor being evaluated for the treatment of type 2 diabetes in collaboration with Pfizer Inc. Ertugliflozin is also being studied in combination with *Januvia* (sitagliptin) and metformin. Merck expects to submit applications for regulatory approval in the United States for ertugliflozin and the two fixed-dose combination tablets by the end of 2016.

MK-8237 is an investigational allergy immunotherapy tablet for house dust mite allergy that is part of a North America partnership between Merck and ALK-Abello. Merck plans to submit an NDA to the FDA for MK-8237 in the first half of 2016.

MK-8931, verubecestat, is Merck's novel investigational oral ß-amyloid precursor protein site-cleaving enzyme (BACE) inhibitor for the treatment of Alzheimer's disease being studied in a Phase 3 trial (APECS) designed to evaluate the safety and efficacy of MK-8931 versus placebo in patients with amnestic mild cognitive impairment due to Alzheimer's disease, also known as prodromal Alzheimer's disease. MK-8931 is also being studied in another Phase 2/3 randomized, placebo-controlled, study in patients with mild-to-moderate Alzheimer's disease (EPOCH). The EPOCH study completed enrollment in the fourth quarter of 2015 and is estimated to reach primary trial completion in mid-2017.

MK-0859, anacetrapib, is an investigational inhibitor of the cholesteryl ester transfer protein (CETP) in development for raising HDL-C and reducing LDL-C. Anacetrapib is being evaluated in a 30,000 patient, event-driven cardiovascular clinical outcomes trial sponsored by Oxford University, REVEAL (Randomized EValuation of the Effects of Anacetrapib Through Lipid-modification), involving patients with preexisting vascular disease, which is projected to conclude in early 2017. In November 2015, Merck announced that the Data Monitoring Committee (DMC) of the REVEAL outcomes study completed its planned review of unblinded study data and recommended the study continue with no changes. The DMC reviewed safety and efficacy data from the study, which included an assessment of futility. Merck remains blinded to the actual results of this analysis and to other REVEAL safety and efficacy data.

The REVEAL Steering Committee and Merck will continue to monitor the progress of the study. No additional interim efficacy analyses are planned.

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-8228, letermovir, is an investigational oral, once-daily antiviral candidate for the prevention and treatment of Human Cytomegalovirus infection. Letermovir has received Orphan Drug Status in the EU and in the United States, where it has also been granted Fast Track designation.

MK-8342B, referred to as the Next Generation Ring, is an investigational combination (etonogestrel and 17β-estradiol) vaginal ring for contraception and the treatment of dysmenorrhea in women seeking contraception.

MK-0431J is an investigational fixed-dose combination of sitagliptin and ipragliflozin under development 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.

V920 is an investigational rVSV-ZEBOV (Ebola) vaccine candidate being studied in large scale Phase 2/3 clinical trials currently underway in West Africa. 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 has been 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 procedure is intended to assist United Nations' procurement agencies and Member States on the acceptability of using a vaccine candidate in an emergency-use setting. EUAL designation is not prequalification by the WHO, but rather is a special procedure implemented when there is an outbreak of a disease with high rates of morbidity and/or mortality and a lack of treatment and/or prevention options. In such instances, the WHO may recommend making a vaccine available for a limited time, while further clinical trial data are being gathered for formal regulatory agency review by a national regulatory authority. 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.

V212 is an inactivated varicella zoster virus (VZV) vaccine in development for the prevention of herpes zoster. The Company is conducting two Phase 3 trials, one in autologous hematopoietic cell transplant patients and the other in patients with solid tumor malignancies undergoing chemotherapy and hematological malignancies.

MK-1439, doravirine, is an investigational, once-daily oral next-generation non-nucleoside reverse transcriptase inhibitor being developed by Merck for the treatment of HIV-1 infection.

In 2015, the Company also divested or discontinued certain drug candidates.

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 receptor antagonists, which are being developed for the treatment and prevention of migraine.

MK-4261, surotomycin, is an investigational oral antibiotic in development for the treatment of *C. difficile* associated diarrhea. Merck acquired surotomycin as part of its purchase of Cubist. During the second quarter of 2015, the Company received unfavorable efficacy data from a randomized, double-blinded, active-controlled study in patients with *C. difficile* associated diarrhea. The evaluation of this data, combined with an assessment of the commercial opportunity for surotomycin, resulted in the discontinuation of the program.

MK-2402, bevenopran, is an oral investigational therapy in development as a potential treatment for opioid-induced constipation in patients with chronic, non-cancer pain. Merck acquired bevenopran as a part of its purchase of Cubist. The Company has made the decision not to continue development of this program and is seeking to out-license the asset.

MK-8962, corifollitropin alfa injection, is an investigational fertility treatment for controlled ovarian stimulation in women participating in assisted reproductive technology. In July 2014, Merck received a CRL from the FDA for its NDA for corifollitropin alfa injection. Merck has made a decision to discontinue development of corifollitropin alfa injection in the United States for business reasons. Corifollitropin alfa injection is marketed as *Elonva* in certain markets outside of the United States.

The chart below reflects the Company's research pipeline as of February 19, 2016. 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 and additional claims, line extensions or formulations for in-line products are not shown.

Phase 2	Phase 3 (Phase 3 entry date)	Under Review
Alzheimer's Disease MK-7622 **Asthma** MK-1029 **Cancer** MK-3475 *Keytruda* Hodgkin Lymphoma PMBCL (Primary Mediastinal Large B-Cell Lymphoma) Advanced Solid Tumors MK-2206 MK-8628 **Diabetes** MK-8521 **Heart Failure** MK-1242 (vericiguat)[1] **Hepatitis C** MK-3682B (MK-3682/MK-8408/ MK-5172 (grazoprevir)) **Pneumoconjugate Vaccine** V114	**Allergy** MK-8237, House Dust Mite (March 2014)[1,2] **Alzheimer's Disease** MK-8931 (verubecestat) (December 2013) **Atherosclerosis** MK-0859 (anacetrapib) (May 2008) **Bacterial Infection** MK-7655A (relebactam+imipenem/cilastatin) (October 2015) **Cancer** MK-3475 *Keytruda* Bladder (October 2014) Breast (October 2015) Colorectal (November 2015) Esophageal (December 2015) Gastric (May 2015) Head and Neck (November 2014) Multiple Myeloma (December 2015) **CMV Prophylaxis in Transplant Patients** MK-8228 (letermovir) (June 2014) **Contraception, Next Generation Ring** MK-8342B (September 2015) **Diabetes Mellitus** MK-3102 (omarigliptin) (September 2012) MK-8835 (ertugliflozin) (November 2013)[1] MK-8835A (ertugliflozin+sitagliptin) (September 2015)[1] MK-8835B (ertugliflozin+metformin) (August 2015)[1] MK-1293 (February 2014) (U.S.)[1] MK-0431J (sitagliptin+ipragliflozin) (October 2015) (Japan)[1] **Ebola Vaccine** V920 (March 2015) **Herpes Zoster** V212 (inactivated VZV vaccine) (December 2010) **HIV** MK-1439 (doravirine) (December 2014) **Osteoporosis** MK-0822 (odanacatib) (September 2007)	**Cancer** MK-3475 *Keytruda* Non-Small-Cell Lung (EU) ***Clostridium difficile* Infection** MK-6072 (bezlotoxumab) (U.S./EU) **Diabetes Mellitus** MK-1293 (EU)[1] **Hepatitis C** MK-5172A *Zepatier* (EU) **Pediatric Hexavalent Combination Vaccine** V419 (U.S.)[3] **Footnotes:** [1] Being developed in a collaboration. [2] North American rights only. [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 Pasteur. On November 2, 2015, the FDA issued a CRL with respect to V419. Both companies are reviewing the CRL and plan to have further communication with the FDA.

Employees

As of December 31, 2015, the Company had approximately 68,000 employees worldwide, with approximately 26,200 employed in the United States, including Puerto Rico. Approximately 32% of worldwide employees of the Company are represented by various collective bargaining groups.

2013 Restructuring Program

In 2013, the Company initiated actions under a global restructuring program (the 2013 Restructuring Program) as part of a global initiative to sharpen its commercial and research and development focus. The actions under

this program primarily include the elimination of positions in sales, administrative and headquarters organizations, as well as research and development. Additionally, these actions include the reduction of the Company's global real estate footprint and improvements in the efficiency of its manufacturing and supply network. Since inception of the 2013 Restructuring Program through December 31, 2015, Merck has eliminated approximately 8,630 positions comprised of employee separations, as well as the elimination of contractors and vacant positions. The actions under the 2013 Restructuring Program were substantially completed by the end of 2015.

Merger Restructuring Program

In 2010, subsequent to the Merck and Schering-Plough merger (Merger), the Company commenced actions under a global restructuring program (the Merger Restructuring Program) designed to streamline the cost structure of the combined company. Further actions under this program were initiated in 2011. The actions under this program primarily 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. Since inception of the Merger Restructuring Program through December 31, 2015, Merck has eliminated approximately 29,645 positions comprised of employee separations, as well as the elimination of contractors and vacant positions. The non-facility related restructuring actions under the Merger Restructuring Program are substantially completed.

Environmental Matters

The Company believes that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on the Company. The Company is also remediating environmental contamination resulting from past industrial activity at certain of its sites. Expenditures for remediation and environmental liabilities were $8 million in 2015, and are estimated at $59 million in the aggregate for the years 2016 through 2020. 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 $109 million and $125 million at December 31, 2015 and 2014, 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 $57 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 56% of sales in 2015, 60% of sales in 2014 and 59% of sales in 2013.

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 expanded its 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 *www.merck.com*. The Company will make available, free of charge at the "Investors" portion of its website, its Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15 (d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after such reports are electronically filed with, or furnished to, the U.S. Securities and Exchange Commission (the SEC).

The Company's corporate governance guidelines and the charters of the Board of Directors' four standing committees are available on the Company's website at *www.merck.com/about/leadership* and all such information is available in print to any 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 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 in 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 infringement and similar claims against the Company. The Company aggressively defends its important patents both within and outside the United States, including by filing claims of infringement against other parties. See Item 8. "Financial Statements and Supplementary Data," Note 10. "Contingencies and Environmental Liabilities" below. In particular, manufacturers of generic pharmaceutical products from time to time file Abbreviated New Drug Applications with the FDA seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned by the Company. The Company normally responds by vigorously 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 further erosion 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 and, in the case of certain products, such a loss could result in a material non-cash impairment charge. 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 U.S. patent protection for certain of the Company's marketed products, 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 patent protection can have a material adverse effect on the Company's business, cash flow, results of operations, financial position and prospects. For example, a court has ruled that a proposed generic form of *Nasonex* does not infringe the Company's U.S. patent for *Nasonex*. If the generic form of *Nasonex* receives marketing approval in the United States, the Company will experience a loss of *Nasonex* sales. In addition, the Company will lose U.S. patent protection for *Cubicin* in June 2016. Also, pursuant to an agreement with a generic manufacturer, that manufacturer may launch in the United States a generic version of *Zetia* in December 2016.

Key Company 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*, *Zetia*, *Janumet*, *Gardasil/Gardasil* 9, *Isentress*, and *Vytorin*. 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 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-market trials, increased competition from the introduction of new, more effective treatments and discontinuation or removal from the market of the product for any reason. If any of these events had a material adverse effect on the sales of certain products, such an event could result in a material non-cash impairment charge.

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 which it may develop through joint ventures and products which 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.

The Company's products, including products in development, can not 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. 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-marketing 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;
- new scientific information and evolution of scientific theories;
- 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 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 which encourages the use of generic 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 pricing pressure with respect to its products.

The Company faces increasing 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, 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 Patient Protection and Affordable Care Act of 2010. 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. The Company also faces the risk of litigation with the government over its pricing calculations. 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.

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 increase 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 Congress and state legislatures.

In 2010, the United States enacted major health care reform legislation (the Patient Protection and Affordable Care Act). Various insurance market reforms have advanced and state and federal insurance exchanges were launched in 2014. By the end of the decade, the law is expected to expand access to health care to about 32 million Americans who did not previously have insurance coverage. 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"). Also, pharmaceutical manufacturers are now required to pay an annual non-tax deductible health care reform fee. The total annual industry fee was $3.0 billion in 2015 and will remain $3.0 billion in 2016. 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.

On January 21, 2016, the Centers for Medicare & Medicaid Services issued the Medicaid Rebate Final Rule that implements provisions of the Patient Protection and Affordable Care Act 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. Merck is still evaluating the rule to determine whether it will have a material impact on Merck's Medicaid rebate liability.

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

The uncertainty in global economic conditions may result in a further 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 many 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 2015. The Company anticipates these pricing actions, including the biennial price reductions in Japan that will occur again in 2016, and other austerity measures will continue to negatively affect revenue performance in 2016.

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;
- foreign exchange fluctuations;
- diminished protection of intellectual property in some countries; and
- possible nationalization and expropriation.

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

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

As previously disclosed, Merck has, in the past, experienced difficulties in manufacturing certain of its vaccines and other products. 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 continue to expand the Company's business 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.

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 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 March 2014, President Obama's administration re-proposed significant changes to the U.S. international tax laws, including changes that would tax companies on "excess returns" attributable to certain offshore intangible assets, limit U.S. tax deductions for expenses related to un-repatriated foreign-source income and modify the U.S. foreign tax credit rules. Other potentially significant changes to the U.S. international laws, including a move toward a territorial tax system and taxing currently the accumulated unrepatriated foreign earnings of controlled foreign corporations, have been set out by various Congressional committees. The Company cannot determine whether these proposals will be enacted into law or what, if any, changes may be made to such proposals prior to their being enacted into law. If these or other changes to the U.S. international tax laws are enacted, they could have a significant impact on the financial results of the Company.

In addition, the Company may be affected by changes in tax laws, including tax rate changes, changes to the laws related to the remittance of foreign earnings (deferral), or other limitations impacting the U.S. tax treatment of foreign earnings, new tax laws, and revised tax law interpretations in domestic and foreign jurisdictions.

Pharmaceutical products can develop unexpected safety or efficacy concerns.

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

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

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

The Company is increasingly dependent on sophisticated information technology and infrastructure.

The Company is increasingly dependent on sophisticated information technology and infrastructure. A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems or infrastructure, by the Company's workforce, others with authorized access to the Company's systems, or unauthorized persons could negatively impact operations. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional dissemination, intentional destruction of confidential information stored in the Company's systems or in non-encrypted portable media or storage devices. The Company could also experience a business interruption, intentional theft of confidential information, or reputational damage from espionage attacks, malware or other cyber-attacks, or insider threat attacks, which may compromise the Company's system infrastructure or lead to data leakage, either internally or at the Company's third-party providers. Although the aggregate impact on the Company's operations and financial condition has not been material to date, the Company has been the target of events of this nature and expects them to continue. The Company monitors its data, information technology and personnel usage of Company 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 systems will prevent service interruption or the loss of critical or sensitive information from the Company's or the Company's third party providers' databases or systems that could result in financial, legal, business or reputational harm to the Company.

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 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, particularly human and animal health vaccines, is a long, expensive and uncertain process. There are unique risks and uncertainties with biologics, 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 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 required for the release of each manufactured commercial lot.
- Manufacturing biologics, 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 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 are frequently costly to manufacture because production ingredients are derived from living animal or plant material, and most biologics 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 allegations of harm, including infections or allergic reactions, or 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. 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.

Changes in laws and regulations could 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.

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 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 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. 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 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.

- 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 and Cokesbury, New Jersey. The Company's vaccines business is conducted through divisional headquarters located in West Point, Pennsylvania. Merck's Animal Health global headquarters function 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 $1.3 billion in 2015, $1.3 billion in 2014 and $1.5 billion in 2013. In the United States, these amounted to $879 million in 2015, $873 million in 2014 and $902 million in 2013. Abroad, such expenditures amounted to $404 million in 2015, $444 million in 2014 and $646 million in 2013.

The Company and its subsidiaries own their principal facilities and manufacturing plants under titles that they consider to be satisfactory. The Company considers 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 10. "Contingencies and Environmental Liabilities".

Item 4. Mine Safety Disclosures.

Not Applicable

Executive Officers of the Registrant (ages as of February 1, 2016)

KENNETH C. FRAZIER — Age 61

December 2011 — Chairman, President and Chief Executive Officer

January 2011 — President and Chief Executive Officer

May 2010 — President — responsible for the Company's three largest global divisions - Global Human Health, Merck Manufacturing Division and Merck Research Laboratories

Prior to May 2010, Mr. Frazier was Executive Vice President and President, Global Human Health from 2007 to 2010.

ADELE D. AMBROSE — Age 59

November 2009 — Senior Vice President and Chief Communications Officer — responsible for the Global Communications organization

ROBERT M. DAVIS — Age 49

April 2014 — Executive Vice President and Chief Financial Officer — responsible for the Company's global financial organization, investor relations, corporate strategy and business development, global facilities, and the Company's joint venture relationships

Prior to April 2014, Mr. Davis was Corporate Vice President and President, Medical Products of Baxter International, Inc. (Baxter) from 2010 to 2014, Corporate Vice President and President, Renal Division of Baxter in 2010 and Baxter's Corporate Vice President and Chief Financial Officer from 2006 to 2010

WILLIE A. DEESE — Age 60

November 2009 — Executive Vice President and President, Merck Manufacturing Division — responsible for the Company's global manufacturing, procurement, and distribution and logistics functions

RICHARD R. DELUCA, JR. — Age 53

September 2011 — Executive Vice President and President, Merck Animal Health — responsible for the Merck Animal Health organization

Prior to September 2011, Mr. DeLuca was Chief Financial Officer, Becton Dickinson Biosciences (a medical technology company) since 2010 and President, Wyeth's Fort Dodge Animal Health division from 2007 to 2010.

JULIE L. GERBERDING, M.D., M.P.H. — Age 60

January 2015 — Executive Vice President for Strategic Communications, Global Public Policy and Population Health — responsible for Merck's Global Public Policy, Corporate Responsibility and Global Communications functions

January 2010 — President, Merck Vaccines — responsible for Merck's portfolio of vaccines, planning for the introduction of vaccines from the Company's pipeline, and accelerating efforts to broaden access to Merck's vaccines around the world

CLARK GOLESTANI — Age 49

December 2012 — Executive Vice President and Chief Information Officer — responsible for the Company's global information technology (IT) organization

August 2008 — Vice President, Merck Research Laboratories Information Technology — responsible for global IT for the Company's Research & Development division, including Basic Research, Pre-Clinical, Clinical and Regulatory

MIRIAN M. GRADDICK-WEIR — Age 61

November 2009 — Executive Vice President, Human Resources — responsible for the Global Human Resources organization

MICHAEL J. HOLSTON — Age 53

July 2015 — Executive Vice President and General Counsel — responsible for the Company's legal function

June 2012 — Executive Vice President and Chief Ethics and Compliance Officer — responsible for the Company's global compliance function, including Global Safety & Environment, Systems Assurance, Ethics and Privacy and security organization

Prior to June 2012, Mr. Holston was Executive Vice President, General Counsel and Board Secretary for Hewlett-Packard Company since 2007, where he oversaw the legal, compliance, government affairs, privacy and ethics operations.

RITA A. KARACHUN — Age 52

March 2014 — Senior Vice President Finance - Global Controller — responsible for the Company's global controller's organization including all accounting, controls, external reporting and financial standards and policies

November 2009 — Assistant Controller — responsible for the global consolidation of the Company's entities as well as acting as controller for the U.S.-based entities

ROGER M. PERLMUTTER, M.D., Ph.D. — Age 63

April 2013 — Executive Vice President and President, Merck Research Laboratories — responsible for the Company's global research and development efforts

Prior to April 2013, Dr. Perlmutter was Executive Vice President of Research and Development, Amgen Inc. from 2001 to 2012.

MICHAEL ROSENBLATT, M.D. — Age 68

December 2009 — Executive Vice President and Chief Medical Officer — the Company's primary voice to the global medical community on critical issues such as patient safety and benefit:risk of medications

ADAM H. SCHECHTER — Age 51

May 2010 — Executive Vice President and President, Global Human Health — responsible for the Company's global pharmaceutical and vaccine business

November 2009 — President, Global Human Health, U.S. Market and Integration Leader — commercial responsibility in the United States for the Company's portfolio of prescription medicines. Leader for the integration efforts for the Merck/Schering-Plough merger across all divisions and functions.

All officers listed above 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 the Board.

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 dividend per share information.

Cash Dividends Paid per Common Share

	Year	4th Q	3rd Q	2nd Q	1st Q
2015	**$ 1.80**	**$ 0.45**	**$ 0.45**	**$ 0.45**	**$ 0.45**
2014	$ 1.76	$ 0.44	$ 0.44	$ 0.44	$ 0.44

Common Stock Market Prices

2015	**4th Q**	**3rd Q**	**2nd Q**	**1st Q**
High	**$ 55.77**	**$ 60.07**	**$ 61.70**	**$ 63.62**
Low	**$ 48.35**	**$ 45.69**	**$ 56.22**	**$ 55.64**
2014				
High	$ 62.20	$ 61.33	$ 59.84	$ 57.65
Low	$ 52.49	$ 55.57	$ 54.40	$ 49.30

As of January 31, 2016, there were approximately 135,000 shareholders of record.

Issuer purchases of equity securities for the three months ended December 31, 2015 were as follows:

Issuer Purchases of Equity Securities

Period	Total Number of Shares Purchased[1]	Average Price Paid Per Share	($ in millions) Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs[1]
October 1 — October 31	8,968,000	$50.45	$9,218
November 1 — November 30	6,136,400	$54.25	$8,885
December 1 — December 31	7,464,600	$53.06	$8,489
Total	22,569,000	$52.35	$8,489

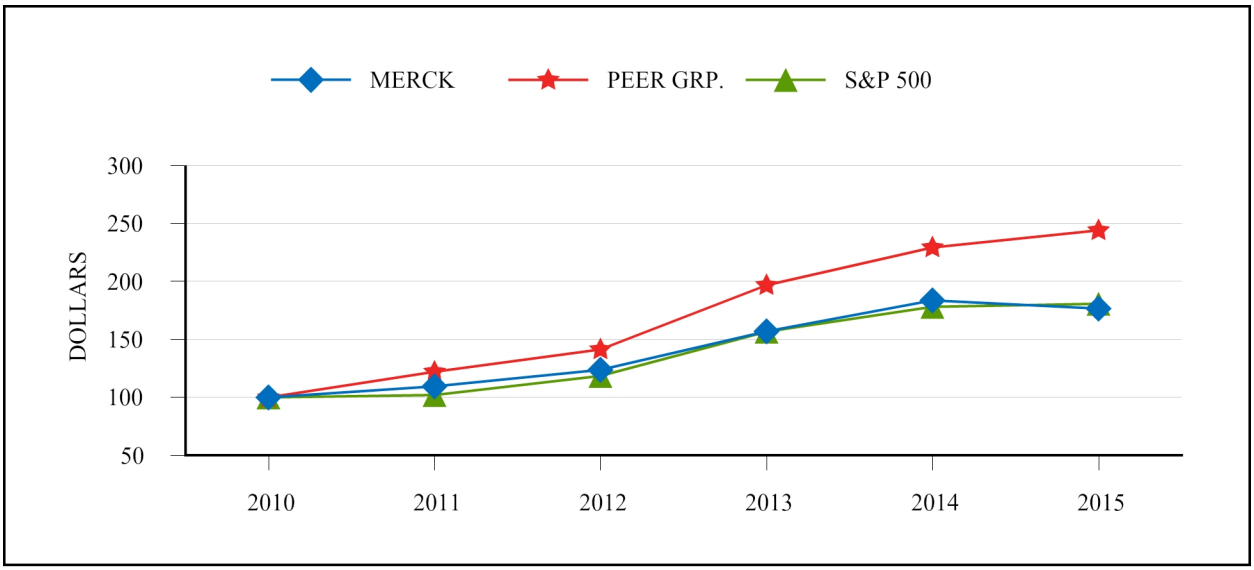
[1] *All shares purchased during the period were made as part of a plan approved by the Board of Directors in March 2015 to purchase up to $10 billion in Merck shares.*

Performance Graph

The following graph assumes a $100 investment on December 31, 2010, and reinvestment of all dividends, in each of the Company's Common Shares, the S&P 500 Index, and a composite peer group of the major U.S.-based pharmaceutical companies, which are: AbbVie Inc., Bristol-Myers Squibb Company, Johnson & Johnson, Eli Lilly and Company, and Pfizer Inc.

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

	End of Period Value	2015/2010 CAGR**
MERCK	$ 177	12%
PEER GRP.**	244	20%
S&P 500	181	13%



	2010	2011	2012	2013	2014	2015
MERCK	100.00	109.40	123.72	156.90	183.56	176.53
PEER GRP.	100.00	122.23	141.20	196.84	229.34	244.08
S&P 500	100.00	102.10	118.44	156.78	178.22	180.67

* *Compound Annual Growth Rate*
** *Peer group average was calculated on a market cap weighted basis. In addition, AbbVie Inc. replaced Abbott Laboratories in the peer group beginning 2013 following the spin off from Abbott Laboratories.*

This Performance Graph will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities and 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)

	2015 [1]	2014 [2]	2013	2012 [3]	2011 [4]
Results for Year:					
Sales	**$ 39,498**	$ 42,237	$ 44,033	$ 47,267	$ 48,047
Materials and production	**14,934**	16,768	16,954	16,446	16,871
Marketing and administrative	**10,313**	11,606	11,911	12,776	13,733
Research and development	**6,704**	7,180	7,503	8,168	8,467
Restructuring costs	**619**	1,013	1,709	664	1,306
Other (income) expense, net	**1,527**	(11,613)	411	474	336
Income before taxes	**5,401**	17,283	5,545	8,739	7,334
Taxes on income	**942**	5,349	1,028	2,440	942
Net income	**4,459**	11,934	4,517	6,299	6,392
Less: Net income attributable to noncontrolling interests	**17**	14	113	131	120
Net income attributable to Merck & Co., Inc.	**4,442**	11,920	4,404	6,168	6,272
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	**$ 1.58**	$ 4.12	$ 1.49	$ 2.03	$ 2.04
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	**$ 1.56**	$ 4.07	$ 1.47	$ 2.00	$ 2.02
Cash dividends declared	**5,115**	5,156	5,132	5,173	4,818
Cash dividends declared per common share	**$ 1.81**	$ 1.77	$ 1.73	$ 1.69	$ 1.56
Capital expenditures	**1,283**	1,317	1,548	1,954	1,723
Depreciation	**1,593**	2,471	2,225	1,999	2,351
Average common shares outstanding (millions)	**2,816**	2,894	2,963	3,041	3,071
Average common shares outstanding assuming dilution (millions)	**2,841**	2,928	2,996	3,076	3,094
Year-End Position:					
Working capital [5]	**$ 10,561**	$ 14,208	$ 17,469	$ 15,926	$ 16,128
Property, plant and equipment, net	**12,507**	13,136	14,973	16,030	16,297
Total assets [5]	**101,779**	98,167	105,440	105,921	104,699
Long-term debt	**23,929**	18,699	20,539	16,254	15,525
Total equity	**44,767**	48,791	52,326	55,463	56,943
Year-End Statistics:					
Number of stockholders of record	**135,500**	142,000	149,400	157,400	166,100
Number of employees	**68,000**	70,000	77,000	83,000	86,000

[1] *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.*

[2] *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.*

[3] *Amounts for 2012 include a net charge recorded in connection with the settlement of certain shareholder litigation.*

[4] *Amounts for 2011 include an arbitration settlement charge.*

[5] *Amounts have been restated to give effect to the early adoption of accounting guidance issued by the Financial Accounting Standards Board. See Note 2 to Item 8(a). "Financial Statements."*

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, which it markets directly and through its joint ventures. The Company's operations are principally managed on a products basis and are comprised of four operating segments, the Pharmaceutical, Animal Health, Alliances and Healthcare Services segments. The Pharmaceutical segment is the only reportable segment. The Pharmaceutical segment includes human health pharmaceutical and vaccine products marketed either directly by the Company or through joint ventures. 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 animal health operations that discover, develop, manufacture and market animal health products, including vaccines, which the Company sells to veterinarians, distributors and animal producers. Merck's Alliances segment primarily includes results from the Company's relationship with AstraZeneca LP until the termination of that relationship on June 30, 2014. 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. On October 1, 2014, the Company divested its Consumer Care segment that developed, manufactured and marketed over-the-counter, foot care and sun care products.

Overview

During 2015, Merck continued to execute its research and development focused-strategy, advance its pipeline and commercial portfolio while maintaining a disciplined approach to cost management and delivering capital returns to shareholders. The Company received several product approvals in 2015 that include expanded indications for *Keytruda*, the Company's anti-PD-1 (programmed death receptor-1) therapy for the treatment of advanced melanoma and metastatic non-small-cell lung cancer (NSCLC) in patients whose tumors express PD-L1 with disease progression following other therapies, as well as U.S. Food and Drug Administration (FDA) approval for *Bridion* (sugammadex) Injection, a medication for the reversal of two types of neuromuscular blocking agents used during surgery. Additionally, in January 2016, the FDA approved *Zepatier*, a once-daily, single tablet combination therapy in the treatment of chronic hepatitis C virus (HCV) genotype (GT) 1 or GT4 infection, with or without ribavirin. Business development is a critical part of the Company's strategy as Merck looks to combine internal and external innovation to enhance its pipeline. During 2015, Merck acquired Cubist Pharmaceuticals, Inc. (Cubist), a leader in the development of new therapies to treat serious and potentially life-threatening infections caused by a broad range of increasingly drug-resistant bacteria, and cCAM Biotherapuetics Ltd. (cCAM), a biopharmaceutical company focused on the discovery and development of novel cancer immunotherapies. Also in 2015, Merck entered into a multi-year collaboration with NGM Biopharmaceuticals, Inc. (NGM) to research, discover, develop and commercialize novel biologic therapies across a wide range of therapeutic areas. In January 2016, Merck acquired IOmet Pharma Ltd (IOmet), a 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.

Worldwide sales were $39.5 billion in 2015, a decline of 6% compared with 2014, including a 6% unfavorable effect from foreign exchange. The acquisition of Cubist in 2015, the divestiture of Merck's Consumer Care business (MCC) in 2014, as well as product divestitures and the termination in 2014 of the Company's relationship with AstraZeneca LP (AZLP) had a net unfavorable impact to sales of approximately 3%. Sales performance was also unfavorably affected by the ongoing impacts of the loss of market exclusivity for several products. These unfavorable impacts were partially offset by volume growth in oncology, diabetes, women's health and vaccine products, and positive performance from Merck's Animal Health business.

Merck continues to support its in-line portfolio, as well as ongoing and upcoming product launches. *Keytruda*, initially approved by the FDA in September 2014 for the treatment of advanced melanoma in patients with disease progression after other therapies, is launching in more than 40 markets, including in the European Union (EU). In 2015, Merck achieved multiple additional regulatory milestones for *Keytruda* including accelerated approval from the FDA

for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 as determined by an FDA-approved test and who have disease progression on or after platinum-containing chemotherapy. In addition, the FDA approved an expanded indication for *Keytruda* to include the first-line treatment of patients with unresectable or metastatic melanoma. Additionally, in 2015, the European Commission (EC) approved *Keytruda* for the treatment of advanced (unresectable or metastatic) melanoma in adults. The *Keytruda* clinical trials program currently includes more than 30 tumor types in more than 200 clinical trials, including over 100 trials that combine *Keytruda* with other cancer treatments (see "Research and Development" below). The Company is also launching *Zepatier* and *Bridion* in the United States.

While the Company continues to execute its strategy of pursuing business development opportunities to complement its internal research capabilities, as part of Merck's prioritization efforts, the Company also continues to review its existing assets to determine whether they can provide the best short- and longer-term value with Merck or elsewhere. In connection with its portfolio assessment process, the Company divested its remaining ophthalmics business in international markets during 2015. The Company's portfolio assessment process is ongoing and future divestitures may occur.

Merck is focusing its research efforts on the therapeutic areas that it believes can make the most impact on addressing critical areas of unmet medical need, such as cancer, hepatitis C, cardiometabolic disease, resistant microbial infection and Alzheimer's disease. During 2015, the Company continued to make strides in its late-stage pipeline. MK-6072, bezlotoxumab, is an investigational antitoxin for the prevention of *Clostridium difficile (C. difficile)* infection recurrence that is currently under review with the FDA and the European Medicines Agency (EMA). MK-1293, an insulin glargine candidate for the treatment of patients with type 1 and type 2 diabetes being developed in a collaboration, is also under review in the EU, as is *Zepatier*. *Keytruda* is under review in the EU for the treatment of NSCLC.

In addition to Phase 3 programs for *Keytruda* in the therapeutic areas of bladder, breast, colorectal, gastric, head and neck, multiple myeloma, and esophageal cancers, the Company also has more than 10 candidates in Phase 3 clinical development in its core therapeutic areas, as well as other areas with significant potential, including MK-3102, omarigliptin, an investigational once-weekly dipeptidyl peptidase-4 (DPP-4) inhibitor in development for the treatment of adults with type 2 diabetes; MK-0822, odanacatib, an oral, once-weekly investigational treatment for patients with osteoporosis; MK-8835, ertugliflozin, an investigational oral sodium glucose cotransporter-2 (SGLT2) inhibitor being evaluated alone and in combination with *Januvia* (sitagliptin) and metformin for the treatment of type 2 diabetes; and MK-8237, an investigational allergy immunotherapy tablet for house dust mite allergy. Merck expects to submit applications for regulatory approval in the United States for each of these candidates, as well as MK-1293 described above, in 2016.

As a result of continued portfolio prioritization, the Company is out-licensing or discontinuing selected late-stage clinical development assets. During 2015, the Company out-licensed MK-1602 and MK-8031, investigational small molecule oral calcitonin gene-related peptide (CGRP) receptor antagonists, which are being developed for the treatment and prevention of migraine.

The Company continued to make strong progress in 2015 reducing its cost base. As a result of disciplined cost management, Merck has achieved its overall savings goal in 2015 as noted below. The Company has in turn invested its resources to grow its strongest brands and to support the most promising assets in its pipeline. *Marketing and administrative* expenses declined in 2015 as compared with 2014 reflecting in part this continued focus by the Company on prioritizing its resources to the highest growth areas.

In 2013, the Company initiated actions under a global restructuring program (the 2013 Restructuring Program) as part of a global initiative to sharpen its commercial and research and development focus. The actions under this program primarily include the elimination of positions in sales, administrative and headquarters organizations, as well as research and development. Additionally, these actions include the reduction of the Company's global real estate footprint and improvements in the efficiency of its manufacturing and supply network. The Company recorded total pretax costs of $527 million in 2015 and $1.2 billion in both 2014 and 2013 related to this restructuring program. The actions under the 2013 Restructuring Program were substantially completed by the end of 2015. The Company has met its projected $2.0 billion in annual net cost savings for actions under the 2013 Restructuring Program. When the actions under the 2013 Restructuring Program are combined with the actions under the Merger Restructuring Program (discussed below), the Company has also met its annual net cost savings projection of $2.5 billion compared with full-year 2012 expense levels.

The global restructuring program (the Merger Restructuring Program) that was initiated in 2010 subsequent to the Merck and Schering-Plough Corporation (Schering-Plough) merger (the Merger) is intended to streamline the cost structure of the combined company. The actions under this plan 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 recorded total pretax costs of $583 million in 2015, $730 million in 2014 and $1.1 billion in 2013 related to this restructuring program. The non-facility related restructuring actions under the Merger Restructuring Program are substantially complete.

Beginning January 1, 2016, the remaining restructuring actions under both plans, which primarily relate to ongoing facility rationalizations, will be accounted for in the aggregate prospectively. The Company expects to complete such actions by the end of 2017 and incur approximately $1.5 billion of additional pretax costs.

Costs associated with the Company's restructuring actions are included in *Materials and production* costs, *Marketing and administrative* expenses, *Research and development* expenses and *Restructuring costs*. The Company estimates that approximately two-thirds of the cumulative pretax costs relate to 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.

In November 2015, Merck's Board of Directors raised the Company's quarterly dividend to $0.46 per share from $0.45 per share. During 2015, the Company returned $9.3 billion to shareholders through dividends and share repurchases.

In January 2016, Merck announced that it had reached an agreement with plaintiffs to resolve *Vioxx* shareholder class action litigation pending in New Jersey federal court. Under the agreement, Merck will pay $830 million to resolve the settlement class members' claims, plus an additional amount for approved attorneys' fees and expenses. In connection with the settlement, Merck recorded a net pretax charge of $680 million in the fourth quarter of 2015, which includes anticipated insurance recoveries. See Note 10 to the consolidated financial statements.

Earnings per common share assuming dilution attributable to common shareholders (EPS) for 2015 were $1.56 compared with $4.07 in 2014. EPS in both years reflect the impact of acquisition and divestiture-related costs and restructuring costs, as well as certain other items, which in 2014 include an $11.2 billion gain recognized in connection with the divestiture of MCC. Non-GAAP EPS, which excludes these items, were $3.59 in 2015 and $3.49 in 2014 (see "Non-GAAP Income and Non-GAAP EPS" below).

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 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 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), which began to be implemented in 2010. Various insurance market reforms have advanced and state and federal insurance exchanges were launched in 2014. By the end of the decade, the law is expected to expand access to health care to about 32 million Americans who did not previously have insurance coverage. 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 $550 million, $430 million and $280 million was recorded by Merck as a reduction to revenue in 2015, 2014 and 2013, respectively, related to the donut hole provision. Also, pharmaceutical manufacturers are now required to pay an annual non-tax deductible health care reform fee. The total annual industry fee was $3.0 billion in 2015 and will remain $3.0 billion in 2016. 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 $173 million, $390 million and $151 million of costs within *Marketing and administrative* expenses in 2015, 2014 and 2013, respectively, for the annual health care reform fee. The higher expenses in 2014 reflect final regulations on the annual health care reform fee issued by the Internal Revenue Service (IRS) on July 28, 2014. The final IRS regulations accelerated the recognition criteria for the fee obligation by one year to the year in which the underlying sales used to allocate the fee occurred rather than the year in which the fee was paid. As a result of this change, Merck recorded an additional year of expense of $193 million in 2014. On January 21, 2016, the Centers for Medicare & Medicaid Services issued the Medicaid Rebate Final Rule that implements provisions of the Patient Protection and Affordable Care Act 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. Merck is still evaluating the rule to determine whether it will have a material impact on Merck's Medicaid rebate liability.

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 Patient Protection and Affordable Care Act. 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.

Efforts toward health care cost containment remain intense in several European countries. Many countries have continued to announce and execute austerity measures, which include the implementation of pricing actions to reduce prices of generic and patented drugs and mandatory switches to generic drugs. While the Company is taking steps to mitigate the impact in these countries, the austerity measures continued to negatively affect the Company's revenue performance in 2015 and the Company anticipates the austerity measures will continue to negatively affect revenue performance in 2016. In addition, a majority of countries 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 2016. 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, 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.

The Company's focus on emerging markets has increased. 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 2016 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 appears to have accelerated the regulatory review process for medicines with this designation.

The EU has adopted directives and other legislation concerning the classification, labeling, advertising, wholesale distribution, integrity of the supply chain, enhanced pharmacovigilance monitoring and approval for marketing of medicinal products for human use. These provide mandatory standards throughout the EU, which may be supplemented or implemented with additional regulations by the EU member states. 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.

Operating Results

Sales

Worldwide sales were $39.5 billion in 2015, a decline of 6% compared with 2014 including a 6% unfavorable effect from foreign exchange. The acquisition of Cubist in 2015, the divestiture of MCC in 2014, as well as product divestitures and the termination of the Company's relationship with AstraZeneca LP (AZLP) also in 2014, as discussed below, had a net unfavorable impact to sales of approximately 3%. In addition, sales performance in 2015 reflects declines in *PegIntron* and *Victrelis*, medicines for the treatment of HCV, *Remicade*, a treatment for inflammatory diseases, *Pneumovax* 23, a vaccine to help prevent pneumococcal disease, *Nasonex*, an inhaled corticosteroid for the treatment of nasal allergy symptoms and *Vytorin*, a cholesterol modifying medicine. These declines were partially offset by volume growth in *Keytruda*, an anti-PD-1 therapy; *Januvia* and *Janumet*, for the treatment of type 2 diabetes, *Gardasil/Gardasil* 9, vaccines to help prevent certain diseases caused by certain types of human papillomavirus (HPV), *Noxafil*, for the prevention of invasive fungal infections, *Simponi*, a once-monthly subcutaneous treatment for inflammatory diseases, *Implanon/Nexplanon*, single-rod subdermal contraceptive implants, *Invanz*, for the treatment of certain infections, *Dulera* Inhalation Aerosol, a combination medicine for the treatment of asthma, and *Bridion*, a medication for the reversal of two types of neuromuscular blocking agents used during surgery, as well as volume growth in Animal Health products and higher third-party manufacturing sales.

In January 2015, the Company acquired Cubist, which contributed sales of $1.3 billion to Merck's revenues in 2015. In 2014, the Company divested certain ophthalmic products in several international markets (most of which closed on July 1, 2014). In addition, on October 1, 2014, the Company divested its MCC business including the prescription rights to Claritin and Afrin. The sales decline in 2015 attributable to these divestitures was approximately $1.9 billion of which $1.5 billion related to the Consumer Care segment and $400 million related to the Pharmaceutical segment. Also, in 2014, the Company sold the U.S. marketing rights to *Saphris*, an antipsychotic indicated for the treatment of schizophrenia and bipolar I disorder in adults, which resulted in revenue of $232 million. Additionally, the Company's relationship with AZLP terminated on June 30, 2014; therefore, effective July 1, 2014, the Company no longer records supply sales to AZLP. These supply sales were $463 million in 2014 through the termination date and were reflected in the Alliances segment.

Sales in the United States were $17.5 billion in 2015, an increase of 3% compared with $17.1 billion in 2014. The increase was driven primarily by the acquisition of Cubist, as well as higher sales of *Keytruda*, *Gardasil/Gardasil* 9, *Januvia/Janumet*, *Zetia*, a cholesterol modifying medicine, and higher third-party manufacturing sales. These increases were partially offset by the 2014 divestiture of MCC, the termination of the Company's relationship with AZLP in 2014, revenue recognized in 2014 in connection with the sale of the U.S. marketing rights to *Saphris*, as well as lower sales in 2015 of *Pneumovax* 23 and *Nasonex*.

International sales were $22.0 billion in 2015, a decline of 13% compared with $25.2 billion in 2014. Foreign exchange unfavorably affected international sales performance by 11% in 2015. Excluding the unfavorable effect of foreign exchange, the sales decrease reflects the divestiture of MCC, as well as lower sales in the Pharmaceutical segment, largely reflecting declines in Europe and Japan, partially offset by growth in the emerging markets. Sales in Europe declined 19% in 2015, to $7.7 billion, including a 14% unfavorable effect from foreign exchange. Excluding the unfavorable effect from foreign exchange, the decline was driven primarily by lower sales of *Remicade*, as well as lower sales of products for the treatment of HCV and from product divestitures and ongoing generic erosion and fiscal austerity measures in this region, partially offset by growth in *Simponi*, *Keytruda*, and *Januvia/Janumet*. Sales in Japan declined 23% in 2015, to $2.6 billion, of which 11% was due to the unfavorable effect of foreign exchange. The sales decline was largely driven by product divestitures and the ongoing impacts of the loss of market exclusivity for several products, including *Cozaar* and *Hyzaar*, treatments for hypertension, as well as lower sales of *PegIntron* and *Januvia*.

Sales in the emerging markets were $7.3 billion in 2015, a decline of 6% including an 11% unfavorable effect from foreign exchange. Excluding the unfavorable effect of foreign exchange, sales performance reflects volume growth of diabetes, hospital acute care, oncology and certain diversified brand products, partially offset by lower sales of HCV products, as well as from product divestitures. Total international sales represented 56% and 60% of total sales in 2015 and 2014, respectively.

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. In the United States, 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 many 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 2015. The Company anticipates these pricing actions, including the biennial price reductions in Japan that will occur again in 2016, and other austerity measures will continue to negatively affect revenue performance in 2016.

Worldwide sales totaled $42.2 billion in 2014, a decline of 4% compared with $44.0 billion in 2013. Foreign exchange unfavorably affected global sales performance by 1% in 2014. The decline reflects lower revenue resulting from the ongoing impacts of the loss of market exclusivity for several products, including *Temodar*, a treatment for certain types of brain tumors, *Singulair*, a once-a-day oral medicine for the chronic treatment of asthma and for the relief of symptoms of allergic rhinitis, and *Cozaar* and *Hyzaar*. In addition, the sales decline was attributable to product divestitures that occurred in 2014 and 2013 as discussed below, the termination of the Company's relationship with AZLP, as well as the divestiture of MCC. The revenue decline was also driven by lower sales of *Victrelis* and *PegIntron*, *Nasonex*, and *Vytorin*. These declines were partially offset by growth in *Remicade* and *Simponi*, the diabetes franchise of *Januvia*/*Janumet*, *Dulera* Inhalation Aerosol, *Implanon*/*Nexplanon*, as well as higher sales from hospital acute care and animal health products. In addition, the Company recognized revenue of $232 million in 2014 in connection with the sale of the U.S. marketing rights to *Saphris*.

In October 2013, the Company sold its active pharmaceutical ingredient (API) manufacturing business and, effective December 31, 2013, certain related products within Diversified Brands. In November 2013, Merck sold the U.S. rights to certain ophthalmic products and in January 2014 sold the U.S. marketing rights to *Saphris*. In addition, the Company sold the U.S. rights to *Zioptan* in April 2014. Also in 2014, as noted above, the Company divested certain ophthalmic products in several international markets and sold its MCC business. The sales decline in 2014 attributable to these divestitures was approximately $1.1 billion, of which approximately $575 million related to the Pharmaceutical segment, $345 million related to the Consumer Care segment and $150 million related to the divested API manufacturing business (non-segment revenues). Also, the termination of the Company's relationship with AZLP resulted in a sales decline of approximately $450 million in the Alliances segment in 2014 compared with 2013.

Sales of the Company's products were as follows:

($ in millions)	**2015**	2014	2013
Primary Care and Women's Health			
Cardiovascular			
Zetia	**$ 2,526**	$ 2,650	$ 2,658
Vytorin	**1,251**	1,516	1,643
Diabetes			
Januvia	**3,863**	3,931	4,004
Janumet	**2,151**	2,071	1,829
General Medicine and Women's Health			
NuvaRing	**732**	723	686
Implanon/Nexplanon	**588**	502	403
Dulera	**536**	460	324
Follistim AQ	**383**	412	481
Hospital and Specialty			
Hepatitis			
PegIntron	**182**	381	496
HIV			
Isentress	**1,511**	1,673	1,643
Hospital Acute Care			
Cubicin [(1)]	**1,127**	25	24
Cancidas	**573**	681	660
Invanz	**569**	529	488
Noxafil	**487**	402	309
Bridion	**353**	340	288
Primaxin	**313**	329	335
Immunology			
Remicade	**1,794**	2,372	2,271
Simponi	**690**	689	500
Oncology			
Keytruda	**566**	55	—
Emend	**535**	553	507
Temodar	**312**	350	708
Diversified Brands			
Respiratory			
Singulair	**931**	1,092	1,196
Nasonex	**858**	1,099	1,335
Clarinex	**187**	232	235
Other			
Cozaar/Hyzaar	**667**	806	1,006
Arcoxia	**471**	519	484
Fosamax	**359**	470	560
Zocor	**217**	258	301
Propecia	**183**	264	283
Vaccines [(2)]			
Gardasil/Gardasil 9	**1,908**	1,738	1,831
ProQuad/M-M-R II*/Varivax*	**1,505**	1,394	1,306
Zostavax	**749**	765	758
RotaTeq	**610**	659	636
Pneumovax 23	**542**	746	653
Other pharmaceutical [(3)]	**4,553**	5,356	6,596
Total Pharmaceutical segment sales	**34,782**	36,042	37,437
Other segment sales [(4)]	**3,659**	5,758	6,397
Total segment sales	**38,441**	41,800	43,834
Other [(5)]	**1,057**	437	199
	$ 39,498	$ 42,237	$ 44,033

[(1)] *Sales of* Cubicin *in 2015 represent sales subsequent to the Cubist acquisition date. Sales of* Cubicin *in 2014 and 2013 reflect sales in Japan pursuant to a previously existing licensing agreement.*

[(2)] *These amounts do not reflect sales of vaccines sold in most major European markets through the Company's joint venture, Sanofi Pasteur MSD, the results of which are reflected in equity income from affiliates which is included in* Other (income) expense, net. *These amounts do, however, reflect supply sales to Sanofi Pasteur MSD.*

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

[(4)] *Represents the non-reportable segments of Animal Health, Alliances and Healthcare Services, as well as Consumer Care until its divestiture on October 1, 2014. The Alliances segment includes revenue from the Company's relationship with AZLP until termination on June 30, 2014.*

[(5)] *Other revenues are primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, as well as third-party manufacturing sales. Other revenues in 2014 also include $232 million received by Merck in connection with the sale of the U.S. marketing rights to* Saphris. *Other revenues in 2013 reflect $50 million of revenue for the out-license of a pipeline compound.*

Pharmaceutical Segment

Primary Care and Women's Health

Cardiovascular

Combined global sales of *Zetia* (marketed in most countries outside the United States as *Ezetrol*) and *Vytorin* (marketed outside the United States as *Inegy*), medicines for lowering LDL cholesterol, were $3.8 billion in 2015, a decline of 9% compared with 2014 including a 7% unfavorable effect from foreign exchange. The sales decline was driven primarily by lower volumes of *Ezetrol* in Canada where it lost market exclusivity in September 2014, as well as by lower volumes in the United States, partially offset by higher pricing in the United States. Combined worldwide sales of *Zetia* and *Vytorin* were $4.2 billion in 2014, a decline of 3% compared with 2013. Foreign exchange unfavorably affected global sales performance by 1% in 2014. The sales decline was driven primarily by lower volumes of *Vytorin* in the United States and *Ezetrol* in Canada due to loss of market exclusivity.

In November 2014, Merck announced that the investigational IMPROVE-IT study (IMProved Reduction of Outcomes: Vytorin Efficacy International Trial) met its primary and all secondary composite efficacy endpoints. In IMPROVE-IT, patients taking *Vytorin* - which combines simvastatin with *Zetia* - experienced significantly fewer major cardiovascular events (as measured by a composite of cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, re-hospitalization for unstable angina or coronary revascularization occurring at least 30 days after randomization) than patients treated with simvastatin alone. The results from this 18,144 patient study of high-risk patients presenting with acute coronary syndromes were presented at the American Heart Association 2014 Scientific Sessions. In April 2015, Merck submitted the data from IMPROVE-IT to the FDA to support a new indication for reduction of cardiovascular events for *Vytorin* and *Zetia*. *Vytorin* and *Zetia* are currently indicated for use along with a healthy diet to reduce elevated LDL cholesterol in patients with hyperlipidemia. The current U.S. Prescribing Information for both products states that the effect of ezetimibe on cardiovascular morbidity and mortality, alone or incremental to statin therapy, has not been determined. In February 2016, Merck announced that the FDA issued a Complete Response Letter (CRL) regarding Merck's supplemental new drug applications. Merck is reviewing the letter and will determine next steps. Also, in February 2016, through a decentralized process, Merck received a positive outcome of the mutual recognition procedure for updated product information for *Ezetrol* and *Inegy* based on the results of IMPROVE-IT. Following the completion of this procedure, the EU Member States concerned will amend local labeling on a country by country basis to include the reduction of risk of cardiovascular events in patients with coronary heart disease and a history of acute coronary syndrome.

By agreement, a generic manufacturer may launch a generic version of *Zetia* in the United States in December 2016. The U.S. patent and exclusivity periods for *Zetia* and *Vytorin* otherwise expire in April 2017. The Company has market exclusivity for *Ezetrol* in major European markets until October 2017; however, the Company expects to apply for pediatric extensions to the term which would extend the date to April 2018. The Company has market exclusivity for *Inegy* in those markets until April 2019.

In May 2014, Merck announced that the FDA approved *Zontivity* for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction or with peripheral arterial disease. The U.S. prescribing information for *Zontivity* includes a boxed warning regarding bleeding risk. In January 2015, *Zontivity* was approved by the EC for coadministration with acetylsalicylic acid and, where appropriate, clopidogrel, to reduce atherothrombotic events in adult patients with a history of myocardial infarction. Merck currently plans to begin launching *Zontivity* in certain European markets in 2016. The Company continues to monitor and assess *Zontivity* and the related intangible asset. Merck continues to focus on building product awareness in the United States for *Zontivity*. If the Company's efforts to build product awareness in the United States or the launches in Europe are not successful, the Company may take a non-cash impairment charge with respect to the *Zontivity* intangible asset, which was $292 million at December 31, 2015.

Diabetes

Worldwide combined sales of *Januvia* and *Janumet*, medicines that help lower blood sugar levels in adults with type 2 diabetes, were $6.0 billion in 2015, essentially flat as compared with 2014 including a 7% unfavorable effect from foreign exchange. Sales performance reflects higher volumes and pricing in the United States, as well as volume growth in the emerging markets and Europe. Volume declines of co-marketed sitagliptin in Japan due to the timing of sales to the licensee partially offset growth in 2015. Combined global sales of *Januvia* and *Janumet* were $6.0 billion in 2014, an increase of 3% compared with 2013 including a 1% unfavorable effect from foreign exchange.

The growth was driven primarily by higher sales of both *Januvia* and *Janumet* in the United States and by volume growth in Europe, partially offset by lower sales of *Januvia* in Japan due to lower pricing. In April 2014, all DPP-4 inhibitors, including *Januvia*, were subject to repricing in Japan.

In June 2015, Merck announced the primary results of the Trial Evaluating Cardiovascular Outcomes with Sitagliptin (TECOS), a placebo-controlled study of the cardiovascular (CV) safety of Merck's DPP-4 inhibitor *Januvia* (sitagliptin), added to usual care in more than 14,000 patients. The study achieved its primary composite CV endpoint of non-inferiority (defined as the time to the first confirmed event of any of the following: CV-related death, nonfatal myocardial infarction, nonfatal stroke, or hospitalization for unstable angina) compared to usual care without sitagliptin. In addition, there was no increase in hospitalization for heart failure and rates of all-cause mortality were similar in both treatments groups, which were two key secondary endpoints. These data were presented at the annual scientific meeting of the American Diabetes Association in June 2015.

In September 2015, Merck announced that the Japanese Pharmaceuticals and Medical Devices Agency approved *Marizev* (omarigliptin) 25 mg and 12.5 mg tablets, an oral, once-weekly DPP-4 inhibitor indicated for the treatment of adults with type 2 diabetes. Japan is the first country to have approved omarigliptin. Other worldwide regulatory submissions will follow.

General Medicine and Women's Health

Worldwide sales of *NuvaRing*, a vaginal contraceptive product, were $732 million in 2015, an increase of 1% compared with 2014, and were $723 million in 2014, an increase of 5% compared with 2013. Foreign exchange unfavorably affected global sales performance by 7% and 1% in 2015 and 2014, respectively. Sales growth in both years largely reflects higher pricing in the United States.

Worldwide sales of *Implanon/Nexplanon*, single-rod subdermal contraceptive implants, rose to $588 million in 2015, a 17% increase compared with 2014 including a 6% unfavorable effect from foreign exchange. The increase was driven primarily by higher demand in the United States and in the emerging markets. *Implanon/Nexplanon* sales grew 25% to $502 million in 2014 compared with 2013 driven primarily by higher demand in the United States.

Global sales of *Dulera* Inhalation Aerosol, a combination medicine for the treatment of asthma, grew 16% in 2015 to $536 million and increased 42% in 2014 to $460 million driven primarily by higher demand in the United States.

Global sales of *Follistim AQ* (marketed in most countries outside the United States as *Puregon*), a fertility treatment, were $383 million in 2015, a decline of 7% compared with 2014, reflecting a 9% unfavorable effect from foreign exchange that was offset by higher pricing in the United States. Worldwide sales of *Follistim AQ* declined 14% to $412 million in 2014 compared with 2013 driven largely by lower pricing in the United States, as well as by lower sales in Europe driven primarily by volume declines. Foreign exchange unfavorably affected global sales performance by 1% in 2014. The patent that provided market exclusivity for *Follistim AQ* in the United States expired in June 2015.

Hospital and Specialty

Hepatitis

Worldwide sales of *PegIntron*, a treatment for chronic HCV, were $182 million in 2015, a decline of 52% compared with 2014 including a 5% unfavorable effect from foreign exchange. The decline was driven by lower volumes in nearly all regions as the availability of newer therapeutic options continues to reduce market share. Global sales of *PegIntron* were $381 million in 2014, a decline of 23% compared with 2013 including a 3% unfavorable effect from foreign exchange. The decrease was driven by lower volumes in most regions as the availability of newer therapeutic options resulted in loss of market share or led to patient treatment delays in markets anticipating the availability of new therapeutic options.

Global sales of *Victrelis*, an oral medicine for the treatment of chronic HCV, were $18 million in 2015, a decline of 89% compared with 2014, driven by lower volumes in Europe and the emerging markets as the availability of newer therapeutic options continues to reduce market share. Worldwide sales of *Victrelis* were $153 million in 2014, a decline of 64% compared with 2013, driven by lower volumes in nearly all regions, particularly within the United States, as the availability of newer therapeutic options resulted in loss of market share or led to patient treatment delays in markets anticipating the availability of newer therapeutic options.

In January 2016, the FDA approved *Zepatier* for the treatment of adult patients with chronic HCV GT1 or GT4 infection, with or without ribavirin. *Zepatier* is a once-daily, fixed-dose combination tablet containing the NS5A inhibitor elbasvir (50 mg) and the NS3/4A protease inhibitor grazoprevir (100 mg). The FDA previously granted two Breakthrough Therapy designations to *Zepatier*, for the treatment of chronic HCV GT1 infection in patients with end stage renal disease on hemodialysis, and for the treatment of patients with chronic HCV GT4 infection. Breakthrough Therapy designation is given to investigational medicines for serious or life-threatening conditions that may offer substantial improvement over existing therapies. Across multiple clinical studies, *Zepatier* achieved high rates of sustained virologic response ranging from 94% to 97% in GT1-infected patients, and 97% to 100% in GT4-infected patients. Sustained virologic response is defined as HCV RNA levels measuring less than the lower limit of quantification at 12 weeks after the cessation of treatment, indicating that a patient's HCV infection has been cured. *Zepatier* became available in the United States in February 2016. *Zepatier* is under review in the EU.

HIV

Worldwide sales of *Isentress,* an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, were $1.5 billion in 2015, a decline of 10% compared with 2014 including an 8% unfavorable effect from foreign exchange. The decline was driven primarily by lower volumes in the United States and lower demand and pricing in Europe due to competitive pressures, partially offset by higher volumes in Latin America and higher pricing in the United States. Global sales of *Isentress* increased 2% in 2014 to $1.7 billion compared with 2013 primarily reflecting volume growth in Europe and the emerging markets, particularly in Latin America resulting from government tenders, partially offset by volume declines in the United States reflecting competitive pressures. Foreign exchange unfavorably affected global sales performance by 1% in 2014.

Hospital Acute Care

In January 2015, Merck acquired Cubist, a leader in the development of therapies to treat serious infections caused by a broad range of bacteria. Cubist's products include *Cubicin*, an I.V. antibiotic for complicated skin and skin structure infections or bacteremia, when caused by designated susceptible organisms. Sales of *Cubicin* were $1.1 billion in 2015 subsequent to the acquisition. The U.S. composition patent for *Cubicin* expires in June 2016 and significant losses of *Cubicin* sales are expected to occur thereafter.

In many markets outside of the United States, *Cubicin* is commercialized by other companies in accordance with distribution agreements established prior to Merck's acquisition of Cubist. In the fourth quarter of 2015, Merck entered into agreements to reacquire the marketing rights to *Cubicin* in certain international markets (including Europe, Latin America, Australia, New Zealand, China, South Africa and certain other Asia Pacific countries).

Cubist's products also include *Zerbaxa*, a combination product approved by the FDA in December 2014 for the treatment of adults with complicated urinary tract infections caused by designated susceptible Gram-negative organisms or with complicated intra-abdominal infections caused by designated susceptible Gram-negative and Gram-positive organisms, and *Sivextro*, a product approved by the FDA in June 2014 for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults caused by designated susceptible Gram-positive organisms. *Sivextro* was also approved by the EC in March 2015 for the treatment of ABSSSI in adults. The Company began launching *Sivextro* in the second quarter of 2015. In September 2015, *Zerbaxa* was approved by the EC for the treatment of complicated intra-abdominal infections, acute pyelonephritis, and complicated urinary tract infections in adults. *Zerbaxa* and *Sivextro* are in Phase 3 development in the United States for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia.

Global sales of *Cancidas*, an anti-fungal product, were $573 million in 2015, a decrease of 16% compared with 2014 reflecting a 12% unfavorable effect from foreign exchange and volume declines in certain emerging markets. Worldwide sales of *Cancidas* grew 3% in 2014 to $681 million compared with 2013 largely reflecting volume growth in the Asia Pacific region, particularly in China. Foreign exchange unfavorably affected global sales performance by 1% in 2014.

Worldwide sales of *Noxafil*, for the prevention of invasive fungal infections, grew 21% in 2015 to $487 million and increased 30% in 2014 to $402 million driven by pricing and higher demand in the United States and volume growth in Europe reflecting a positive impact from the approval of new formulations. Foreign exchange unfavorably affected global sales performance by 12% in 2015.

Sales of *Bridion*, for the reversal of two types of neuromuscular blocking agents used during surgery, grew 4% in 2015 to $353 million and rose 18% in 2014 to $340 million driven by volume growth in the international markets where it is sold. Foreign exchange unfavorably affected global sales performance by 19% in 2015 and 6% in 2014. *Bridion* is approved and marketed in many countries outside of the United States. In December 2015, the FDA approved *Bridion* for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery.

Immunology

Sales of *Remicade,* a treatment for inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were $1.8 billion in 2015, a decline of 24% compared with 2014 including a 14% unfavorable effect from foreign exchange. In February 2015, the Company lost market exclusivity for *Remicade* in major European markets 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. While the Company has retained a majority of its existing patients, the Company has lost market share as new patients are prescribed biosimilars. The Company expects the *Remicade* sales decline to accelerate throughout 2016. Sales of *Remicade* were $2.4 billion in 2014, an increase of 4% compared with 2013 reflecting sales growth in Europe, partially offset by a decline in Russia.

Sales of *Simponi*, a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were $690 million in 2015, essentially flat as compared with 2014, driven by higher demand in Europe, reflecting in part an ongoing positive impact from the ulcerative colitis indication, which was offset by a 19% unfavorable effect from foreign exchange. Sales of *Simponi* grew 38% in 2014 to $689 million compared with 2013 driven by demand in Europe reflecting in part a positive impact from the ulcerative colitis indication.

Other products contained in Hospital and Specialty include among others, *Invanz* for the treatment of certain infections; and *Primaxin*, an anti-bacterial product.

Oncology

Sales of *Keytruda*, an anti-PD-1 (programmed death receptor-1) therapy, were $566 million in 2015 and $55 million in 2014. The increase primarily reflects higher sales in the United States, as well as in the emerging markets and Europe as the Company continues to launch *Keytruda*. In September 2014, the FDA granted accelerated approval of *Keytruda* at a dose of 2 mg/kg every three weeks for the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor. In December 2015, the Company announced that the FDA approved an expanded indication for *Keytruda* to include the first-line treatment of patients with unresectable or metastatic melanoma regardless of BRAF status. Additionally, the FDA approved an update to the product labeling for *Keytruda* for the treatment of patients with ipilimumab-refractory advanced melanoma.

In addition, in October 2015, the FDA granted accelerated approval of *Keytruda* at a dose of 2 mg/kg every three weeks for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 as determined by an FDA-approved test and who have disease progression on or after platinum-containing chemotherapy across both squamous and non-squamous metastatic NSCLC. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving *Keytruda*. In addition to approving *Keytruda* for NSCLC, the FDA approved the first companion diagnostic that will enable physicians to determine the level of PD-L1 expression in a patient's tumor.

In July 2015, Merck announced that the EC approved *Keytruda* for the treatment of advanced (unresectable or metastatic) melanoma in adults. In October 2015, Merck announced the National Institute for Health and Care Excellence (NICE) of the UK issued a draft recommendation, in the form of a Final Appraisal Determination, recommending *Keytruda* as a first-line treatment option for adults with advanced melanoma. In addition, the NICE issued final guidance recommending *Keytruda* for the treatment of advanced melanoma after disease progression with ipilimumab.

The Company has made additional regulatory filings in other countries and further filings are planned. The *Keytruda* clinical development program includes studies across a broad range of cancer types (see "Research and Development" below).

Global sales of *Emend*, for the prevention of chemotherapy-induced and post-operative nausea and vomiting, were $535 million in 2015, a decline of 3% reflecting a 6% unfavorable effect from foreign exchange that was partially offset by higher pricing in the United States and volume growth in Europe. Worldwide sales of *Emend* were $553 million in 2014, an increase of 9% compared with 2013 including a 1% unfavorable effect from foreign exchange, largely reflecting volume growth in most regions. In February 2016, Merck announced that the FDA approved a supplemental new drug application for single-dose *Emend* for injection for the prevention of delayed nausea and vomiting in adults receiving initial and repeat courses of moderately emetogenic chemotherapy. With this approval, *Emend* for injection is the first intravenous single-dose NK1 receptor antagonist approved in the United States for both highly emetogenic chemotherapy as well as moderately emetogenic chemotherapy.

Sales of *Temodar* (marketed as *Temodal* outside the United States), a treatment for certain types of brain tumors, were $312 million in 2015, a decline of 11% compared with 2014, reflecting a 14% unfavorable effect from foreign exchange that was partially offset by growth in the emerging markets. Global sales of *Temodar* declined 51% to $350 million in 2014. Foreign exchange unfavorably affected global sales performance by 3% in 2014. The sales decline in 2014 was driven primarily by generic competition in the United States, as well as in Europe. By agreement, a generic manufacturer launched a generic version of *Temodar* in the United States in August 2013. The U.S. patent and exclusivity periods otherwise expired in February 2014.

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 $931 million in 2015, a decline of 15% compared with 2014 including a 10% unfavorable effect from foreign exchange. The sales decline in 2015 was driven primarily by lower volumes in Japan and lower demand in Europe as a result of generic competition. Global sales of *Singulair* were $1.1 billion in 2014, a decline of 9% compared with 2013 including a 5% unfavorable effect from foreign exchange, primarily reflecting lower sales in Europe as a result of generic competition. The Company has lost market exclusivity for *Singulair* in the United States and in most major international markets with the exception of Japan and expects generic competition in these markets to continue. The patent that provides market exclusivity for *Singulair* in Japan will expire in 2016. *Singulair* sales in Japan were $452 million in 2015.

Global sales of *Nasonex*, an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, were $858 million in 2015, a decline of 22% compared with 2014 including a 6% unfavorable effect from foreign exchange. The decline was driven primarily by lower volumes in the United States reflecting competition from alternative generic treatment options, as well as from supply constraints. The supply issue was resolved and *Nasonex* became available again in October. In addition, lower volumes and pricing in Europe from ongoing generic erosion also contributed to the *Nasonex* sales decline. By agreement, generic manufacturers were able to launch a generic version of *Nasonex* in most European markets on January 1, 2014 and generic versions of *Nasonex* have since launched in most of these markets. Accordingly, the Company continues to experience volume and pricing declines in *Nasonex* sales in Europe. Worldwide sales of *Nasonex* decreased 18% to $1.1 billion in 2014 compared with 2013. Foreign exchange unfavorably affected global sales performance by 2% in 2014. The sales decline was driven primarily by lower demand in the United States, as well as by lower volumes in Europe and Canada resulting from generic competition. In 2009, Apotex Inc. and Apotex Corp. (collectively, Apotex) filed an application with the FDA seeking approval to sell its generic version of *Nasonex*. In June 2012, the U.S. District Court for the District of New Jersey ruled against the Company in a patent infringement suit against Apotex holding that Apotex's generic version of *Nasonex* does not infringe on the Company's formulation patent. In June 2013, the Court of Appeals for the Federal Circuit issued a decision affirming the U.S. District Court decision and the Company has exhausted all of its appeal options. Apotex has not yet launched a generic version of *Nasonex* in the United States; however, if Apotex's generic version becomes available, significant losses of U.S. *Nasonex* sales could occur. U.S. sales of *Nasonex* were $449 million in 2015.

Other

Global sales of *Cozaar* and its companion agent *Hyzaar* (a combination of *Cozaar* and hydrochlorothiazide), treatments for hypertension, declined 17% in 2015 to $667 million and decreased 20% in 2014 to $806 million. Foreign exchange unfavorably affected global sales performance by 9% and 4% in 2015 and 2014, respectively. The patents that provided market exclusivity for *Cozaar* and *Hyzaar* in the United States and in most major international markets have expired. Accordingly, the Company is experiencing declines in *Cozaar* and *Hyzaar* sales and expects the declines to continue.

Worldwide sales of ophthalmic products *Cosopt* and *Trusopt* were $61 million in 2015, $257 million in 2014 and $416 million in 2013. The declines were driven largely by the divestiture of *Cosopt* and *Trusopt* in many international markets in 2014. In addition, the sale of the U.S. rights to *Cosopt* and *Cosopt PF* in 2013 also contributed to the sales decline in 2014 as compared with 2013. In December 2015, the Company divested its remaining ophthalmics portfolio in international markets to Mundipharma Ophthalmology Products Limited (see Note 4 to the consolidated financial statements).

Other products contained in Diversified Brands include among others, *Clarinex*, a non-sedating antihistamine; *Arcoxia* for the treatment of arthritis and pain (which the Company markets outside the United States); *Fosamax* (marketed as *Fosamac* in Japan) and *Fosamax Plus D* (marketed as *Fosavance* throughout the EU) for the treatment and, in the case of *Fosamax*, prevention of osteoporosis; *Zocor*, a statin for modifying cholesterol; and *Propecia*, a product for the treatment of male pattern hair loss.

Vaccines

The following discussion of vaccines does not include sales of vaccines sold in most major European markets through Sanofi Pasteur MSD (SPMSD), the Company's joint venture with Sanofi Pasteur, the results of which are reflected in equity income from affiliates included in *Other (income) expense, net* (see "Selected Joint Venture and Affiliate Information" below). Supply sales to SPMSD, however, are included.

Merck's sales of *Gardasil/Gardasil* 9, vaccines to help prevent certain diseases caused by certain types of HPV, were $1.9 billion in 2015, an increase of 10% compared with 2014 including a 1% unfavorable effect from foreign exchange. Sales growth was driven primarily by higher sales in the United States resulting from higher pricing and increased volumes reflecting the timing of public sector purchases, as well as increased government tenders in the Asia Pacific region, partially offset by declines in Latin America due to both price and volume. *Gardasil* 9, Merck's 9-valent HPV vaccine, was approved by the FDA in December 2014 for use in girls and young women 9 to 26 years of age. *Gardasil* 9 includes the greatest number of HPV types in any available HPV vaccine. In December 2015, the FDA approved an expanded age indication for *Gardasil* 9, to include use in males 16 through 26 years of age for the prevention of anal cancers, precancerous or dysplastic lesions and genital warts caused by certain HPV types. Merck's sales of *Gardasil* were $1.7 billion in 2014, a decline of 5% compared with 2013 including a 2% unfavorable effect from foreign exchange. The decline reflects lower sales in Asia Pacific, Japan and Canada, partially offset by higher government tenders in Brazil from the national immunization program, as well as higher public sector purchases in the United States. Sales in 2014 and 2013 included $56 million and $37 million, respectively, of purchases for the U.S. Centers for Disease Control and Prevention (CDC) Pediatric Vaccine Stockpile. The Company is a party to certain third-party license agreements with respect to *Gardasil/Gardasil* 9 (including a cross-license and settlement agreement with GlaxoSmithKline). As a result of these agreements, the Company pays royalties on worldwide *Gardasil/Gardasil* 9 sales of 17% to 25% which vary by country and are included in *Materials and production* costs.

Merck's sales of *ProQuad*, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, were $454 million in 2015, $395 million in 2014 and $314 million in 2013. Sales growth in 2015 as compared with 2014 was driven by higher sales in the United States reflecting increased volumes, which were driven in part by measles outbreaks in the United States, as well as higher pricing. The increase in 2014 as compared with 2013 was driven primarily by higher sales in the United States reflecting approximately $30 million of government purchases for the CDC Pediatric Vaccine Stockpile.

Merck's sales of *M-M-R* II, a vaccine to help protect against measles, mumps and rubella, were $365 million in 2015, $326 million in 2014 and $307 million in 2013. Sales growth in 2015 as compared with 2014 was driven by higher demand resulting from measles outbreaks in the United States and higher pricing.

Merck's sales of *Varivax,* a vaccine to help prevent chickenpox (varicella), were $686 million in 2015, $672 million in 2014 and $684 million in 2013. Sales growth in 2015 as compared with 2014 reflects higher volumes in certain emerging markets and higher pricing in the United States, partially offset by lower volumes in the United States. Sales performance in 2014 as compared with 2013 reflects lower sales in the United States largely offset by growth in the emerging markets.

Merck's sales of *Zostavax,* a vaccine to help prevent shingles (herpes zoster) in adults 50 years of age and older, were $749 million in 2015, a decline of 2% compared with 2014 including a 2% unfavorable effect from foreign exchange. Sales performance in 2015 as compared with 2014 reflects lower volumes in the United States, partially offset by higher demand in Canada and higher pricing in the United States. Merck's sales of *Zostavax* were $765 million in 2014, an increase of 1% compared with 2013, driven primarily by higher sales in the Asia Pacific region due to ongoing launches, partially offset by lower demand in the United States, as well as in Canada. The Company is continuing to educate U.S. customers on the broad managed care coverage for *Zostavax* and the process for obtaining reimbursement. Merck is continuing to launch *Zostavax* outside of the United States.

Merck's sales of *RotaTeq,* a vaccine to help protect against rotavirus gastroenteritis in infants and children, were $610 million in 2015, a decline of 7% compared with 2014 including a 3% unfavorable effect from foreign exchange. The decline was driven primarily by the effects of public sector purchasing in the United States. Merck's sales of *RotaTeq* increased 4% in 2014 to $659 million compared with 2013 primarily reflecting higher sales in certain emerging markets.

Merck's sales of *Pneumovax* 23, a vaccine to help prevent pneumococcal disease, declined 27% in 2015 to $542 million compared with 2014 driven primarily by lower demand in the United States due to near term market dynamics and sales in the emerging markets. Merck's sales of *Pneumovax* 23 grew 14% in 2014 to $746 million compared with 2013 driven primarily by higher sales in Japan from the national immunization program, as well as higher sales in the United States attributable to both price and volume. Foreign exchange unfavorably affected sales performance by 2% and 3% in 2015 and 2014, respectively.

Other Segments

The Company's other segments are the Animal Health, Alliances and Healthcare Services segments, which are not material for separate reporting. Prior to its disposition on October 1, 2014, the Company also had a Consumer Care segment which had sales of $1.5 billion in 2014 and $1.9 billion in 2013.

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. Global sales of Animal Health products were $3.3 billion in 2015, a decline of 4% compared with 2014 including a 13% unfavorable effect from foreign exchange. Sales performance in 2015 reflects volume growth in companion animal products, driven primarily by higher sales of *Bravecto* chewable tablets for dogs to treat fleas and ticks that began launching in Europe and the United States in 2014, as well as volume growth in swine and aqua products. Worldwide sales of Animal Health products totaled $3.5 billion in 2014, growth of 3% compared with 2013 including a 2% unfavorable effect from foreign exchange. The sales growth was driven primarily by higher sales of companion animal products, reflecting the launch of *Bravecto* in Europe and the United States, as well as higher sales of poultry and aqua products, partially offset by lower sales of *Zilmax*, a feed supplement for beef cattle.

Alliances

The Alliances segment includes results from the Company's relationship with AZLP. On June 30, 2014, AstraZeneca exercised its option to buy Merck's interest in a subsidiary and, through it, Merck's interest in Nexium and Prilosec. As a result, as of July 1, 2014, the Company no longer records equity income from AZLP and supply sales to AZLP, primarily relating to sales of Nexium and Prilosec, have terminated (see "Selected Joint Venture and Affiliate Information" below). Revenue from AZLP was $463 million in 2014 through the June 30 termination date and $920 million in 2013.

Costs, Expenses and Other

($ in millions)	**2015**	**Change**	2014	Change	2013
Materials and production	**$ 14,934**	**-11%**	$ 16,768	-1%	$ 16,954
Marketing and administrative	**10,313**	**-11%**	11,606	-3%	11,911
Research and development [(1)]	**6,704**	**-7%**	7,180	-4%	7,503
Restructuring costs	**619**	**-39%**	1,013	-41%	1,709
Other (income) expense, net	**1,527**	*	(11,613)	*	411
	$ 34,097	**37%**	$ 24,954	-35%	$ 38,488

** 100% or greater.*

[(1)] *Includes $63 million, $49 million and $279 million of IPR&D impairment charges in 2015, 2014 and 2013, respectively.*

Materials and Production

Materials and production costs were $14.9 billion in 2015, $16.8 billion in 2014 and $17.0 billion in 2013. Costs include expenses for the amortization of intangible assets recorded in connection with business acquisitions which totaled $4.7 billion in 2015, $4.2 billion in 2014 and $4.7 billion in 2013. In addition, expenses for 2015 include $105 million of amortization of purchase accounting adjustments to Cubist's inventories. Costs in 2015, 2014 and 2013 also include intangible asset impairment charges of $45 million, $1.1 billion and $486 million, respectively, related to marketed products and other intangibles (see Note 7 to the consolidated financial statements). The Company may recognize additional non-cash impairment charges in the future related to intangibles that were measured at fair value and capitalized in connection with acquisitions and such charges could be material. Additionally, costs in 2013 include a $41 million intangible asset impairment charge related to a licensing agreement. Also included in materials and production are costs associated with restructuring activities which amounted to $361 million, $482 million and $446 million in 2015, 2014 and 2013, respectively, including 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 62.2% in 2015 compared with 60.3% in 2014 and 61.5% in 2013. The amortization of intangible assets and purchase accounting adjustments to inventories, as well as the restructuring and impairment charges noted above reduced gross margin by 13.2 percentage points in 2015, 13.6 percentage points in 2014 and 12.8 percentage points in 2013. Excluding these impacts, the gross margin improvement in 2015 as compared with 2014 was driven primarily by the favorable effects of foreign exchange and lower inventory write-offs, as well as the net impact of acquisitions and divestitures. The gross margin decline in 2014 as compared with 2013 was driven primarily by the unfavorable effects of inventory write-offs largely related to *Victrelis*, as well as by changes in product mix, partially offset by the sale of the U.S. marketing rights to *Saphris*.

Marketing and Administrative

Marketing and administrative expenses declined 11% in 2015 to $10.3 billion in 2015 largely reflecting the favorable effects from foreign exchange, the prior year divestiture of MCC, additional expenses in the prior year related to the health care reform fee as discussed below, lower restructuring costs, as well as lower selling costs, partially offset by higher promotional spending largely related to product launches, as well as higher costs related to the January acquisition of Cubist and higher acquisition and divestiture-related costs. Marketing and administrative expenses decreased 3% in 2014 to $11.6 billion driven primarily by lower selling costs and promotional spending, the divestiture of MCC and the favorable effects of foreign exchange, partially offset by an additional year of expense related to the health care reform fee, as well as higher acquisition and divestiture-related costs. Expenses for 2015, 2014 and 2013 include restructuring costs of $78 million, $200 million and $145 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. Expenses also include $436 million, $234 million and $94 million of acquisition and divestiture-related costs in 2015, 2014 and 2013, respectively, consisting of integration, transaction, and certain other costs related to business acquisitions, including severance costs which are not part of the Company's formal restructuring programs, as well as transaction and certain other costs related to divestitures.

On July 28, 2014, the IRS issued final regulations on the annual non-tax deductible health care reform fee imposed by the Patient Protection and Affordable Care Act that is based on an allocation of a company's market share of prior year branded pharmaceutical sales to certain government programs. The final IRS regulations accelerated the recognition criteria for the fee obligation by one year to the year in which the underlying sales used to allocate the fee occurred rather than the year in which the fee was paid. As a result of this change, Merck recorded an additional year of expense of $193 million during 2014.

Research and Development

Research and development expenses were $6.7 billion in 2015, a decline of 7% compared with $7.2 billion in 2014 driven primarily by the favorable effects of foreign exchange, expenses recognized in the prior year to increase the estimated fair value of liabilities for contingent consideration, lower restructuring costs, a charge in the prior year related to a collaboration with Bayer AG (Bayer) and the prior year divestiture of MCC, partially offset by the acquisition of Cubist, higher licensing costs and higher clinical development spending. Research and development expenses declined 4% in 2014 to $7.2 billion compared with $7.5 billion in 2013 reflecting targeted reductions and lower clinical development spend as a result of portfolio prioritization, cost savings resulting from restructuring activities and lower acquired in-process research and development (IPR&D) impairment charges, partially offset by higher charges to increase the estimated fair value of liabilities for contingent consideration, higher restructuring costs and a charge related to a collaboration with Bayer.

Research and development 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 approximately $4.0 billion in 2015, $3.7 billion in 2014 and $4.2 billion in 2013. Also included in research and development expenses are costs incurred by other divisions in support of research and development 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 $2.6 billion, $2.8 billion and $2.9 billion for 2015, 2014 and 2013, respectively. Research and development expenses also include IPR&D impairment charges of $63 million, $49 million and $279 million in 2015, 2014 and 2013, respectively (see "Research and Development" below). The Company may recognize additional non-cash impairment charges in the future for the cancellation or delay of other pipeline programs that were measured at fair value and capitalized in connection with acquisitions and such charges could be material. In addition, research and development 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 2015, the Company recorded a reduction of expenses of $24 million to decrease the fair value of liabilities for contingent consideration and during 2014 recorded a charge of $316 million to increase the estimated fair value of liabilities for contingent consideration (see Note 5 to the consolidated financial statements). Research and development expenses in 2015, 2014 and 2013 also reflect $52 million, $283 million and $101 million, respectively, of accelerated depreciation and asset abandonment costs associated with restructuring activities.

Restructuring Costs

Restructuring costs, primarily representing separation and other related costs associated with restructuring activities, were $619 million, $1.0 billion and $1.7 billion in 2015, 2014 and 2013, respectively. Costs in 2015, 2014 and 2013 include $363 million, $594 million and $898 million, respectively, of expenses related to the 2013 Restructuring Program. The remaining costs in 2015, 2014 and nearly all of the remaining costs recorded in 2013 related to the Merger Restructuring Program. In 2015, 2014 and 2013, separation costs of $208 million, $674 million and $1.4 billion, 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. Positions eliminated under the 2013 Restructuring Program were approximately 2,535 in 2015, 4,555 in 2014 and 1,540 in 2013. Positions eliminated under the Merger Restructuring Program were approximately 1,235 in 2015, 1,530 in 2014 and 4,475 in 2013. These position eliminations are comprised of actual headcount reductions, and the elimination of contractors and vacant positions. 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.

Other (Income) Expense, Net

Other (income) expense, net was $1.5 billion of expense in 2015 compared with $11.6 billion of income in 2014. The unfavorability was driven primarily by gains recognized in 2014, including an $11.2 billion gain related to the divestiture of MCC (see Note 4 to the consolidated financial statements), a $741 million gain related to AstraZeneca's option exercise (see Note 8 to the consolidated financial statements), a $480 million gain on the divestiture of certain ophthalmic products in several international markets (see Note 4 to the consolidated financial statements) and a $204 million gain related to the divestiture of the Company's Sirna Therapeutics, Inc. subsidiary (see Note 4 to the consolidated financial statements). The unfavorability was also driven by a $680 million net charge recorded in 2015 related to the settlement of *Vioxx* shareholder class action litigation (see Note 10 to the consolidated financial statements), foreign exchange losses of $876 million in 2015 related to the devaluation of the Company's net monetary assets in Venezuela (see Note 14 to the consolidated financial statements), and lower equity income from AZLP. Partially offsetting the unfavorability of these items was a $628 million loss on extinguishment of debt in 2014 (see Note 9 to the consolidated financial statements), a $250 million gain in 2015 on the sale of certain migraine clinical development programs (see Note 4 to the consolidated financial statements), a $147 million gain on the divestiture of the Company's remaining ophthalmics business in international markets (see Note 4 to the consolidated financial statements), higher equity income from certain research investment funds, and a $93 million goodwill impairment charge in 2014 related to the Company's joint venture with Supera (see Note 7 to the consolidated financial statements).

Other (income) expense, net was $11.6 billion of income in 2014 compared with $411 million of expense in 2013 driven primarily by gains recognized in 2014 as noted above, lower foreign exchange losses due to a Venezuelan currency devaluation in 2013, partially offset by charges recognized in 2014 related to the extinguishment of debt and goodwill impairment as noted above, as well as lower equity income from AZLP in 2014.

Segment Profits

($ in millions)	**2015**	2014	2013
Pharmaceutical segment profits	**$ 21,658**	$ 22,164	$ 22,983
Other non-reportable segment profits	**1,659**	2,458	3,049
Other	**(17,916)**	(7,339)	(20,487)
Income before income taxes	**$ 5,401**	$ 17,283	$ 5,545

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 and intangible asset impairment charges, restructuring costs, taxes paid at the joint venture level 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 gains on divestitures, a net charge related to the settlement of *Vioxx* shareholder class action litigation, the gain on AstraZeneca's option exercise, foreign exchange losses related to the devaluation of the Company's net monetary assets in Venezuela, the loss on extinguishment of debt and an additional year of expense related to the health care reform fee, 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 declined 2% in 2015 compared with 2014 primarily reflecting the unfavorable effect of foreign exchange. Pharmaceutical segment profits declined 4% in 2014 compared with 2013 driven primarily by the unfavorable effects of product divestitures and loss of market exclusivity for certain products, partially offset by cost savings from productivity measures. The declines in other segment profits in 2015 and 2014 reflect the termination of the Company's relationship with AZLP, as well as the divestiture of MCC.

Taxes on Income

The effective income tax rates of 17.4% in 2015, 30.9% in 2014 and 18.5% in 2013 reflect the impacts of acquisition and divestiture-related costs and restructuring costs, partially offset by the beneficial impact of foreign earnings. The effective income tax rate for 2015 also reflects the favorable impact of a net benefit of $410 million related to the settlement of certain federal income tax issues, the impact of the net charge related to the settlement of *Vioxx* shareholder class action litigation being fully deductible at combined 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 14 to the consolidated financial statements). The effective income tax rate for 2014 reflects the impact of the gain on the divestiture of MCC being taxed at combined U.S. federal and state tax rates. In addition, the effective income tax rate for 2014 includes a net tax benefit of $517 million recorded in connection with AstraZeneca's option exercise (see Note 8 to the consolidated financial statements) and a benefit of approximately $300 million associated with a capital loss generated in connection with the sale of Sirna (see Note 4 to the consolidated financial statements). The effective income tax rate for 2014 also includes the unfavorable impact of an additional year of expense for the non-tax deductible health care reform fee that the Company recorded in accordance with final regulations issued in the third quarter by the IRS. The effective income tax rate in 2013 reflects a net benefit of $165 million from the settlements of certain federal income tax issues, net benefits from reductions in tax reserves upon expiration of applicable statutes of limitations, the favorable impact of tax legislation enacted in the first quarter of 2013 that extended the R&D tax credit for both 2012 and 2013, as well as an out-of-period net tax benefit of approximately $160 million associated with the resolution of a previously disclosed legacy Schering-Plough federal income tax issue (see Note 15 to the consolidated financial statements).

The Company is under examination by numerous tax authorities in various jurisdictions globally. 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. However, there is one item that is currently under discussion with the IRS relating to the 2006 through 2008 examination. The Company has concluded that its position should be sustained upon audit. However, if this item were to result in an unfavorable outcome or settlement, it could have a material adverse impact on the Company's financial position, liquidity and results of operations.

Net Income Attributable to Noncontrolling Interests

Net income attributable to noncontrolling interests was $17 million in 2015, $14 million in 2014 and $113 million in 2013. The declines in 2015 and 2014 as compared with 2013 reflect in part the termination of the Company's relationship with AZLP and the resulting retirement of KBI preferred stock (see Note 11 to the consolidated financial statements). In addition, the amount for 2014 includes the portion of intangible asset and goodwill impairment charges related to the Company's joint venture with Supera (see Note 7 to the consolidated financial statements) that are attributable to noncontrolling interests.

Net Income and Earnings per Common Share

Net income attributable to Merck & Co., Inc. was $4.4 billion in 2015, $11.9 billion in 2014 and $4.4 billion in 2013. EPS was $1.56 in 2015, $4.07 in 2014 and $1.47 in 2013.

Non-GAAP Income and Non-GAAP EPS

Non-GAAP income and non-GAAP EPS are alternative views of the Company's performance used by management that Merck is providing because management believes this information enhances investors' understanding of the Company's results. 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 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. Therefore, the information on non-GAAP income and non-GAAP EPS should be considered in addition to, but not in lieu of, net income and EPS prepared in accordance with generally accepted accounting principles in the United States (GAAP). Additionally, 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.

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 income and non-GAAP EPS and the performance of the Company is measured on this basis along with other performance metrics. Senior management's annual compensation is derived in part using non-GAAP income and non-GAAP EPS.

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

($ in millions except per share amounts)	**2015**	2014	2013
Pretax income as reported under GAAP	**$ 5,401**	$ 17,283	$ 5,545
Increase (decrease) for excluded items:			
Acquisition and divestiture-related costs	**5,398**	5,946	5,549
Restructuring costs	**1,110**	1,978	2,401
Other items:			
Foreign currency devaluation related to Venezuela	**876**	—	—
Net charge related to the settlement of *Vioxx* shareholder class action litigation	**680**	—	—
Gain sale of certain migraine clinical development programs	**(250)**	—	—
Gain on the divestiture of certain ophthalmic products	**(147)**	(480)	—
Gain on divestiture of Merck Consumer Care	**—**	(11,209)	—
Gain on AstraZeneca option exercise	**—**	(741)	—
Loss on extinguishment of debt	**—**	628	—
Additional year of expense for health care reform fee	**—**	193	—
Other	**(34)**	(9)	(13)
	13,034	13,589	13,482
Taxes on income as reported under GAAP	**942**	5,349	1,028
Estimated tax benefit (provision) on excluded items [(1)]	**1,470**	(2,345)	1,573
Net tax benefits from settlements of federal income tax issues	**410**	—	325
Tax benefits related to sale of Sirna Therapeutics, Inc. subsidiary	**—**	300	—
	2,822	3,304	2,926
Non-GAAP net income	**10,212**	10,285	10,556
Less: Net income attributable to noncontrolling interests as reported under GAAP	**17**	14	113
Acquisition and divestiture-related costs attributable to non-controlling interests	**—**	56	—
	17	70	113
Non-GAAP net income attributable to Merck & Co., Inc.	**$ 10,195**	$ 10,215	$ 10,443
EPS assuming dilution as reported under GAAP	**$ 1.56**	$ 4.07	$ 1.47
EPS difference [(2)]	**2.03**	(0.58)	2.02
Non-GAAP EPS assuming dilution	**$ 3.59**	$ 3.49	$ 3.49

[(1)] *Amount for 2014 includes a net benefit of $517 million recorded in connection with AstraZeneca's option exercise.*

[(2)] *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 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, including severance costs which are not part

of the Company's formal restructuring programs, as well as transaction and certain other costs related to divestitures. These costs should not be considered non-recurring; however, management excludes these amounts from non-GAAP income and non-GAAP EPS because it believes it is helpful for understanding the performance of the continuing business.

Restructuring Costs

Non-GAAP income and non-GAAP EPS exclude costs related to restructuring actions (see Note 3 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 site, based upon the anticipated date the site will be closed or divested, 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. The Company has undertaken restructurings of different types during the covered periods and, therefore, these charges should not be considered non-recurring; however, management excludes these amounts from non-GAAP income and non-GAAP EPS because it believes it is helpful for understanding the performance of the continuing business.

Certain Other Items

Non-GAAP income and non-GAAP EPS exclude certain other items. These items represent substantive, unusual items that are evaluated on an individual basis. Such evaluation considers both the quantitative and the qualitative aspect of their unusual nature and generally represent items that, either as a result of their nature or magnitude, management would not anticipate that they would occur as part of the Company's normal business on a regular basis. Excluded from 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 14 to the consolidated financial statements), a net charge related to the settlement of *Vioxx* shareholder class action litigation (see Note 10 to the consolidated financial statements), a gain on the sale of certain migraine clinical development programs (see Note 4 to the consolidated financial statements), a gain on the divestiture of the Company's remaining ophthalmics business in international markets (see Note 4 to the consolidated financial statements), as well as a net tax benefit related to the settlement of certain federal income tax issues (see Note 15 to the consolidated financial statements). Excluded from non-GAAP income and non-GAAP EPS in 2014 are certain gains, including a gain on the divestiture of MCC (see Note 4 to the consolidated financial statements), a gain recognized in conjunction with AstraZeneca's option exercise, including a related net tax benefit on the transaction (see Note 8 to the consolidated financial statements), a gain on the divestiture of certain ophthalmic products in several international markets (see Note 4 to the consolidated financial statements), as well as a loss on extinguishment of debt (see Note 9 to the consolidated financial statements), an additional year of expense related to the health care reform fee as discussed above, and a tax benefit from the sale of Sirna and tax benefits from the settlements of certain federal income tax issues (see Note 15 to the consolidated financial statements).

Research and Development

A chart reflecting the Company's current research pipeline as of February 19, 2016 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 or internationally.

Keytruda is an FDA-approved anti-PD-1 (programmed death receptor-1) therapy in clinical development for expanded indications in different cancer types. *Keytruda* is currently approved for the treatment of melanoma, advanced melanoma and NSCLC (see "Pharmaceutical Segment" above).

In December 2015, Merck announced results from the pivotal KEYNOTE-010 study to evaluate the potential of an immunotherapy compared to chemotherapy based on prospective measurement of PD-L1 expression in patients with advanced NSCLC. In the Phase 2/3 study, *Keytruda* significantly improved overall survival compared to chemotherapy in patients with any level of PD-L1 expression. Based on these data, Merck has submitted a supplemental Biologics License Application to the FDA and has filed a Marketing Authorization Application with the EMA.

In November 2015, Merck announced that the FDA granted Breakthrough Therapy designation to *Keytruda* for the treatment of patients with microsatellite instability high metastatic colorectal cancer. 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. *Keytruda* was previously granted Breakthrough Therapy status for advanced melanoma and advanced NSCLC.

The *Keytruda* clinical development program consists of more than 200 clinical trials, including over 100 trials that combine *Keytruda* with other cancer treatments. These studies encompass more than 30 cancer types including: bladder, colorectal, esophageal, gastric, head and neck, melanoma, multiple myeloma, non-small-cell lung, and triple negative breast, several of which are currently in Phase 3 clinical development.

MK-6072, bezlotoxumab, is an investigational antitoxin for the prevention of *C. difficile* infection recurrence currently under review with the FDA and EMA. In January 2016, Merck announced that the FDA accepted for review the Biologics License Application (BLA) for bezlotoxumab and granted Priority Review with a Prescription Drug User Fee Act action date of July 23, 2016. In September 2015, Merck announced that the two pivotal Phase 3 clinical studies for bezlotoxumab met their primary efficacy endpoint: the reduction in *C. difficile* recurrence through week 12 compared to placebo, when used in conjunction with standard of care antibiotics for the treatment of *C. difficile*. The Company is also seeking approval in the EU and intends to file in Canada in 2016. Currently, there are no therapies approved for the prevention of recurrent disease caused by *C. difficile*.

MK-1293 is an insulin glargine candidate for the treatment of patients with type 1 and type 2 diabetes being developed in collaboration with Samsung Bioepis. In December 2015, the Company submitted an application for regulatory approval in the EU and plans to submit MK-1293 to the FDA in 2016.

MK-5172A, *Zepatier*, currently under review in the EU for the treatment of chronic HCV, is a once-daily, fixed-dose combination tablet containing the NS5A inhibitor elbasvir (50 mg) and the NS3/4A protease inhibitor grazoprevir (100 mg). *Zepatier* was approved by the FDA in January 2016 for the treatment of adult patients with chronic HCV GT1 or GT4 infection, with or without ribavirin.

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 partnership of Merck and Sanofi Pasteur. 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. On November 2, 2015, the FDA issued a CRL with respect to the BLA for V419. Both companies are reviewing the CRL and plan to have further communication with the FDA. In February 2016, the EC granted marketing authorization for V419 for prophylaxis against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis, and invasive disease caused by Hib, in infants and toddlers from the age of 6 weeks. V419 will be marketed as *Vaxelis* in the EU through SPMSD, the Company's joint venture with Sanofi Pasteur.

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. The Company anticipates filing applications for regulatory approval with the FDA with respect to certain of these candidates in 2016, including MK-1293 as noted above.

MK-0822, odanacatib, is an oral, once-weekly investigational treatment for patients with osteoporosis. Osteoporosis is a disease that reduces bone density and strength and results in an increased risk of bone fractures. Odanacatib is a cathepsin K inhibitor that selectively inhibits the cathepsin K enzyme. Cathepsin K is known to play a central role in the function of osteoclasts, which are cells that break down existing bone tissue, particularly the protein components of bone. Inhibition of cathepsin K is a novel approach to the treatment of osteoporosis. In September 2014, Merck announced data from the pivotal Phase 3 fracture outcomes study for odanacatib in postmenopausal women with osteoporosis. In the Long-Term Odanacatib Fracture Trial (LOFT), odanacatib met its primary endpoints and significantly reduced the risk of three types of osteoporotic fractures (radiographically-assessed vertebral, clinical hip, and clinical non-vertebral) compared to placebo and also reduced the risk of the secondary endpoint of clinical vertebral fractures. In addition, treatment with odanacatib led to progressive increases over five years in bone mineral density at the lumbar spine and total hip. The rates of adverse events overall in LOFT were generally balanced between patients

taking odanacatib and placebo. Adjudicated events of morphea-like skin lesions and atypical femoral fractures occurred more often in the odanacatib group than in the placebo group. Adjudicated major adverse cardiovascular events were generally balanced overall between the treatment groups. There were numerically more adjudicated stroke events with odanacatib than with placebo. Adjudicated atrial fibrillation was reported more often in the odanacatib group than in the placebo group. A numeric imbalance in mortality was observed; this numeric difference does not appear to be related to a particular reported cause or causes of death. Merck continues to collect data from the blinded extension study and is planning additional analyses of data from the trial, including an independent re-adjudication of major adverse cardiovascular events (MACE), in support of regulatory submissions. Merck plans to submit a New Drug Application (NDA) to the FDA for odanacatib in 2016 following completion of the independent adjudication and analysis of MACE. Merck also plans to submit applications to the EMA and the Ministry of Health, Labour, and Welfare in Japan.

MK-3102, omarigliptin, is an investigational once-weekly DPP-4 inhibitor in development for the treatment of adults with type 2 diabetes. In September 2015, the Company announced that omarigliptin achieved its primary efficacy endpoint in a Phase 3 study. Omarigliptin was found to be non-inferior to *Januvia*, at reducing patients' A1C (an estimate of a person's blood glucose over a two-to three-month period) levels from baseline, with similar A1C reductions achieved in both groups. The head-to-head study was designed to evaluate once-weekly treatment with omarigliptin 25 mg compared to 100 mg of *Januvia* once daily. Results were presented during an oral session at the 51st European Association for the Study of Diabetes Annual Meeting. Also, in September 2015, Merck announced that the Japanese Pharmaceuticals and Medical Devices Agency approved *Marizev* (omarigliptin) 25 mg and 12.5 mg tablets. Japan is the first country to have approved omarigliptin. Merck plans to submit omarigliptin for regulatory approval in the United States in 2016. Other worldwide regulatory submissions will follow.

MK-8835, ertugliflozin, is an investigational oral SGLT2 inhibitor being evaluated for the treatment of type 2 diabetes in collaboration with Pfizer Inc. Ertugliflozin is also being studied in combination with *Januvia* (sitagliptin) and metformin. Merck expects to submit applications for regulatory approval in the United States for ertugliflozin and the two fixed-dose combination tablets by the end of 2016.

MK-8237 is an investigational allergy immunotherapy tablet for house dust mite allergy that is part of a North America partnership between Merck and ALK-Abello. Merck plans to submit an NDA to the FDA for MK-8237 in the first half of 2016.

MK-8931, verubecestat, is Merck's novel investigational oral ß-amyloid precursor protein site-cleaving enzyme (BACE) inhibitor for the treatment of Alzheimer's disease being studied in a Phase 3 trial (APECS) designed to evaluate the safety and efficacy of MK-8931 versus placebo in patients with amnestic mild cognitive impairment due to Alzheimer's disease, also known as prodromal Alzheimer's disease. MK-8931 is also being studied in another Phase 2/3 randomized, placebo-controlled, study in patients with mild-to-moderate Alzheimer's disease (EPOCH). The EPOCH study completed enrollment in the fourth quarter of 2015 and is estimated to reach primary trial completion in mid-2017.

MK-0859, anacetrapib, is an investigational inhibitor of the cholesteryl ester transfer protein (CETP) in development for raising HDL-C and reducing LDL-C. Anacetrapib is being evaluated in a 30,000 patient, event-driven cardiovascular clinical outcomes trial sponsored by Oxford University, REVEAL (Randomized EValuation of the Effects of Anacetrapib Through Lipid-modification), involving patients with preexisting vascular disease, which is projected to conclude in early 2017. In November 2015, Merck announced that the Data Monitoring Committee (DMC) of the REVEAL outcomes study completed its planned review of unblinded study data and recommended the study continue with no changes. The DMC reviewed safety and efficacy data from the study, which included an assessment of futility. Merck remains blinded to the actual results of this analysis and to other REVEAL safety and efficacy data. The REVEAL Steering Committee and Merck will continue to monitor the progress of the study. No additional interim efficacy analyses are planned.

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-8228, letermovir, is an investigational oral, once-daily antiviral candidate for the prevention and treatment of Human Cytomegalovirus infection. Letermovir has received Orphan Drug Status in the EU and in the United States, where it has also been granted Fast Track designation.

MK-8342B, referred to as the Next Generation Ring, is an investigational combination (etonogestrel and 17β-estradiol) vaginal ring for contraception and the treatment of dysmenorrhea in women seeking contraception.

MK-0431J is an investigational fixed-dose combination of sitagliptin and ipragliflozin under development 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.

V920 is an investigational rVSV-ZEBOV (Ebola) vaccine candidate being studied in large scale Phase 2/3 clinical trials currently underway in West Africa. 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 has been 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 procedure is intended to assist United Nations' procurement agencies and Member States on the acceptability of using a vaccine candidate in an emergency-use setting. EUAL designation is not prequalification by the WHO, but rather is a special procedure implemented when there is an outbreak of a disease with high rates of morbidity and/or mortality and a lack of treatment and/or prevention options. In such instances, the WHO may recommend making a vaccine available for a limited time, while further clinical trial data are being gathered for formal regulatory agency review by a national regulatory authority. 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.

V212 is an inactivated varicella zoster virus vaccine in development for the prevention of herpes zoster. The Company is conducting two Phase 3 trials, one in autologous hematopoietic cell transplant patients and the other in patients with solid tumor malignancies undergoing chemotherapy and hematological malignancies.

MK-1439, doravirine, is an investigational, once-daily oral next-generation non-nucleoside reverse transcriptase inhibitor being developed by Merck for the treatment of HIV-1 infection.

In 2015, the Company also divested or discontinued certain drug candidates.

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 CGRP receptor antagonists, which are being developed for the treatment and prevention of migraine (see Note 4 to the consolidated financial statements).

MK-4261, surotomycin, is an investigational oral antibiotic in development for the treatment of *C. difficile* associated diarrhea. Merck acquired surotomycin as part of its purchase of Cubist. During the second quarter of 2015, the Company received unfavorable efficacy data from a randomized, double-blinded, active-controlled study in patients with *C. difficile* associated diarrhea. 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 in 2015 (see Note 7 to the consolidated financial statements).

MK-2402, bevenopran, is an oral investigational therapy in development as a potential treatment for opioid-induced constipation in patients with chronic, non-cancer pain. Merck acquired bevenopran as a part of its purchase of Cubist. The Company has made the decision not to continue development of this program and is seeking to out-license the asset.

MK-8962, corifollitropin alfa injection, is an investigational fertility treatment for controlled ovarian stimulation in women participating in assisted reproductive technology. In July 2014, Merck received a CRL from the FDA for its NDA for corifollitropin alfa injection. Merck has made a decision to discontinue development of corifollitropin alfa injection in the United States for business reasons. Corifollitropin alfa injection is marketed as *Elonva* in certain markets outside of the United States.

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 making externally sourced programs a greater component of its pipeline strategy, with a renewed 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 which 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 atherosclerosis, cancer, cardiovascular diseases, diabetes, infectious diseases, inflammatory/autoimmune diseases, neurodegenerative diseases, osteoporosis, respiratory diseases and women's health.

Acquired In-Process Research and Development

In connection with 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, 2015, the balance of IPR&D was $4.2 billion. Of this amount, $3.2 billion relates to the clinical development program for MK-3682, which the Company acquired in 2014 with the acquisition of Idenix Pharmaceuticals, Inc. (Idenix).

During 2015, 2014 and 2013, approximately $280 million, $654 million and $346 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 program. 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.

During 2015, the Company recorded $63 million of IPR&D impairment charges within *Research and development* expenses. Of this amount, $50 million relates to the surotomycin clinical development program obtained in connection with the acquisition of Cubist. During 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. During 2014, the Company recorded $49 million of IPR&D impairment charges primarily as a result of changes in cash flow assumptions for certain compounds obtained in connection with the Supera joint venture, as well as for the discontinuation of certain Animal Health programs. During 2013, the Company recorded $279 million of IPR&D impairment charges. Of this amount, $181 million related to the write-off of the intangible asset associated with preladenant as a result of the discontinuation of the clinical development program for this compound. In addition, the Company recorded impairment charges resulting from changes in cash flow assumptions for certain compounds, as well as for pipeline programs that had previously been deprioritized and were subsequently deemed to have no alternative use in the period.

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. As of December 31, 2015, the estimated costs to complete projects acquired in connection with acquisitions in Phase 3 development for human health and the analogous stage of development for animal health were approximately $480 million.

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 significant transactions are described below. Merck is actively monitoring the landscape for growth opportunities that meet the Company's strategic criteria.

In January 2016, Merck acquired 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. Total purchase consideration in the transaction included an upfront cash payment of $150 million and future additional milestone payments of up to $250 million that are contingent upon certain clinical and regulatory milestones being achieved. The acquisition provides Merck with IOmet's pre-clinical pipeline of IDO (indoleamine-2,3-dioxygenase 1), TDO (tryptophan-2,3-dioxygenase), and dual-acting IDO/TDO inhibitors. The Company is in the process of determining the preliminary fair value of assets acquired, liabilities assumed and total consideration transferred for this business acquisition. This transaction closed on January 11, 2016; accordingly, the results of operations of the acquired business will be included in the Company's results of operations beginning after that date.

In July 2015, Merck acquired cCAM, a privately held biopharmaceutical company focused on the discovery and development of novel cancer immunotherapies. The acquisition provides Merck with cCAM's lead pipeline candidate, CM-24, a novel monoclonal antibody targeting the immune checkpoint protein CEACAM1 that is being evaluated in a Phase 1 study for the treatment of advanced or recurrent malignancies, including melanoma, non-small-cell lung, bladder, gastric, colorectal, and ovarian cancers. Total purchase consideration in the transaction of $201 million included an upfront payment of $96 million in cash and future additional payments of up to $510 million associated with the attainment of certain clinical development, regulatory and commercial milestones, which the Company determined had a fair value of $105 million at the acquisition date. The transaction was accounted for as an acquisition of a business; accordingly, the assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date. Merck recognized an intangible asset for IPR&D of $180 million and other net assets of $7 million. The excess of the consideration transferred over the fair value of net assets acquired of $14 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair value of the identifiable intangible asset related to IPR&D was determined using an income approach through which fair value is estimated based on the asset's probability-adjusted future net cash flows, which reflects the stage of development of the project and the associated probability of successful completion. The asset's probability-adjusted future net cash flows were then discounted to present value using a discount rate of 10.5%. The fair value of the contingent consideration was determined utilizing a probability-weighted estimated cash flow stream adjusted for the expected timing of each payment also utilizing a discount rate of 10.5%. Actual cash flows are likely to be different than those assumed. This transaction closed on July 31, 2015; accordingly, the results of operations of the acquired business have been included in the Company's results of operations beginning after that date.

In February 2015, Merck and 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. The collaboration includes multiple drug candidates currently in preclinical development at NGM, including NP201, which is being evaluated for the treatment of diabetes, obesity and nonalcoholic steatohepatitis. NGM will lead the research and development of the existing preclinical candidates and have the autonomy to identify and pursue other discovery stage programs at its discretion. Merck will have the option to license all resulting NGM programs following human proof of concept trials. If Merck exercises this option, Merck will lead global product development and commercialization for the resulting products, if approved. Under the terms of the agreement, Merck made an upfront payment to NGM of $94 million, which is 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 will have the option to extend the research agreement for two additional two-year terms. Each party has certain termination rights under the agreement in the event of an uncured material breach by the other party. Additionally, Merck has certain termination rights in the event of the occurrence of certain defined conditions. Upon a termination event, depending on the circumstances, the parties have varying rights and obligations with respect to the continued development and commercialization of compounds discovered under the agreement and certain related payment obligations.

In January 2015, Merck acquired Cubist, a leader in the development of therapies to treat serious infections caused by a broad range of bacteria, for total consideration of $8.3 billion (see Note 4 to the consolidated financial statements). 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. 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 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 were then discounted to present value utilizing a discount rate of 8%. Actual cash flows are likely to be different than those assumed. The most significant intangible assets relate to *Zerbaxa*, *Cubicin* and *Sivextro*.

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. The amount was capitalized and accounted for as an indefinite-lived intangible asset, subject to impairment testing until completion or abandonment of the project. The fair value of surotomycin was determined by using an income approach. The probability-adjusted future net cash flows were then discounted to present value using a discount rate of 9%. 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.

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.

Selected Joint Venture and Affiliate Information

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 the 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 such revenue was $463 million in 2014 and $920 million in 2013 primarily relating to sales of Nexium, as well as Prilosec. In addition, Merck earned certain Partnership

returns from AZLP of $192 million in 2014 and $352 million in 2013, which were recorded in equity income from affiliates.

On June 30, 2014, AstraZeneca exercised its option to purchase Merck's interest in KBI for $419 million in cash. Of this amount, $327 million reflects an estimate of the fair value of Merck's interest in Nexium and Prilosec. This portion of the exercise price, which is subject to a true-up in 2018 based on actual sales from closing in 2014 to June 2018, was deferred and is being recognized over time in *Other (income) expense, net* as the contingency is eliminated as sales occur. During 2015 and 2014, $182 million and $140 million, respectively, of the deferred income was recognized bringing cumulative deferred income recognized through December 31, 2015 to $322 million. The remaining exercise price of $91 million primarily represents a multiple of ten times Merck's average 1% annual profit allocation in the partnership for the three years prior to exercise. Merck recognized the $91 million as a gain in 2014 within *Other (income) expense, net*. As a result of AstraZeneca's option exercise, the Company's remaining interest in AZLP was redeemed. Accordingly, the Company also recognized a non-cash gain of approximately $650 million in 2014 within *Other (income) expense, net* resulting from the retirement of $2.4 billion of KBI preferred stock (see Note 11 to the consolidated financial statements), the elimination of the Company's $1.4 billion investment in AZLP and a $340 million reduction of goodwill. This transaction resulted in a net tax benefit of $517 million in 2014 primarily reflecting the reversal of deferred taxes on the AZLP investment balance.

As a result of AstraZeneca exercising its option, as of July 1, 2014, the Company no longer records equity income from AZLP and supply sales to AZLP have terminated.

Sanofi Pasteur MSD

In 1994, Merck and Pasteur Mérieux Connaught (now Sanofi Pasteur S.A.) established an equally-owned joint venture to market vaccines in Europe and to collaborate in the development of combination vaccines for distribution in Europe.

Sales of joint venture products were as follows:

($ in millions)	**2015**	2014	2013
Gardasil	**$ 184**	$ 248	$ 291
Influenza vaccines	**128**	159	162
Zostavax	**87**	103	68
Other viral vaccines	**77**	87	104
RotaTeq	**56**	65	55
Hepatitis vaccines	**62**	38	31
Other vaccines	**329**	430	453
	$ 923	$ 1,130	$ 1,164

Simcere MSD (Shanghai) Pharmaceutical Co., Ltd.

In March 2015, Merck and Simcere Pharmaceutical Co., Ltd. (Simcere) executed a restructuring agreement in which Merck agreed to transfer its 51% ownership interest in the Simcere MSD (Shanghai) Pharmaceutical Co., Ltd. joint venture to Simcere. As a result, Merck deconsolidated the joint venture and recorded a net loss of $7 million in *Other (income) expense, net* in 2015.

Capital Expenditures

Capital expenditures were $1.3 billion in 2015, $1.3 billion in 2014 and $1.5 billion in 2013. Expenditures in the United States were $879 million in 2015, $873 million in 2014 and $902 million in 2013.

Depreciation expense was $1.6 billion in 2015, $2.5 billion in 2014 and $2.2 billion in 2013 of which $1.1 billion, $2.0 billion and $1.5 billion, respectively, applied to locations in the United States. Total depreciation expense in 2015, 2014 and 2013 included accelerated depreciation of $174 million, $900 million and $577 million, respectively, associated with restructuring activities (see Note 3 to the consolidated financial statements).

Analysis of Liquidity and Capital Resources

Merck's strong financial profile enables it to fully 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)	**2015**	2014	2013
Working capital	**$ 10,561**	$ 14,208	$ 17,469
Total debt to total liabilities and equity	**26.1%**	21.8%	23.8%
Cash provided by operations to total debt	**0.5:1**	0.4:1	0.5:1

Cash provided by operating activities was $12.4 billion in 2015, $7.9 billion in 2014 and $11.7 billion in 2013. The decline in cash provided by operating activities in 2014 as compared with 2013 reflects approximately $5.0 billion of taxes paid on the divestiture of MCC. Cash provided by operating activities in 2013 includes a payment made by the Company of $480 million in connection with the settlement of the ENHANCE Litigation. Cash provided by operating activities continues to be the Company's primary source of funds to finance operating needs, capital expenditures, a portion of treasury stock purchases and dividends paid to shareholders.

Cash used in investing activities was $4.8 billion in 2015 compared with $374 million in 2014 primarily reflecting cash received in 2014 from the divestiture of MCC, higher cash received in 2014 from other dispositions of businesses and in connection with AstraZeneca's option exercise, as well as cash used for the acquisition of Cubist in 2015, partially offset by lower purchases of securities and other investments and higher proceeds from the sales of securities and other investments, cash used in 2014 for the acquisition of Idenix and a cash payment made in 2014 upon the formation of the collaboration with Bayer. Cash used in investing activities was $374 million in 2014 compared with $3.1 billion in 2013 reflecting cash received in 2014 from the divestiture of MCC and from other dispositions of businesses, as well as cash received in connection with AstraZeneca's option exercise, partially offset by higher purchases of and lower proceeds from the sale of securities and other investments, cash used for the acquisition of Idenix and a cash payment made upon formation of the collaboration with Bayer.

Cash used in financing activities was $5.3 billion in 2015 compared with $15.1 billion in 2014 driven primarily by higher proceeds from the issuance of debt, lower payments on debt and lower purchases of treasury stock, partially offset by lower proceeds from the exercise of stock options and a decrease in short-term borrowings. Cash used in financing activities was $15.1 billion in 2014 compared with $6.0 billion in 2013 driven primarily by higher payments on debt, lower proceeds from the issuance of debt, higher purchases of treasury stock and a decrease in short-term borrowings, partially offset by 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 14 to the consolidated financial statements).

At December 31, 2015, the total of worldwide cash and investments was $26.5 billion, including $13.4 billion of cash, cash equivalents and short-term investments, and $13.0 billion of long-term investments. Generally 80%-90% of cash and investments are held by foreign subsidiaries and would be subject to significant tax payments if such cash and investments were repatriated in the form of dividends. The Company records U.S. deferred tax liabilities for certain unremitted earnings, but when amounts earned overseas are expected to be indefinitely reinvested outside of the United States, no accrual for U.S. taxes is provided. The amount of cash and investments held by U.S. and foreign subsidiaries fluctuates due to a variety of factors including the timing and receipt of payments in the normal course of business. Cash provided by operating activities in the United States continues to be the Company's primary source of funds to finance domestic operating needs, capital expenditures, a portion of treasury stock purchases and dividends paid to shareholders.

The Company's contractual obligations as of December 31, 2015 are as follows:

Payments Due by Period

($ in millions)	Total	2016	2017—2018	2019—2020	Thereafter
Purchase obligations [1]	$ 2,333	$ 605	$ 786	$ 435	$ 507
Loans payable and current portion of long-term debt [2]	2,585	2,585	—	—	—
Long-term debt	23,785	—	3,328	3,216	17,241
Interest related to debt obligations	9,752	651	1,274	1,187	6,640
Vioxx shareholder class action settlement reserve [3]	1,062	1,062	—	—	—
Unrecognized tax benefits [4]	1,244	1,244	—	—	—
Operating leases	789	213	250	166	160
	$ 41,550	$ 6,360	$ 5,638	$ 5,004	$ 24,548

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

[2] *In January 2016, $850 million of debt matured and was repaid.*

[3] *The Company anticipates receiving insurance proceeds of approximately $380 million to partially fund this liability (see Note 10 to the consolidated financial statements).*

[4] *As of December 31, 2015, the Company's Consolidated Balance Sheet reflects liabilities for unrecognized tax benefits, interest and penalties of $4.2 billion, including $1.2 billion 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 2016 cannot be made.*

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. Also excluded from research and development obligations are potential future funding commitments of up to approximately $120 million for investments in research venture capital funds. Loans payable and current portion of long-term debt reflects $226 million of long-dated notes that are subject to repayment at the option of the holders. Required funding obligations for 2016 relating to the Company's pension and other postretirement benefit plans are not expected to be material. However, the Company currently anticipates contributing approximately $50 million to its U.S. pension plans, $150 million to its international pension plans and $60 million to its other postretirement benefit plans during 2016.

In August 2014, the Company terminated its existing credit facility and entered into a $6.0 billion, five-year credit facility that matures in August 2019. 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 February 2015, Merck issued $8.0 billion aggregate principal amount of senior unsecured notes consisting of $300 million principal amount of floating rate notes due 2017, $700 million principal amount of floating rate notes due 2020, $1.25 billion principal amount of 1.85% notes due 2020, $1.25 billion aggregate principal amount of 2.35% notes due 2022, $2.5 billion aggregate principal amount of 2.75% notes due 2025 and $2.0 billion aggregate principal amount of 3.70% notes due 2045. 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 4 to the consolidated financial statements).

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.

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 2015, the Board of Directors declared a quarterly dividend of $0.46 per share on the Company's common stock payable in January 2016.

In March 2015, 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 $4.2 billion of its common stock (75 million shares) for its treasury during 2015. The Company has approximately $8.5 billion remaining under the March share repurchase program. The Company purchased $7.7 billion and $6.5 billion of its common stock during 2014 and 2013, respectively, under this and previously 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 primary objective of the revenue hedging program is to reduce the potential for longer-term unfavorable changes in foreign exchange rates to decrease 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 that are expected to occur over its planning cycle, typically no more than three years into the future. The Company will layer in hedges over time, increasing the portion of third-party and intercompany distributor entity sales hedged as it gets closer to the expected date of the forecasted foreign currency denominated sales. The portion of 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 hedged anticipated sales are a specified component of a portfolio of similarly denominated foreign currency-based sales transactions, each of which responds to the hedged currency risk in the same manner. The Company manages its anticipated transaction exposure principally with purchased local currency put options, which provide the Company with a right, but not an obligation, to sell foreign currencies in the future at a predetermined price. If the U.S. dollar strengthens relative to the currency of the hedged anticipated sales, total changes in the options' cash flows offset the decline in the expected future U.S. dollar equivalent cash flows of the hedged foreign currency sales. Conversely, if the U.S. dollar weakens, the options' value reduces to zero, but the Company benefits from the increase in the U.S. dollar equivalent value of the anticipated foreign currency cash flows.

In connection with the Company's revenue hedging program, a purchased collar option strategy may be utilized. With a purchased collar option strategy, the Company writes a local currency call option and purchases a local currency put option. As compared to a purchased put option strategy alone, a purchased collar strategy reduces the upfront costs associated with purchasing puts through the collection of premiums by writing call options. If the U.S. dollar weakens relative to the currency of the hedged anticipated sales, the purchased put option value of the collar strategy reduces to zero and the Company benefits from the increase in the U.S. dollar equivalent value of its anticipated

foreign currency cash flows; however, this benefit would be capped at the strike level of the written call. If the U.S. dollar strengthens relative to the currency of the hedged anticipated sales, the written call option value of the collar strategy reduces to zero and the changes in the purchased put cash flows of the collar strategy would offset the decline in the expected future U.S. dollar equivalent cash flows of the hedged foreign currency sales.

The Company may also utilize forward contracts in its revenue hedging program. If the U.S. dollar strengthens relative to the currency of the hedged anticipated sales, the increase in the fair value of the forward contracts offsets the decrease in the expected future U.S. dollar cash flows of the hedged foreign currency sales. Conversely, if the U.S. dollar weakens, the decrease in the fair value of the forward contracts offsets the increase in the value of the anticipated foreign currency cash flows. While a weaker U.S. dollar would result in a net benefit, the market value of Merck's hedges would have declined by an estimated $502 million and $660 million at December 31, 2015 and 2014, 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. Because Merck principally uses purchased local currency put options, a uniform weakening of the U.S. dollar would yield the largest overall potential loss in the market value of these options. The sensitivity measurement assumes that a change in one foreign currency relative to the U.S. dollar would not affect other foreign currencies relative to the U.S. dollar. Although not predictive in nature, the Company believes that a 10% threshold reflects reasonably possible near-term changes in Merck's major foreign currency exposures relative to the U.S. dollar. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

The primary objective of the balance sheet risk management program is 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, which enable the Company to buy and sell foreign currencies in the future at fixed exchange rates and economically offset the consequences of changes in foreign exchange from the monetary assets. Merck routinely enters into 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 Company will also minimize the effect of exchange on monetary assets and liabilities by managing operating activities and net asset positions at the local level. 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 strengthened by 10% against all currency exposures of the Company at December 31, 2015 and 2014, *Income before taxes* would have declined by approximately $45 million in 2015 and $25 million in 2014. Because the Company was in a net long (receivable) position relative to its major foreign currencies after consideration of forward contracts, a uniform strengthening 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.

In February 2013, the Venezuelan government devalued its currency (Bolívar Fuertes) from 4.30 VEF per U.S. dollar to 6.30 VEF per U.S. dollar. The Company recognized losses due to exchange of approximately $140 million in 2013 resulting from the remeasurement of the local monetary assets and liabilities at the new rate.

In addition to the official rate of 6.30 VEF per U.S. dollar, the Venezuelan government maintains two other official rates. These are the Sistema Complementario de Administracion de Divisas, or SICAD, and the Sistema Marginal de Divisas, or SIMADI. Both the SICAD and SIMADI average rates are published by the Central Bank of Venezuela and at December 31, 2015, the average exchange rates inferred were 13.50 VEF per U.S. dollar and 198.70 VEF per U.S. dollar, respectively. Historically, the Venezuelan government has indicated that essential goods, including food and medicine, would remain at the official rate of 6.30 VEF per U.S. dollar.

During the second quarter of 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 official rate, the Company determined it was unlikely that all outstanding net monetary assets would be settled at the official rate. Accordingly, during the second quarter of 2015, the Company recorded a charge of $715 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. During the third quarter of 2015, the Company recorded additional exchange losses of $138 million reflecting the ongoing effect of translating transactions and net monetary assets consistent with the second quarter. As a result of the further deterioration of economic conditions in Venezuela and continued declines in transactions which were settled at the official rate, in the fourth quarter of 2015, the Company began using the SIMADI rate to report its Venezuelan operations. The Company also revalued its remaining net monetary assets at the SIMADI rate, which resulted in an additional charge in the fourth quarter of 2015 of $161 million. Accordingly, at December 31, 2015, the Company had approximately $20 million (U.S. dollar equivalent at the SIMADI rate) of remaining net monetary assets in its Venezuelan entities, of which the large majority was cash. Merck's sales in Venezuela were approximately $625 million in 2015. The Company has reduced its operations in Venezuela; however, Merck continues to work with the government of Venezuela to import essential medicines into the country. As a result of transitioning to the SIMADI rate in the fourth quarter of 2015 for purposes of reporting its Venezuelan operations, Merck anticipates that sales in Venezuela in 2016 will be *de minimis*.

The Company also uses forward exchange contracts to hedge its net investment in foreign operations against movements in exchange rates. The forward contracts are designated as hedges of the net investment in a foreign operation. The Company hedges a portion of the net investment in certain of its foreign operations and measures ineffectiveness based upon changes in spot foreign exchange rates. 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, 2015, the Company was a party to 30 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)	**2015**		
Debt Instrument	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
0.70% notes due 2016	$ 1,000	4	$ 1,000
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 December 31, 2015 and 2014 would have positively affected the net aggregate market value of these instruments by $1.2 billion and $1.0 billion, respectively. A one percentage point decrease at December 31, 2015 and 2014 would have negatively affected the net aggregate market value by $1.5 billion and $1.2 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 measurement. 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

To determine whether acquisitions qualify as business combinations or asset acquisitions, 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 the acquisition consists of inputs, as well as processes that when applied to those inputs have the ability to create outputs, the acquisition is determined to be a business combination.

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 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.

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 acquisition of assets 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 at the acquisition date.

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 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.

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 as direct discounts at the point-of-sale, indirectly through an intermediary wholesaler, known as chargebacks, or indirectly 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 indirect 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 indirect 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 indirect customer discounts. There were no material adjustments to estimates associated with the aggregate indirect customer discount provision in 2015, 2014 or 2013.

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

($ in millions)	**2015**	2014
Balance January 1	**$ 2,154**	$ 1,688
Current provision	**8,068**	6,560
Adjustments to prior years	**(77)**	(18)
Payments	**(7,347)**	(6,076)
Balance December 31	**$ 2,798**	$ 2,154

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 $145 million and $2.7 billion, respectively, at December 31, 2015 and were $112 million and $2.0 billion, respectively, at December 31, 2014.

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 1.5% in 2015, 1.7% in 2014 and 1.5% in 2013.

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

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

Inventories Produced in Preparation for Product Launches

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

Inventories produced in preparation for product launches capitalized at December 31, 2015 and 2014 were $63 million and $74 million, respectively.

Contingencies and Environmental Liabilities

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

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of December 31, 2015 and 2014 of approximately $245 million and $215 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 $8 million in 2015, and are estimated at $59 million in the aggregate for the years 2016 through 2020. In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $109 million and $125 million at December 31, 2015 and 2014, 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 $57 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 $299 million in 2015, $278 million in 2014 and $276 million in 2013. At December 31, 2015, there was $407 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 and other postretirement benefit plans totaled $253 million in 2015, $169 million in 2014 and $716 million in 2013. Pension and other postretirement benefit plan information for financial reporting purposes is calculated using actuarial assumptions including a discount rate for plan benefit obligations and an expected rate of return on plan assets. The changes in net periodic benefit cost year over year for pension and other postretirement benefit plans are largely attributable to changes in the discount rate affecting net amortization.

The Company reassesses its benefit plan assumptions on a regular basis. For both the pension and other postretirement benefit plans, the discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due. At December 31, 2015, the discount rates for the Company's U.S. pension and other postretirement benefit plans ranged from 3.80% to 4.80% compared with a range of 3.20% to 4.20% at December 31, 2014.

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 as well as 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. As a result of this analysis, for 2016, the Company's expected rate of return will range from 7.30% to 8.75%, the same range as in 2015 for its U.S. pension and other postretirement benefit plans.

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 40% to 60% in U.S. equities, 20% to 40% in international equities, 15% to 25% 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 an estimated $46 million favorable (unfavorable) impact on its net periodic benefit cost. A reasonably possible change of plus (minus) 25 basis points in the expected rate of return assumption, with other assumptions held constant, would have an estimated $45 million favorable (unfavorable) impact on its net periodic benefit cost. Required funding obligations for 2016 relating to the Company's pension and other postretirement benefit plans are not expected to be material. The preceding hypothetical changes in the discount rate and expected rate of return assumptions would not impact the Company's funding requirements.

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

Restructuring Costs

Restructuring costs have been recorded in connection with restructuring programs designed to reduce the cost structure, increase efficiency and enhance competitiveness. 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 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 intangibles (excluding IPR&D) are 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 may combine separately recorded IPR&D intangible assets into one unit of account based on the relevant facts and circumstances. Generally, the Company will combine IPR&D intangible assets for testing purposes if they operate as a single asset and are essentially inseparable. If the fair value is less than the carrying amount, an impairment loss is recognized within the Company's operating results.

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

Impairments of Investments

The Company reviews its investments 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 based on the technical merits of the tax position. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely of being realized upon ultimate settlement in the financial statements. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit in the financial statements. If the more likely than not threshold is not met in the period for which a tax position is taken, the Company may subsequently recognize the benefit of that tax position if the tax matter is effectively settled, the statute of limitations expires, or if the more likely than not threshold is met in a subsequent period (see Note 15 to the consolidated financial statements.)

Tax regulations require items to be included in the tax return at different times than the items are reflected in the financial statements. Timing differences create deferred tax assets and liabilities. Deferred tax assets generally represent items that can be used as a tax deduction or credit in the tax return in future years for which the Company has already recorded the tax benefit in the financial statements. The Company establishes valuation allowances for its deferred tax assets when the amount of expected future taxable income is not likely to support the use of the deduction or credit. Deferred tax liabilities generally represent tax expense recognized in the financial statements for which payment has been deferred or expense for which the Company has already taken a deduction on the tax return, but has not yet recognized as expense in the financial statements. At December 31, 2015, foreign earnings of $59.2 billion have been retained indefinitely by subsidiary companies for reinvestment; therefore, no provision has been made for income taxes that would be payable upon the distribution of such earnings and it would not be practicable to determine the amount of the related unrecognized deferred income tax liability.

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. In August 2015, the FASB approved a one-year deferral of the effective date making this guidance effective for interim and annual periods beginning in 2018. Reporting entities may choose to adopt the standard as of the original effective date. The Company is currently assessing the impact of adoption on its consolidated financial statements.

In April 2015, the FASB issued accounting guidance which requires debt issuance costs to be presented as a direct deduction from the carrying amount of that debt on the balance sheet as opposed to being presented as a deferred charge. The new guidance is effective for interim and annual periods beginning in 2016. As of December 31, 2015, the Company had debt issuance costs recorded as deferred charges of approximately $100 million.

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. This guidance is effective for interim and annual periods beginning in 2018. Early adoption is not permitted. The Company is currently assessing the impact of adoption on its 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. 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, 2015 and 2014, 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, 2015, the notes to consolidated financial statements, and the report dated February 26, 2016 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)

	2015	2014	2013
Sales	**$ 39,498**	$ 42,237	$ 44,033
Costs, Expenses and Other			
Materials and production	**14,934**	16,768	16,954
Marketing and administrative	**10,313**	11,606	11,911
Research and development	**6,704**	7,180	7,503
Restructuring costs	**619**	1,013	1,709
Other (income) expense, net	**1,527**	(11,613)	411
	34,097	24,954	38,488
Income Before Taxes	**5,401**	17,283	5,545
Taxes on Income	**942**	5,349	1,028
Net Income	**4,459**	11,934	4,517
Less: Net Income Attributable to Noncontrolling Interests	**17**	14	113
Net Income Attributable to Merck & Co., Inc.	**$ 4,442**	$ 11,920	$ 4,404
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	**$ 1.58**	$ 4.12	$ 1.49
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	**$ 1.56**	$ 4.07	$ 1.47

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

	2015	2014	2013
Net Income Attributable to Merck & Co., Inc.	**$ 4,442**	$ 11,920	$ 4,404
Other Comprehensive Income (Loss) Net of Taxes:			
Net unrealized (loss) gain on derivatives, net of reclassifications	**(126)**	398	229
Net unrealized (loss) gain on investments, net of reclassifications	**(70)**	57	(19)
Benefit plan net gain (loss) and prior service credit (cost), net of amortization	**579**	(2,077)	2,758
Cumulative translation adjustment	**(208)**	(504)	(483)
	175	(2,126)	2,485
Comprehensive Income Attributable to Merck & Co., Inc.	**$ 4,617**	$ 9,794	$ 6,889

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)

	2015	2014
Assets		
Current Assets		
Cash and cash equivalents	**$ 8,524**	$ 7,441
Short-term investments	**4,903**	8,278
Accounts receivable (net of allowance for doubtful accounts of $165 in 2015 and $153 in 2014) (excludes accounts receivable of $10 in 2015 and $80 in 2014 classified in Other assets - see Note 5)	**6,484**	6,626
Inventories (excludes inventories of $1,569 in 2015 and $1,664 in 2014 classified in Other assets - see Note 6)	**4,700**	5,571
Other current assets	**5,153**	4,689
Total current assets	**29,764**	32,605
Investments	**13,039**	13,515
Property, Plant and Equipment (at cost)		
Land	**490**	541
Buildings	**12,154**	13,101
Machinery, equipment and office furnishings	**14,261**	16,050
Construction in progress	**1,525**	1,448
	28,430	31,140
Less: accumulated depreciation	**15,923**	18,004
	12,507	13,136
Goodwill	**17,723**	12,992
Other Intangibles, Net	**22,602**	20,386
Other Assets	**6,144**	5,533
	$ 101,779	$ 98,167
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	**$ 2,585**	$ 2,704
Trade accounts payable	**2,533**	2,625
Accrued and other current liabilities	**11,216**	10,523
Income taxes payable	**1,560**	1,237
Dividends payable	**1,309**	1,308
Total current liabilities	**19,203**	18,397
Long-Term Debt	**23,929**	18,699
Deferred Income Taxes	**6,535**	4,467
Other Noncurrent Liabilities	**7,345**	7,813
Merck & Co., Inc. Stockholders' Equity		
Common stock, $0.50 par value Authorized - 6,500,000,000 shares Issued - 3,577,103,522 shares in 2015 and 2014	**1,788**	1,788
Other paid-in capital	**40,222**	40,423
Retained earnings	**45,348**	46,021
Accumulated other comprehensive loss	**(4,148)**	(4,323)
	83,210	83,909
Less treasury stock, at cost: 795,975,449 shares in 2015 and 738,963,326 shares in 2014	**38,534**	35,262
Total Merck & Co., Inc. stockholders' equity	**44,676**	48,647
Noncontrolling Interests	**91**	144
Total equity	**44,767**	48,791
	$ 101,779	$ 98,167

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, 2013	$1,788	$40,646	$ 39,985	$ (4,682)	$ (24,717)	$ 2,443	$ 55,463
Net income attributable to Merck & Co., Inc.	—	—	4,404	—	—	—	4,404
Other comprehensive income, net of tax	—	—	—	2,485	—	—	2,485
Cash dividends declared on common stock ($1.73 per share)	—	—	(5,132)	—	—	—	(5,132)
Treasury stock shares purchased	—	—	—	—	(6,516)	—	(6,516)
Supera joint venture formation	—	116	—	—	—	112	228
Net income attributable to noncontrolling interests	—	—	—	—	—	113	113
Distributions attributable to noncontrolling interests	—	—	—	—	—	(120)	(120)
Share-based compensation plans and other	—	(254)	—	—	1,642	13	1,401
Balance December 31, 2013	1,788	40,508	39,257	(2,197)	(29,591)	2,561	52,326
Net income attributable to Merck & Co., Inc.	—	—	11,920	—	—	—	11,920
Other comprehensive loss, net of tax	—	—	—	(2,126)	—	—	(2,126)
Cash dividends declared on common stock ($1.77 per share)	—	—	(5,156)	—	—	—	(5,156)
Treasury stock shares purchased	—	—	—	—	(7,703)	—	(7,703)
AstraZeneca option exercise	—	—	—	—	—	(2,400)	(2,400)
Net income attributable to noncontrolling interests	—	—	—	—	—	14	14
Distributions attributable to noncontrolling interests	—	—	—	—	—	(77)	(77)
Share-based compensation plans and other	—	(85)	—	—	2,032	46	1,993
Balance December 31, 2014	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 tax	**—**	**—**	**—**	**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**

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

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

	2015	2014	2013
Cash Flows from Operating Activities			
Net income	**$ 4,459**	$ 11,934	$ 4,517
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	**6,375**	6,691	6,988
Intangible asset impairment charges	**162**	1,222	765
Foreign currency devaluation related to Venezuela	**876**	—	140
Net charge related to the settlement of *Vioxx* shareholder class action litigation	**680**	—	—
Gain on divestiture of Merck Consumer Care business	**—**	(11,209)	—
Gain on AstraZeneca option exercise	**—**	(741)	—
Loss on extinguishment of debt	**—**	628	—
Equity income from affiliates	**(205)**	(257)	(404)
Dividends and distributions from equity method affiliates	**50**	185	237
Deferred income taxes	**(764)**	(2,600)	(330)
Share-based compensation	**299**	278	276
Other	**757**	(95)	259
Net changes in assets and liabilities:			
Accounts receivable	**(480)**	(554)	436
Inventories	**805**	79	(365)
Trade accounts payable	**(37)**	593	522
Accrued and other current liabilities	**(8)**	1,635	(397)
Income taxes payable	**(266)**	(21)	(1,421)
Noncurrent liabilities	**(277)**	190	(132)
Other	**(5)**	(98)	563
Net Cash Provided by Operating Activities	**12,421**	7,860	11,654
Cash Flows from Investing Activities			
Capital expenditures	**(1,283)**	(1,317)	(1,548)
Purchases of securities and other investments	**(16,681)**	(24,944)	(17,991)
Proceeds from sales of securities and other investments	**20,413**	15,114	16,298
Divestiture of Merck Consumer Care business, net of cash divested	**—**	13,951	—
Dispositions of other businesses, net of cash divested	**316**	1,169	46
Proceeds from AstraZeneca option exercise	**—**	419	—
Acquisition of Cubist Pharmaceuticals, Inc., net of cash acquired	**(7,598)**	—	—
Acquisition of Idenix Pharmaceuticals, Inc., net of cash acquired	**—**	(3,700)	—
Acquisitions of other businesses, net of cash acquired	**(146)**	(181)	(246)
Acquisition of Bayer AG collaboration rights	**—**	(1,000)	—
Cash inflows from net investment hedges	**139**	195	350
Other	**82**	(80)	(57)
Net Cash Used in Investing Activities	**(4,758)**	(374)	(3,148)
Cash Flows from Financing Activities			
Net change in short-term borrowings	**(1,540)**	(460)	(159)
Payments on debt	**(2,906)**	(6,617)	(1,775)
Proceeds from issuance of debt	**7,938**	3,146	6,467
Purchases of treasury stock	**(4,186)**	(7,703)	(6,516)
Dividends paid to stockholders	**(5,117)**	(5,170)	(5,157)
Other dividends paid	**—**	(77)	(120)
Proceeds from exercise of stock options	**485**	1,560	1,210
Other	**56**	208	60
Net Cash Used in Financing Activities	**(5,270)**	(15,113)	(5,990)
Effect of Exchange Rate Changes on Cash and Cash Equivalents	**(1,310)**	(553)	(346)
Net Increase (Decrease) in Cash and Cash Equivalents	**1,083**	(8,180)	2,170
Cash and Cash Equivalents at Beginning of Year	**7,441**	15,621	13,451
Cash and Cash Equivalents at End of Year	**$ 8,524**	$ 7,441	$ 15,621

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, which it markets directly and through its joint ventures. The Company's operations are principally managed on a products basis and are comprised of four operating segments, the Pharmaceutical, Animal Health, Alliances and Healthcare Services segments. The Pharmaceutical segment is the only reportable segment. The Pharmaceutical segment includes human health pharmaceutical and vaccine products marketed either directly by the Company or through joint ventures. 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 animal health operations that discover, develop, manufacture and market animal health products, including vaccines, which the Company sells to veterinarians, distributors and animal producers. Merck's Alliances segment primarily includes results from the Company's relationship with AstraZeneca LP until the termination of that relationship on June 30, 2014. 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.

On January 21, 2015, the Company acquired Cubist Pharmaceuticals, Inc. (Cubist) and, on July 31, 2015, Merck acquired cCAM Biotherapeutics Ltd. (cCAM). The results of Cubist's and cCAM's businesses have been included in Merck's financial statements subsequent to their respective acquisition dates (see Note 4). On October 1, 2014, the Company divested its Consumer Care segment that developed, manufactured and marketed over-the-counter, foot care and sun care products see (Note 4).

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 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. 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 *OCI*. Realized gains and losses for both debt and equity securities are included 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 as direct discounts at the point-of-sale, indirectly through an intermediary wholesaler, known as chargebacks, or indirectly 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 $145 million and $2.7 billion, respectively, at December 31, 2015 and $112 million and $2.0 billion, respectively, at December 31, 2014.

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.

Depreciation — Depreciation is provided over the estimated useful lives of the assets, principally using the straight-line method. For tax purposes, accelerated tax methods are used. The estimated useful lives primarily range from 25 to 45 years for *Buildings*, and from 3 to 15 years for *Machinery, equipment and office furnishings*. Depreciation expense was $1.6 billion in 2015, $2.5 billion in 2014 and $2.2 billion in 2013.

Advertising and Promotion Costs — Advertising and promotion costs are expensed as incurred. The Company recorded advertising and promotion expenses of $2.1 billion, $2.3 billion and $2.5 billion in 2015, 2014 and 2013, 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 $421 million and $505 million, net of accumulated amortization at December 31, 2015 and 2014, respectively. All other capitalized software costs are being amortized over periods ranging from 3 to 5 years. Costs incurred during the preliminary project stage and post-implementation stage, as well as maintenance and training costs, are expensed as incurred.

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

Acquired Intangibles — Acquired intangibles include products and product rights, tradenames and patents, which are 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 1 to 20 years (see Note 7). 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 of the IPR&D intangible asset is less than its carrying amount. If the Company concludes it is more likely than not that the fair value is less than the carrying amount, a quantitative test that compares the fair value of the IPR&D intangible asset with its carrying value is performed. If the fair value is less than the carrying amount, an impairment loss is recognized in operating results.

Contingent Consideration — Certain of the Company's business acquisitions involve the potential for future payment of consideration that is contingent upon the achievement of performance milestones, including product development milestones and royalty payments on future product sales. The fair value of contingent consideration liabilities is determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-

adjusted discount rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date, at each reporting period, the contingent consideration liability is remeasured at current fair value with changes (either expense or income) recorded in earnings. Changes in any of the inputs may result in a significantly different fair value adjustment.

Research and Development — Research and development is expensed as incurred. Upfront and milestone payments due to third parties in connection with research and development collaborations prior to regulatory approval are expensed as incurred. Payments due to third parties upon or subsequent to regulatory approval are capitalized and amortized over the shorter of the remaining license or product patent life. Amounts due from collaborative partners related to development activities are generally reflected as a reduction of research and development expenses when the specific milestone has been achieved. 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 expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration.

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 Adopted Accounting Standards — In November 2015, the Financial Accounting Standards Board (FASB) issued accounting guidance on the balance sheet classification of deferred taxes as part of its simplification initiative aimed at reducing complexity in accounting standards. The new guidance requires that all deferred tax assets and liabilities, along with any related valuation allowance, be classified as noncurrent on the balance sheet. The Company elected to early adopt the new guidance in the fourth quarter of 2015 (see Note 15).

Recently Issued Accounting Standards — In May 2014, the 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. In August 2015, the FASB approved a one-year deferral of the effective date making this guidance effective for interim and annual periods beginning in 2018. Reporting entities may choose to adopt the standard as of the original effective date. The Company is currently assessing the impact of adoption on its consolidated financial statements.

In April 2015, the FASB issued accounting guidance which requires debt issuance costs to be presented as a direct deduction from the carrying amount of that debt on the balance sheet as opposed to being presented as a deferred charge. The new guidance is effective for interim and annual periods beginning in 2016. As of December 31, 2015, the Company had debt issuance costs recorded as deferred charges of approximately $100 million.

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. This guidance is effective for interim and annual periods beginning in 2018. Early adoption is not permitted. The Company is currently assessing the impact of adoption on its consolidated financial statements.

3. Restructuring

2013 Restructuring Program

In 2013, the Company initiated actions under a global restructuring program (the 2013 Restructuring Program) as part of a global initiative to sharpen its commercial and research and development focus. The actions under this program primarily include the elimination of positions in sales, administrative and headquarters organizations, as well as research and development. Additionally, these actions include the reduction of the Company's global real estate footprint and improvements in the efficiency of its manufacturing and supply network. The Company recorded total pretax costs of $527 million in 2015 and $1.2 billion in both 2014 and 2013 related to this restructuring program. Since inception of the 2013 Restructuring Program through December 31, 2015, Merck has recorded total pretax accumulated costs of approximately $3.0 billion and eliminated approximately 8,630 positions comprised of employee separations, as well as the elimination of contractors and vacant positions. The actions under the 2013 Restructuring Program were substantially completed by the end of 2015. Accordingly, as of January 1, 2016, the remaining accrued liability for future separations under the 2013 Restructuring Program was combined with the remaining accrued liability for the Merger Restructuring Program (see below) and any remaining activities under both programs will be accounted for in the aggregate prospectively.

Merger Restructuring Program

In 2010, subsequent to the Merck and Schering-Plough Corporation (Schering-Plough) merger, the Company commenced actions under a global restructuring program (the Merger Restructuring Program) designed to streamline the cost structure of the combined company. Further actions under this program were initiated in 2011. The actions under this program primarily 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 recorded total pretax costs of $583 million in 2015, $730 million in 2014 and $1.1 billion in 2013 related to this restructuring program. Since inception of the Merger Restructuring Program through December 31, 2015, Merck has recorded total pretax accumulated costs of approximately $8.5 billion and eliminated approximately 29,645 positions comprised of employee separations, as well as the elimination of contractors and vacant positions. The non-facility related restructuring actions under the Merger Restructuring Program are substantially complete. Accordingly, as noted above, as of January 1, 2016, the remaining accrued liability for future separations under the 2013 Restructuring Program was combined with the remaining accrued liability for the Merger Restructuring Program and any remaining activities under both programs, which primarily relate to ongoing facility rationalizations, will be accounted for in the aggregate prospectively. The Company expects to complete such actions by the end of 2017 and incur approximately $1.5 billion of additional pretax costs.

The Company estimates that approximately two-thirds of the cumulative pretax costs relate to 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.

On October 1, 2013, the Company sold its active pharmaceutical ingredient (API) manufacturing business, including the related manufacturing facility, in the Netherlands to Aspen Holdings (Aspen) as part of planned manufacturing facility rationalizations under the Merger Restructuring Program. In connection with the sale, Aspen acquired certain branded products from Merck, which transferred to Aspen effective December 31, 2013. Consideration for the transaction included cash of $705 million and notes receivable with a present value of $198 million at the time of disposition. Of the cash portion of the consideration, the Company received $172 million in the fourth quarter of 2013. The remaining $533 million was received by the Company in January 2014.

2008 Restructuring Program

In 2008, Merck announced a global restructuring program (the 2008 Restructuring Program) to reduce its cost structure, increase efficiency, and enhance competitiveness. Pretax costs of $54 million were recorded in 2013 related to the 2008 Restructuring Program.

For segment reporting, restructuring charges are unallocated expenses.

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

Year Ended December 31, 2015	Separation Costs	Accelerated Depreciation	Other	Total
2013 Restructuring Program				
Materials and production	**$ —**	**$ 41**	**$ 2**	**$ 43**
Marketing and administrative	**—**	**52**	**18**	**70**
Research and development	**—**	**36**	**15**	**51**
Restructuring costs	**199**	**—**	**164**	**363**
	199	**129**	**199**	**527**
Merger Restructuring Program				
Materials and production	**—**	**37**	**281**	**318**
Marketing and administrative	**—**	**7**	**1**	**8**
Research and development	**—**	**1**	**—**	**1**
Restructuring costs	**9**	**—**	**247**	**256**
	9	**45**	**529**	**583**
	$ 208	**$ 174**	**$ 728**	**$ 1,110**
Year Ended December 31, 2014				
2013 Restructuring Program				
Materials and production	$ —	$ 204	$ 23	$ 227
Marketing and administrative	—	142	3	145
Research and development	—	273	9	282
Restructuring costs	566	—	28	594
	566	619	63	1,248
Merger Restructuring Program				
Materials and production	—	225	30	255
Marketing and administrative	—	56	(1)	55
Research and development	—	—	1	1
Restructuring costs	108	—	311	419
	108	281	341	730
	$ 674	$ 900	$ 404	$ 1,978
Year Ended December 31, 2013				
2013 Restructuring Program				
Materials and production	$ —	$ 186	$ 7	$ 193
Marketing and administrative	—	72	3	75
Research and development	—	76	(1)	75
Restructuring costs	866	—	32	898
	866	334	41	1,241
Merger Restructuring Program				
Materials and production	—	151	98	249
Marketing and administrative	—	63	3	66
Research and development	—	27	(1)	26
Restructuring costs	481	—	284	765
	481	241	384	1,106
2008 Restructuring Program				
Materials and production	—	(2)	6	4
Marketing and administrative	—	4	—	4
Restructuring costs	34	—	12	46
	34	2	18	54
	$ 1,381	$ 577	$ 443	$ 2,401

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 the 2013 Restructuring Program were approximately 2,535 in 2015, 4,555 in 2014 and 1,540 in 2013. Positions eliminated under the Merger Restructuring Program were approximately 1,235 in 2015, 1,530 in 2014 and 4,475 in 2013. These position eliminations were comprised of actual headcount reductions and the elimination of contractors and vacant positions.

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 site, based upon the anticipated date the site will be closed or divested, 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 was required to accelerate depreciation of the site assets rather than record an impairment charge. 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 2015, 2014 and 2013 includes $550 million, $240 million and $259 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 13) and share-based compensation. Other activity also reflects net pretax losses resulting from sales of facilities and related assets of $117 million in 2015, $133 million in 2014 and $64 million in 2013 (primarily reflecting a loss on the transaction with Aspen discussed above).

Adjustments to previously recorded amounts were not material in any period.

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

	Separation Costs	Accelerated Depreciation	Other	Total
2013 Restructuring Program				
Restructuring reserves January 1, 2014	$ 745	$ —	$ 23	$ 768
Expenses	566	619	63	1,248
(Payments) receipts, net	(816)	—	(124)	(940)
Non-cash activity	—	(619)	52	(567)
Restructuring reserves December 31, 2014	495	—	14	509
Expenses	**199**	**129**	**199**	**527**
(Payments) receipts, net	**(425)**	**—**	**(212)**	**(637)**
Non-cash activity	**—**	**(129)**	**1**	**(128)**
Restructuring reserves December 31, 2015 [(1)]	**$ 269**	**$ —**	**$ 2**	**$ 271**
Merger Restructuring Program				
Restructuring reserves January 1, 2014	$ 725	$ —	$ 12	$ 737
Expenses	108	281	341	730
(Payments) receipts, net	(297)	—	(232)	(529)
Non-cash activity	—	(281)	(115)	(396)
Restructuring reserves December 31, 2014	536	—	6	542
Expenses	**9**	**45**	**529**	**583**
(Payments) receipts, net	**(222)**	**—**	**(223)**	**(445)**
Non-cash activity	**—**	**(45)**	**(261)**	**(306)**
Restructuring reserves December 31, 2015 [(1)]	**$ 323**	**$ —**	**$ 51**	**$ 374**

[(1)] *The non-facility related cash outlays associated with both the 2013 Restructuring Program and the Merger Restructuring Program were substantially completed by the end of 2015; the remaining cash outlays are expected to be substantially completed by the end of 2017.*

4. Acquisitions, Divestitures, Research Collaborations and License Agreements

The Company continues its strategy of establishing external alliances to complement its internal research capabilities, including research collaborations, licensing preclinical and clinical compounds to drive both near- and long-term growth. The Company supplements 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. These arrangements often include upfront payments, as well as expense reimbursements or payments to the third party, and milestone, royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development. The Company also reviews its pipeline to examine candidates which may provide more value through out-licensing and, as part of its portfolio assessment process, may also divest certain products.

Acquisition of Cubist Pharmaceuticals, Inc.

In January 2015, Merck acquired Cubist, a leader in the development of therapies to treat serious infections caused by a broad range of bacteria. The acquisition complements Merck's existing hospital acute care business. Total consideration transferred of $8.3 billion includes 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; accordingly, the assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date.

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

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 [(1)]		(233)
Deferred income tax liabilities		(2,519)
Long-term debt		(1,900)
Other noncurrent liabilities [(1)]		(122)
Total identifiable net assets		3,661
Goodwill [(2)]		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.*

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

The estimated fair values of identifiable intangible assets related to currently marketed products were determined using an income approach through which fair value is estimated based on market participant expectations of each asset's discounted projected net cash flows. 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 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 were then discounted to present value utilizing a discount rate of 8%. Actual cash flows are likely to be different than those assumed. The most significant intangible assets relate to *Zerbaxa*, *Cubicin* and *Sivextro* (see Note 7).

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. The amount was capitalized and accounted for as an indefinite-lived intangible asset, subject to impairment testing until completion or abandonment of the project. The fair value of surotomycin was determined by using an income approach, through which fair value is estimated based on the asset's probability-adjusted future net cash flows, which reflects the stage of development of the project and the associated probability of successful completion. The net cash flows were then

discounted to present value using a discount rate of 9%. 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 7).

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. Cubist contributed sales of $1.3 billion in 2015 to Merck's revenues. The Company is no longer able to provide the results of operations attributable to Cubist during 2015 as the operations of Cubist have been largely integrated. 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**	2014
Sales	**$ 39,584**	$ 43,437
Net income attributable to Merck & Co., Inc.	**4,640**	10,887
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	**1.65**	3.76
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	**1.63**	3.72

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.

Other 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, a privately held biopharmaceutical company focused on the discovery and development of novel cancer immunotherapies. The acquisition provides Merck with cCAM's lead pipeline candidate, CM-24, a novel monoclonal antibody targeting the immune checkpoint protein CEACAM1 that is being evaluated in a Phase 1 study for the treatment of advanced or recurrent malignancies, including melanoma, non-small-cell lung, bladder, gastric, colorectal, and ovarian cancers. Total purchase consideration in the transaction of $201 million included an upfront payment of $96 million in cash and future additional payments of up to $510 million associated with the attainment of certain clinical development, regulatory and commercial milestones, which the Company determined had a fair value of $105 million at the acquisition date. The transaction was accounted for as an acquisition of a business; accordingly, the assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date. Merck recognized an intangible asset for IPR&D of $180 million and other net assets of $7 million. The excess of the consideration transferred over the fair value of net assets acquired of $14 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair value of the identifiable intangible asset related to IPR&D was determined using an income approach. The asset's probability-adjusted future net cash flows were then discounted to present value using a discount rate of 10.5%. The

fair value of the contingent consideration was determined utilizing a probability-weighted estimated cash flow stream adjusted for the expected timing of each payment also utilizing a discount rate of 10.5%. Actual cash flows are likely to be different than those assumed. This transaction closed on July 31, 2015; accordingly, the results of operations of the acquired business have been included in the Company's results of operations beginning after that date. Pro forma financial information has not been included because cCAM's historical financial results are not significant when compared with the Company's financial results.

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, $125 million of which was paid in August 2015 upon closing of the transaction and $125 million of which is payable in April of 2016. Merck will additionally be entitled to receive potential development and commercial milestone payments and tiered double-digit royalties based on commercialization of the programs. Allergan will be fully responsible for development of the CGRP programs, as well as manufacturing and commercialization upon approval and launch of the products. The Company recorded a gain of $250 million within *Other (income) expense, net* in 2015 related to the transaction.

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. The collaboration includes multiple drug candidates currently in preclinical development at NGM, including NP201, which is being evaluated for the treatment of diabetes, obesity and nonalcoholic steatohepatitis. NGM will lead the research and development of the existing preclinical candidates and have the autonomy to identify and pursue other discovery stage programs at its discretion. Merck will have the option to license all resulting NGM programs following human proof of concept trials. If Merck exercises this option, Merck will lead global product development and commercialization for the resulting products, if approved. Under the terms of the agreement, Merck made an upfront payment to NGM of $94 million, which is 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 will have the option to extend the research agreement for two additional two-year terms. Each party has certain termination rights under the agreement in the event of an uncured material breach by the other party. Additionally, Merck has certain termination rights in the event of the occurrence of certain defined conditions. Upon a termination event, depending on the circumstances, the parties have varying rights and obligations with respect to the continued development and commercialization of compounds discovered under the agreement and certain related payment obligations.

In December 2014, Merck acquired OncoEthix, a privately held biotechnology company specializing in oncology drug development. Total purchase consideration in the transaction of $153 million included an upfront cash payment of $110 million and future additional milestone payments of up to $265 million that are contingent upon certain clinical and regulatory milestones being achieved, which the Company determined had a fair value of $43 million at the acquisition date. The transaction was accounted for as an acquisition of a business; accordingly, the assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date. Merck recognized an intangible asset for IPR&D of $143 million related to MK-8628 (formerly OTX015), an investigational, novel oral BET (bromodomain) inhibitor currently in Phase 2 studies for the treatment of hematological malignancies and advanced solid tumors, as well as a liability for contingent consideration of $43 million and other net assets of $10 million. 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 then discounted to present value using a discount rate of 11.5%. The fair value of the contingent consideration was determined utilizing a probability-weighted estimated cash flow stream adjusted for the expected timing of each payment also utilizing a discount rate of 11.5%. Actual cash flows are likely to be different than those assumed. This transaction closed on December 18, 2014; accordingly, the results of operations of the acquired business have been included in the Company's results of operations beginning after that date. Pro forma

financial information has not been included because OncoEthix's historical financial results are not significant when compared with the Company's financial results.

On October 1, 2014, the Company completed the sale of its Merck Consumer Care (MCC) business to Bayer AG (Bayer) for $14.2 billion ($14.0 billion net of cash divested), less customary closing adjustments as well as certain contingent amounts held back that were payable upon the manufacturing site transfer in Canada and regulatory approval in Korea. Under the terms of the agreement, Bayer acquired Merck's existing over-the-counter business, including the global trademark and prescription rights for Claritin and Afrin. The Company recognized a pretax gain from the sale of MCC of $11.2 billion in 2014.

Also on October 1, 2014, the Company entered into a worldwide clinical development collaboration with Bayer to market and develop its portfolio of soluble guanylate cyclase (sGC) modulators. This includes Bayer's Adempas (riociguat), the first member of this novel class of compounds. Adempas is approved to treat pulmonary arterial hypertension (PAH) and is approved for patients with chronic thromboembolic pulmonary hypertension (CTEPH). Adempas is marketed in the United States and Europe for both PAH and CTEPH and in Japan for CTEPH. The two companies will equally share costs and profits from the collaboration and implement a joint development and commercialization strategy. The collaboration also includes clinical development of Bayer's vericiguat, which is currently in Phase 2 trials for worsening heart failure, as well as opt-in rights for other early-stage sGC compounds in development at Bayer. Merck will in turn make available its early-stage sGC compounds under similar terms. In return for these broad collaboration rights, Merck made an upfront payment to Bayer of $1.0 billion with the potential for additional milestone payments of up to $1.1 billion upon the achievement of agreed-upon sales goals. For Adempas, Bayer will continue to lead commercialization in the Americas, while Merck will lead commercialization in the rest of the world. For vericiguat and other potential opt-in products, Bayer will lead 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. The Company determined that Merck's payment to access Bayer's compounds constituted an acquisition of an asset. Of the $1.0 billion consideration paid by Merck, $915 million of fair value related to Adempas and was capitalized as an intangible asset subject to amortization over its estimated useful life of 12 years, and the remaining $85 million of fair value related to the vericiguat compound in clinical development and was expensed within *Research and development* expenses. The fair values of Adempas and vericiguat were determined using an income approach, through which fair value is estimated based upon probability-adjusted future net cash flows, and for vericiguat also for the stage of development of the project and the associated probability of successful completion. The net cash flows were then discounted to present value using a discount rate of 10.0% for Adempas and 10.5% for vericiguat. Future sales based milestones will be accrued when probable of being achieved; the related intangible asset will be recognized and amortized to *Materials and production* costs over its applicable useful life. The Company and Bayer each have the right to terminate the agreement for cause on a product-by-product basis for all products being developed and commercialized under the agreement (other than Adempas for which Bayer has no termination rights) in the event of the other party's material, uncured breach related to any such product.

In September 2014, Merck and Sun Pharmaceutical Industries Ltd. (Sun Pharma) entered into an exclusive worldwide licensing agreement for Merck's investigational therapeutic antibody candidate, MK-3222, tildrakizumab, for the treatment of chronic plaque psoriasis, a skin ailment. Under terms of the agreement, Sun Pharma acquired worldwide rights to tildrakizumab for use in all human indications from Merck in exchange for an upfront payment of $80 million. Merck will continue all clinical development and regulatory activities, which will be funded by Sun Pharma. Upon product approval, Sun Pharma will be responsible for regulatory activities, including subsequent submissions, pharmacovigilance, post approval studies, manufacturing and commercialization of the approved product. Merck is also eligible to receive future payments associated with regulatory (including product approval) and sales milestones, as well as tiered royalties ranging from mid-single digit through teen percentage rates on sales. Merck recorded a loss of $47 million in 2014 on the transaction included in *Other (income) expense, net*.

In August 2014, Merck completed the acquisition of Idenix Pharmaceuticals, Inc. (Idenix) for approximately $3.9 billion in cash ($3.7 billion net of cash acquired). Idenix was a biopharmaceutical company engaged in the discovery and development of medicines for the treatment of human viral diseases, whose primary focus was on the development of next-generation oral antiviral therapeutics to treat hepatitis C virus (HCV) infection. The transaction was accounted for as an acquisition of a business; accordingly, the assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date. Merck recognized an intangible asset for IPR&D of $3.2 billion related

to MK-3682 (formerly IDX21437), net deferred tax liabilities of $951 million and other net liabilities of $12 million. MK-3682 is a nucleotide prodrug in Phase 2 clinical development being evaluated for potential inclusion in the development of all oral, pan-genotypic fixed-dose combination regimens. The excess of the consideration transferred over the fair value of net assets acquired of $1.5 billion was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair value of the identifiable intangible asset related to IPR&D was determined using an income approach. The asset's probability-adjusted future net cash flows were then discounted to present value using a discount rate of 11.5%. Actual cash flows are likely to be different than those assumed. This transaction closed on August 5, 2014; accordingly, the results of operations of the acquired business have been included in the Company's results of operations beginning after that date. Pro forma financial information has not been included because Idenix's historical financial results are not significant when compared with the Company's financial results.

In May 2014, Merck entered into an agreement to sell certain ophthalmic products to Santen Pharmaceutical Co., Ltd. (Santen) in Japan and markets in Europe and Asia Pacific. The agreement provided for upfront payments from Santen and additional payments based on defined sales milestones. Santen will also purchase supply of ophthalmology products covered by the agreement for a two- to five-year period. The transaction closed in most markets on July 1, 2014 and in the remaining markets on October 1, 2014. The Company received $565 million of upfront payments from Santen, net of certain adjustments, and recognized gains of $480 million on the transactions in 2014 included in *Other (income) expense, net*.

In March 2014, Merck divested its Sirna Therapeutics, Inc. (Sirna) subsidiary to Alnylam Pharmaceuticals, Inc. (Alnylam) for consideration of $25 million and 2,520,044 shares of Alnylam common stock. Merck is eligible to receive future payments associated with the achievement of certain regulatory and commercial milestones, as well as royalties on future sales. Merck recorded a gain of $204 million in *Other (income) expense, net* in 2014 related to this transaction. The excess of Merck's tax basis in its investment in Sirna over the value received resulted in an approximate $300 million tax benefit recorded in 2014.

In January 2014, Merck sold the U.S. marketing rights to *Saphris*, an antipsychotic indicated for the treatment of schizophrenia and bipolar I disorder in adults to Forest Laboratories, Inc. (Forest). Under the terms of the agreement, Forest made upfront payments of $232 million, which were recorded in *Sales* in 2014, and will make additional payments to Merck based on defined sales milestones. In addition, as part of this transaction, Merck agreed to supply product to Forest (subsequently acquired by Allergan) until patent expiry.

In February 2013, Merck and Supera Farma Laboratorios S.A. (Supera), a Brazilian pharmaceutical company co-owned by Cristália and Eurofarma, established a joint venture that markets, distributes and sells a portfolio of pharmaceutical and branded generic products from Merck, Cristália and Eurofarma in Brazil. Merck owns 51% of the joint venture, and Cristália and Eurofarma collectively own 49%. The transaction was accounted for as an acquisition of a business; accordingly, the assets acquired and liabilities assumed were recorded at their respective fair values. This resulted in Merck recognizing intangible assets for currently marketed products of $89 million, IPR&D of $100 million, goodwill of $103 million, and deferred tax liabilities of $64 million. The Company also recorded increases to *Noncontrolling interests* and *Other paid-in capital* in the amounts of $112 million and $116 million, respectively. This transaction closed on February 1, 2013; accordingly, the results of operations of the acquired business have been included in the Company's results of operations beginning after that date. The Company has recorded certain intangible asset impairments charges related to the Supera joint venture (see Note 7).

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. In 2007, Schering-Plough and Centocor revised their distribution agreement regarding the development, commercialization and distribution of both *Remicade* and *Simponi*, extending the Company's rights to exclusively market *Remicade* to match the duration of the Company's exclusive marketing rights for *Simponi*. In addition, Schering-Plough and Centocor agreed to share certain development costs relating to *Simponi*'s auto-injector delivery system. In 2009, the European Commission approved *Simponi* as a treatment for rheumatoid arthritis and other immune system disorders in two presentations — a novel auto-injector and a prefilled syringe. As a result, the Company's marketing rights for both products extend for 15 years from the first commercial

sale of *Simponi* in the European Union (EU) following the receipt of pricing and reimbursement approval within the EU. *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.

5. 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 primary objective of the revenue hedging program is to reduce the potential for longer-term unfavorable changes in foreign exchange rates to decrease 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 that are expected to occur over its planning cycle, typically no more than three years into the future. The Company will layer in hedges over time, increasing the portion of third-party and intercompany distributor entity sales hedged as it gets closer to the expected date of the forecasted foreign currency denominated sales. The portion of 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 hedged anticipated sales are a specified component of a portfolio of similarly denominated foreign currency-based sales transactions, each of which responds to the hedged currency risk in the same manner. The Company manages its anticipated transaction exposure principally with purchased local currency put options, which provide the Company with a right, but not an obligation, to sell foreign currencies in the future at a predetermined price. If the U.S. dollar strengthens relative to the currency of the hedged anticipated sales, total changes in the options' cash flows offset the decline in the expected future U.S. dollar equivalent cash flows of the hedged foreign currency sales. Conversely, if the U.S. dollar weakens, the options' value reduces to zero, but the Company benefits from the increase in the U.S. dollar equivalent value of the anticipated foreign currency cash flows.

In connection with the Company's revenue hedging program, a purchased collar option strategy may be utilized. With a purchased collar option strategy, the Company writes a local currency call option and purchases a local currency put option. As compared to a purchased put option strategy alone, a purchased collar strategy reduces the upfront costs associated with purchasing puts through the collection of premiums by writing call options. If the U.S. dollar weakens relative to the currency of the hedged anticipated sales, the purchased put option value of the collar strategy reduces to zero and the Company benefits from the increase in the U.S. dollar equivalent value of its anticipated foreign currency cash flows; however, this benefit would be capped at the strike level of the written call. If the U.S. dollar strengthens relative to the currency of the hedged anticipated sales, the written call option value of the collar strategy reduces to zero and the changes in the purchased put cash flows of the collar strategy would offset the decline in the expected future U.S. dollar equivalent cash flows of the hedged foreign currency sales.

The Company may also utilize forward contracts in its revenue hedging program. If the U.S. dollar strengthens relative to the currency of the hedged anticipated sales, the increase in the fair value of the forward contracts offsets the decrease in the expected future U.S. dollar cash flows of the hedged foreign currency sales. Conversely, if the U.S. dollar weakens, the decrease in the fair value of the forward contracts offsets the increase in the value of the anticipated foreign currency cash flows.

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 primary objective of the balance sheet risk management program is 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, which enable the Company to buy and sell foreign currencies in the future at fixed exchange rates and economically offset the consequences of changes in foreign exchange from the monetary assets. Merck routinely enters into 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 Company will also minimize the effect of exchange on monetary assets and liabilities by managing operating activities and net asset positions at the local level. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

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

The Company also uses forward exchange contracts to hedge 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. 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 gains of $304 million in 2015 and $294 million in 2014 and pretax losses of $84 million in 2013 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, 2015, the Company was a party to 30 pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes as detailed in the table below.

Debt Instrument	2015 Par Value of Debt	2015 Number of Interest Rate Swaps Held	2015 Total Swap Notional Amount
0.70% notes due 2016	$ 1,000	4	$ 1,000
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:

		2015			2014		
		Fair Value of Derivative			Fair Value of Derivative		
	Balance Sheet Caption	**Asset**	**Liability**	**U.S. Dollar Notional**	Asset	Liability	U.S. Dollar Notional
Derivatives Designated as Hedging Instruments							
Interest rate swap contracts (noncurrent)	Other assets	**$ 42**	**$ —**	**$ 2,700**	$ 19	$ —	$ 1,950
Interest rate swap contracts (current)	Accrued and other current liabilities	**—**	**1**	**1,000**	—	—	—
Interest rate swap contracts (noncurrent)	Other noncurrent liabilities	**—**	**23**	**3,500**	—	15	2,000
Foreign exchange contracts (current)	Other current assets	**579**	**—**	**4,171**	772	—	5,513
Foreign exchange contracts (noncurrent)	Other assets	**386**	**—**	**4,136**	691	—	6,253
Foreign exchange contracts (current)	Accrued and other current liabilities	**—**	**1**	**77**	—	—	—
		$ 1,007	**$ 25**	**$ 15,584**	$ 1,482	$ 15	$ 15,716
Derivatives Not Designated as Hedging Instruments							
Foreign exchange contracts (current)	Other current assets	**$ 212**	**$ —**	**$ 8,783**	$ 365	$ —	$ 6,966
Foreign exchange contracts (noncurrent)	Other assets	**18**	**—**	**179**	—	—	—
Foreign exchange contracts (current)	Accrued and other current liabilities	**—**	**37**	**2,508**	—	88	3,386
Foreign exchange contracts (noncurrent)	Other noncurrent liabilities	**—**	**1**	**6**	—	—	—
		$ 230	**$ 38**	**$ 11,476**	$ 365	$ 88	$ 10,352
		$ 1,237	**$ 63**	**$ 27,060**	$ 1,847	$ 103	$ 26,068

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:

	2015		2014	
	Asset	**Liability**	Asset	Liability
Gross amounts recognized in the consolidated balance sheet	**$ 1,237**	**$ 63**	$ 1,847	$ 103
Gross amount subject to offset in master netting arrangements not offset in the consolidated balance sheet	**(59)**	**(59)**	(97)	(97)
Cash collateral (received) posted	**(862)**	**—**	(1,410)	—
Net amounts	**$ 316**	**$ 4**	$ 340	$ 6

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	**2015**	2014	2013
Derivatives designated in a fair value hedging relationship			
Interest rate swap contracts			
Amount of (gain) loss recognized in *Other (income) expense, net* on derivatives [1]	**$ (14)**	$ (17)	$ 12
Amount of loss (gain) recognized in *Other (income) expense, net* on hedged item [1]	**7**	14	(14)
Derivatives designated in foreign currency cash flow hedging relationships			
Foreign exchange contracts			
Amount of (gain) loss reclassified from *AOCI* to *Sales*	**(724)**	(143)	45
Amount of gain recognized in *OCI* on derivatives	**(526)**	(775)	(306)
Derivatives designated in foreign currency net investment hedging relationships			
Foreign exchange contracts			
Amount of gain recognized in *Other (income) expense, net* on derivatives [2]	**(4)**	(6)	(10)
Amount of gain recognized in *OCI* on derivatives	**(10)**	(192)	(363)
Derivatives not designated in a hedging relationship			
Foreign exchange contracts			
Amount of (gain) loss recognized in *Other (income) expense, net* on derivatives [3]	**(461)**	(516)	183
Amount of (gain) loss recognized in *Sales*	**(1)**	15	8

[1] *There was $7 million, $3 million and $2 million of ineffectiveness on the hedge during 2015, 2014 and 2013, respectively.*

[2] *There was no ineffectiveness on the hedge. Represents the amount excluded from hedge effectiveness testing.*

[3] *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, 2015, the Company estimates $429 million of pretax net unrealized gains on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from *AOCI* to *Sales*. The amount ultimately reclassified to *Sales* may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.

Investments in Debt and Equity Securities

Information on available-for-sale investments at December 31 is as follows:

	2015				2014			
	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses
Corporate notes and bonds	**$ 10,259**	**$ 10,299**	**$ 7**	**$ (47)**	$ 10,107	$ 10,102	$ 22	$ (17)
Commercial paper	**2,977**	**2,977**	**—**	**—**	6,970	6,970	—	—
U.S. government and agency securities	**1,761**	**1,767**	**—**	**(6)**	1,774	1,775	1	(2)
Asset-backed securities	**1,284**	**1,290**	**—**	**(6)**	1,460	1,462	1	(3)
Mortgage-backed securities	**694**	**697**	**1**	**(4)**	602	604	2	(4)
Foreign government bonds	**607**	**586**	**22**	**(1)**	385	385	—	—
Equity securities	**534**	**409**	**125**	**—**	730	557	173	—
	$ 18,116	**$ 18,025**	**$ 155**	**$ (64)**	$ 22,028	$ 21,855	$ 199	$ (26)

Available-for-sale debt securities included in *Short-term investments* totaled $4.8 billion at December 31, 2015. Of the remaining debt securities, $11.8 billion mature within five years. At December 31, 2015 and 2014, there were no debt securities pledged as collateral.

Fair Value Measurements

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

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

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

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

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

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

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

	Fair Value Measurements Using				Fair Value Measurements Using			
	Quoted Prices In Active Markets for Identical Assets (Level 1)	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**	**Total**	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
	2015				2014			
Assets								
Investments								
Corporate notes and bonds	**$ —**	**$ 10,259**	**$ —**	**$ 10,259**	$ —	$ 10,107	$ —	$ 10,107
Commercial paper	**—**	**2,977**	**—**	**2,977**	—	6,970	—	6,970
U.S. government and agency securities	**—**	**1,761**	**—**	**1,761**	—	1,774	—	1,774
Asset-backed securities [1]	**—**	**1,284**	**—**	**1,284**	—	1,460	—	1,460
Mortgage-backed securities [1]	**—**	**694**	**—**	**694**	—	602	—	602
Foreign government bonds	**—**	**607**	**—**	**607**	—	385	—	385
Equity securities	**360**	**—**	**—**	**360**	495	—	—	495
	360	**17,582**	**—**	**17,942**	495	21,298	—	21,793
Other assets								
Securities held for employee compensation	**155**	**19**	**—**	**174**	181	54	—	235
Derivative assets [2]								
Purchased currency options	**—**	**1,041**	**—**	**1,041**	—	1,252	—	1,252
Forward exchange contracts	**—**	**154**	**—**	**154**	—	576	—	576
Interest rate swaps	**—**	**42**	**—**	**42**	—	19	—	19
	—	**1,237**	**—**	**1,237**	—	1,847	—	1,847
Total assets	**$ 515**	**$ 18,838**	**$ —**	**$ 19,353**	$ 676	$ 23,199	$ —	$ 23,875
Liabilities								
Other liabilities								
Contingent consideration	**$ —**	**$ —**	**$ 590**	**$ 590**	$ —	$ —	$ 428	$ 428
Derivative liabilities [2]								
Forward exchange contracts	**—**	**38**	**—**	**38**	—	46	—	46
Written currency options	**—**	**1**	**—**	**1**	—	42	—	42
Interest rate swaps	**—**	**24**	**—**	**24**	—	15	—	15
	—	**63**	**—**	**63**	—	103	—	103
Total liabilities	**$ —**	**$ 63**	**$ 590**	**$ 653**	$ —	$ 103	$ 428	$ 531

[1] *Primarily all of the asset-backed securities are highly-rated (Standard & Poor's rating of AAA and Moody's Investors Service rating of Aaa), secured primarily by credit card, auto loan, and home equity 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] *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 2015. As of December 31, 2015, *Cash and cash equivalents* of $8.5 billion included $7.7 billion of cash equivalents (considered Level 2 in the fair value hierarchy).

Contingent Consideration

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

	2015	2014
Fair value January 1	**$ 428**	$ 69
Changes in fair value [(1)]	**(16)**	316
Additions	**228**	43
Payments	**(50)**	—
Fair value December 31	**$ 590**	$ 428

[(1)] *Recorded in* Research and development *expenses and* Materials and production *costs.*

During 2015, the Company recognized liabilities for contingent consideration of $123 million related to the acquisition of Cubist and $105 million related to the acquisition of cCAM (see Note 4). In addition, in 2015, the Company paid $50 million of contingent consideration related to the first commercial sale of *Zerbaxa* in the United States. During 2014, the fair value of a liability for contingent consideration related to an acquisition that occurred in 2010 increased by $316 million resulting from the progression of the program from preclinical to Phase 1. The increase resulted from a higher fair value of future regulatory milestone and royalty payments due to an increased probability of success of the program given its progression into Phase 1. In addition, during 2014, the Company recognized a liability of $43 million for contingent consideration related to the acquisition of OncoEthix in 2014 (see Note 4).

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, 2015, was $27.0 billion compared with a carrying value of $26.5 billion and at December 31, 2014, was $22.5 billion compared with a carrying value of $21.4 billion. Fair value was estimated using recent observable market prices and would be considered Level 2 in the fair value hierarchy.

Concentrations of Credit Risk

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

The majority of the Company's accounts receivable arise from product sales in the United States and Europe and are primarily due from drug wholesalers and retailers, hospitals, government agencies, managed health care providers and pharmacy benefit managers. The Company monitors the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in their credit profile. The Company also continues to monitor economic conditions, including the volatility associated with international sovereign economies, and associated impacts on the financial markets and its business, taking into consideration global economic conditions and the ongoing sovereign debt issues in certain European countries. At December 31, 2015 and 2014, *Other assets* included $10 million and $80 million, respectively, of accounts receivable not expected to be collected within one year. As of December 31, 2015, the Company's total net accounts receivable outstanding for more than one year were approximately $125 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: AmerisourceBergen Corporation, Cardinal Health, Inc., McKesson Corporation, Zuellig Pharma Ltd. (Asia Pacific), and AAH Pharmaceuticals Ltd (UK) which represented, in aggregate, approximately one-third of total accounts receivable at December 31, 2015. 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, 2015 and 2014, the Company had received cash collateral of $862 million and $1.4 billion, 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, 2015 or 2014.

6. Inventories

Inventories at December 31 consisted of:

	2015	2014
Finished goods	**$ 1,343**	$ 1,588
Raw materials and work in process	**4,374**	5,141
Supplies	**168**	197
Total (approximates current cost)	**5,885**	6,926
Increase to LIFO costs	**384**	309
	$ 6,269	$ 7,235
Recognized as:		
Inventories	**$ 4,700**	$ 5,571
Other assets	**1,569**	1,664

Inventories valued under the LIFO method comprised approximately $2.4 billion and $2.6 billion of inventories at December 31, 2015 and 2014, respectively. Amounts recognized as *Other assets* are comprised almost entirely of raw materials and work in process inventories. At December 31, 2015 and 2014, these amounts included $1.5 billion and $1.6 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included $63 million and $74 million at December 31, 2015 and 2014, respectively, of inventories produced in preparation for product launches.

7. Goodwill and Other Intangibles

The following table summarizes goodwill activity by segment:

	Pharmaceutical	All Other	Total
Balance January 1, 2014	$ 10,065	$ 2,236	$ 12,301
Acquisitions	1,369	38	1,407
Divestitures	(200)	(362)	(562)
Impairments	(93)	—	(93)
Other [1]	(33)	(28)	(61)
Balance December 31, 2014	11,108	1,884	12,992
Acquisitions	**4,684**	**29**	**4,713**
Divestitures	**(18)**	**—**	**(18)**
Impairments	**—**	**(47)**	**(47)**
Other [1]	**88**	**(5)**	**83**
Balance December 31, 2015 [2]	**$ 15,862**	**$ 1,861**	**$ 17,723**

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

[2] *Accumulated goodwill impairment losses at December 31, 2015 and 2014 were $140 million and $93 million, respectively.*

In 2015, the additions to goodwill in the Pharmaceutical segment resulted primarily from the acquisition of Cubist (see Note 4). The reductions to Pharmaceutical segment goodwill resulted from the divestiture of the Company's remaining ophthalmics business in international markets (see Note 4). The impairments of goodwill within other non-reportable segments relates primarily to certain businesses within the Healthcare Services segment.

In 2014, the additions to goodwill in the Pharmaceutical segment primarily resulted from the acquisition of Idenix and the reductions resulted both from the sale of MCC and the divestiture of certain ophthalmic products in several international markets (see Note 4). The reductions to goodwill in other segments during 2014 resulted from the termination of the Company's relationship with AstraZeneca LP (AZLP) (see Note 8) and the divestiture of MCC. Also, during the third quarter of 2014, the Company recorded an impairment charge on the goodwill related to the Supera joint venture as a result of changes in cash flow assumptions for certain compounds and currently marketed products.

Other intangibles at December 31 consisted of:

	2015			2014		
	Gross Carrying Amount	**Accumulated Amortization**	**Net**	Gross Carrying Amount	Accumulated Amortization	Net
Products and product rights	**$ 45,949**	**$ 28,514**	**$ 17,435**	$ 38,714	$ 23,830	$ 14,884
In-process research and development	**4,226**	**—**	**4,226**	4,345	—	4,345
Tradenames	**198**	**79**	**119**	198	71	127
Other	**1,418**	**596**	**822**	1,527	497	1,030
	$ 51,791	**$ 29,189**	**$ 22,602**	$ 44,784	$ 24,398	$ 20,386

Acquired intangibles include products and product rights, tradenames and patents, which are recorded at fair value, assigned an estimated useful life, and are amortized primarily on a straight-line basis over their estimated useful lives. The increase in intangible assets for products and product rights in 2015 primarily relates to the acquisition of Cubist (see Note 4). Some of the Company's more significant acquired intangibles related to marketed products (included in product and product rights above) at December 31, 2015 include *Zerbaxa*, $3.5 billion*; Zetia*, $2.4 billion; *Vytorin*, $1.5 billion; *Sivextro*, $1.0 billion; *Implanon/Nexplanon* $645 million; *Dificid*, $644 million*; NuvaRing*, $502 million; *Nasonex*, $431 million and *Cubicin,* $418 million. During 2014, the Company recognized an intangible asset related to Adempas as a result of the formation of a collaboration with Bayer (see Note 4) that had a carrying value of $706 million at December 31, 2015 reflected in "Other" in the table above.

During 2015, 2014 and 2013, the Company recorded impairment charges related to marketed products and other intangibles of $45 million, $1.1 billion and $486 million, respectively, within *Material and production* costs. The charges in 2015 primarily relate to the impairment of customer relationship and tradename intangibles for certain businesses within in the Healthcare Services segment. Of the amount recorded in 2014, $793 million related to *PegIntron,* $244 million related to *Victrelis* and $35 million related to *Rebetol*, all of which are products marketed by the Company for the treatment of chronic HCV infection. During 2014, sales of these products were adversely affected by loss of market share or patient treatment delays in markets anticipating the availability of newer therapeutic options. In 2014, these trends accelerated more rapidly than previously anticipated by the Company. In addition, developments in the competitive HCV treatment market led to market share losses that were greater than the Company had predicted. These factors caused changes in cash flow projections for *PegIntron*, *Victrelis* and *Rebetol* that indicated the intangible asset values were not recoverable on an undiscounted cash flows basis. The Company utilized market participant assumptions to determine its best estimate of the fair values of the intangible assets related to *PegIntron*, *Victrelis* and *Rebetol* that, when compared with their related carrying values, resulted in the impairment charges noted above. Of the impairment charges recorded in 2013, $330 million resulted from lower cash flow projections for *Saphris/Sycrest,* due to reduced expectations in international markets and in the United States. These revisions to cash flows indicated that the *Saphris/ Sycrest* intangible asset value was not recoverable on an undiscounted cash flows basis. The Company utilized market participant assumptions and considered several different scenarios to determine its best estimate of the fair value of the intangible asset related to *Saphris/Sycrest* that, when compared with its related carrying value, resulted in the impairment charge noted above. The remaining $156 million of impairment charges in 2013 resulted from lower cash flow projections for *Rebetol* due to reduced expectations in Japan and Europe. These revisions to cash flows indicated that the *Rebetol* intangible asset value was not 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 *Rebetol* that, when compared with its related carrying value, resulted in the impairment charge noted above.

IPR&D that the Company acquires through business combinations represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. Amounts

capitalized as IPR&D are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, the Company will make a separate determination as to the then useful life of the assets and begin amortization. During 2015, 2014 and 2013, $280 million, $654 million and $346 million, respectively, of IPR&D was reclassified to products and product rights upon receipt of marketing approval in a major market.

During 2015, the Company recorded $63 million of IPR&D impairment charges within *Research and development* expenses. Of this amount, $50 million relates to the surotomycin clinical development program obtained in connection with the acquisition of Cubist. During 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. During 2014, the Company recorded $49 million of IPR&D impairment charges primarily as a result of changes in cash flow assumptions for certain compounds obtained in connection with the Supera joint venture, as well as for the discontinuation of certain Animal Health programs. During 2013, the Company recorded $279 million of IPR&D impairment charges. Of this amount, $181 million related to the write-off of the intangible asset associated with preladenant as a result of the discontinuation of the clinical development program for this compound. In addition, the Company recorded impairment charges resulting from changes in cash flow assumptions for certain compounds, as well as for pipeline programs that had previously been deprioritized and were subsequently deemed to have no alternative use in the period.

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 $4.8 billion in 2015, $4.2 billion in 2014 and $4.8 billion in 2013. The estimated aggregate amortization expense for each of the next five years is as follows: 2016, $4.0 billion; 2017, $3.5 billion; 2018, $2.0 billion; 2019, $1.2 billion; 2020, $1.0 billion.

8. 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 Sanofi Pasteur MSD, certain investments funds, as well as AZLP until the termination of the Company's relationship with AZLP on June 30, 2014 as discussed below. Equity income from affiliates was $205 million in 2015, $257 million in 2014 and $404 million in 2013 and is included in *Other (income) expense, net* (see Note 14).

Investments in affiliates accounted for using the equity method, including the below joint ventures, totaled $702 million at December 31, 2015 and $337 million at December 31, 2014. These amounts are reported in *Other assets*. Amounts due from the above joint ventures included in *Other current assets* were $34 million at December 31, 2015 and $45 million at December 31, 2014.

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 the 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 such revenue was $463 million in 2014 and $920 million in 2013 primarily relating to sales of Nexium, as well as Prilosec. In addition, Merck earned certain Partnership returns from AZLP of $192 million in 2014 and $352 million in 2013, which were recorded in equity income from affiliates.

On June 30, 2014, AstraZeneca exercised its option to purchase Merck's interest in KBI for $419 million in cash. Of this amount, $327 million reflects an estimate of the fair value of Merck's interest in Nexium and Prilosec. This portion of the exercise price, which is subject to a true-up in 2018 based on actual sales from closing in 2014 to June 2018, was deferred and is being recognized over time in *Other (income) expense, net* as the contingency is eliminated as sales occur. During 2015 and 2014, $182 million and $140 million, respectively, of the deferred income was recognized bringing cumulative deferred income recognized through December 31, 2015 to $322 million. The remaining exercise price of $91 million primarily represents a multiple of ten times Merck's average 1% annual profit allocation in the partnership for the three years prior to exercise. Merck recognized the $91 million as a gain in 2014 within *Other (income) expense, net*. As a result of AstraZeneca's option exercise, the Company's remaining interest in AZLP was redeemed. Accordingly, the Company also recognized a non-cash gain of approximately $650 million in 2014 within *Other (income) expense, net* resulting from the retirement of $2.4 billion of KBI preferred stock (see Note 11), the elimination of the Company's $1.4 billion investment in AZLP and a $340 million reduction of goodwill. This transaction resulted in a net tax benefit of $517 million in 2014 primarily reflecting the reversal of deferred taxes on the AZLP investment balance.

As a result of AstraZeneca exercising its option, as of July 1, 2014, the Company no longer records equity income from AZLP and supply sales to AZLP have terminated.

Summarized financial information for AZLP is as follows:

Years Ended December 31	2014 [1]	2013
Sales	$ 2,205	$ 4,611
Materials and production costs	1,044	2,222
Other expense, net	604	1,175
Income before taxes [2]	557	1,214

[1] *Includes results through the June 30, 2014 termination date.*

[2] *Merck's partnership returns from AZLP were generally contractually determined as noted above and were not based on a percentage of income from AZLP, other than with respect to Merck's 1% limited partnership interest.*

Sanofi Pasteur MSD

In 1994, Merck and Pasteur Mérieux Connaught (now Sanofi Pasteur S.A.) established an equally-owned joint venture to market vaccines in Europe and to collaborate in the development of combination vaccines for distribution in Europe. Joint venture vaccine sales were $923 million for 2015, $1.1 billion for 2014 and $1.2 billion for 2013.

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

Loans payable at December 31, 2015 included $2.3 billion of notes due in 2016, $10 million of short-term foreign borrowings and $226 million of long-dated notes that are subject to repayment at the option of the holder. Loans payable at December 31, 2014 included $1.0 billion of notes due in 2015, $1.5 billion of commercial paper, $55 million of short-term foreign borrowings and $143 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 0.07% and 0.15% for the years ended December 31, 2015 and 2014, respectively.

Long-term debt at December 31 consisted of:

	2015	2014
2.75% notes due 2025	**$ 2,496**	$ —
3.70% notes due 2045	**1,989**	—
2.80% notes due 2023	**1,749**	1,749
5.00% notes due 2019	**1,285**	1,291
4.15% notes due 2043	**1,247**	1,246
1.85% notes due 2020	**1,243**	—
2.35% notes due 2022	**1,237**	—
3.875% notes due 2021	**1,161**	1,150
1.125% euro-denominated notes due 2021	**1,096**	1,218
1.875% euro-denominated notes due 2026	**1,090**	1,210
2.40% notes due 2022	**1,014**	1,000
Floating-rate borrowing due 2018	**1,000**	1,000
1.10% notes due 2018	**999**	999
1.30% notes due 2018	**987**	984
6.50% notes due 2033	**809**	812
Floating-rate notes due 2020	**700**	—
6.55% notes due 2037	**596**	597
2.50% euro-denominated notes due 2034	**543**	603
3.60% notes due 2042	**493**	493
5.85% notes due 2039	**418**	418
5.75% notes due 2036	**371**	371
5.95% debentures due 2028	**356**	356
6.40% debentures due 2028	**326**	326
Floating-rate notes due 2017	**300**	—
6.30% debentures due 2026	**152**	152
0.70% notes due 2016	**—**	998
2.25% notes due 2016	**—**	858
Floating-rate borrowing due 2016	**—**	500
Other	**272**	368
	$ 23,929	$ 18,699

Other (as presented in the table above) included $225 million and $309 million at December 31, 2015 and 2014, respectively, of borrowings at variable rates that resulted in effective interest rates of zero for 2015 and 2014. Other also included foreign borrowings of $43 million and $53 million at December 31, 2015 and 2014, respectively, at varying rates up to 4.75% and 6.25%, 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 February 2015, Merck issued $8.0 billion aggregate principal amount of senior unsecured notes consisting of $300 million principal amount of floating rate notes due 2017, $700 million principal amount of floating rate notes due 2020, $1.25 billion principal amount of 1.85% notes due 2020, $1.25 billion aggregate principal amount of 2.35% notes due 2022, $2.5 billion aggregate principal amount of 2.75% notes due 2025 and $2.0 billion aggregate principal amount of 3.70% notes due 2045. 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 4).

In October 2014, the Company issued €2.5 billion principal amount of senior unsecured notes. The net proceeds of the offering of $3.1 billion were used in part to repay debt that was validly tendered in connection with tender offers launched by the Company for certain outstanding notes and debentures. The Company paid $2.5 billion in aggregate consideration (applicable purchase price together with accrued interest) to redeem $1.8 billion principal amount of debt. In November 2014, Merck redeemed an additional $2.0 billion principal amount of senior unsecured notes. The Company recorded a pretax loss of $628 million in 2014 in connection with these transactions.

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, 2015, 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: 2016, $2.4 billion; 2017, $317 million; 2018, $3.0 billion; 2019, $1.3 billion; 2020, $2.0 billion.

In August 2014, the Company terminated its existing credit facility and entered into a $6.0 billion, five-year credit facility that matures in August 2019. 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 $303 million in 2015, $350 million in 2014 and $367 million in 2013. The minimum aggregate rental commitments under noncancellable leases are as follows: 2016, $213 million; 2017, $136 million; 2018, $114 million; 2019, $97 million; 2020, $69 million and thereafter, $160 million. The Company has no significant capital leases.

10. Contingencies and Environmental Liabilities

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property, and commercial litigation, as well as certain additional matters including 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.

Vioxx Litigation

Product Liability Lawsuits

As previously disclosed, Merck is a defendant in approximately 10 active federal and state lawsuits (*Vioxx* Product Liability Lawsuits) alleging personal injury as a result of the use of *Vioxx*. Most of these cases are coordinated in a multidistrict litigation in the U.S. District Court for the Eastern District of Louisiana (*Vioxx* MDL) before Judge Eldon E. Fallon.

As previously disclosed, Merck is also a defendant in approximately 30 putative class action lawsuits alleging economic injury as a result of the purchase of *Vioxx*. All but one of those cases are in the *Vioxx* MDL. Merck has reached a resolution, approved by Judge Fallon, of these class actions in the *Vioxx* MDL. Under the settlement, Merck will pay up to $23 million to resolve all properly documented claims submitted by class members, approved attorneys' fees and expenses, and approved settlement notice costs and certain other administrative expenses. The court entered an order approving the settlement in January 2014 and the claims review process was recently completed.

Merck is also a defendant in lawsuits brought by state Attorneys General of three states — Alaska, Montana and Utah. The lawsuits are pending in state courts. These actions allege that Merck misrepresented the safety of *Vioxx* and seek recovery for expenditures on *Vioxx* by government-funded health care programs, such as Medicaid, and/or penalties for alleged Consumer Fraud Act violations. Trial has been scheduled in the Montana case for September 12, 2016, and trial has been set in the Alaska case for January 9, 2017. Motions for judgment on the pleadings in the Alaska and Montana cases are currently pending, and a motion to dismiss was recently filed in the Utah case.

Shareholder Lawsuits

As previously disclosed, in addition to the *Vioxx* Product Liability Lawsuits, various putative class actions and individual lawsuits have been filed against Merck and certain former employees alleging that the defendants violated federal securities laws by making alleged material misstatements and omissions with respect to the cardiovascular safety of *Vioxx* (*Vioxx* Securities Lawsuits). The *Vioxx* Securities Lawsuits are coordinated in a multidistrict litigation in the U.S. District Court for the District of New Jersey before Judge Stanley R. Chesler, and have been consolidated for all purposes. In August 2011, Judge Chesler granted in part and denied in part Merck's motion to dismiss the Fifth Amended Class Action Complaint in the consolidated securities class action. Among other things, the court dismissed certain defendants from the case, and also dismissed claims based on statements made on or after the voluntary withdrawal of *Vioxx* on September 30, 2004. In October 2011, the remaining defendants answered the Fifth Amended Class Action Complaint. In April 2012, plaintiffs filed a motion for class certification for the period from May 21, 1999, through September 29, 2004, which the court granted in January 2013. In March 2013, plaintiffs filed a motion for leave to amend their complaint to add certain allegations to expand the class period. In May 2013, the court denied plaintiffs' motion for leave to amend their complaint to expand the class period, but granted plaintiffs' leave to amend their complaint to add certain allegations within the existing class period. In June 2013, plaintiffs filed their Sixth Amended Class Action Complaint (the Class Action). In July 2013, defendants answered the Class Action. Discovery has been completed and is now closed. On May 13, 2015, the court granted in part and denied in part defendants' motions for summary judgment; the court granted judgment in defendants' favor on five of the alleged misstatements, including all statements prior to March 27, 2000, but denied the motion with respect to the remaining statements. On January 15, 2016, the Company announced that it had reached an agreement with plaintiffs to settle the Class Action for $830 million, plus an additional amount for attorneys' fees and expenses, in exchange for, among other things, a dismissal with prejudice of the Class Action and full releases of all claims against defendants. After available funds under certain insurance policies, Merck's net cash payment for the settlement and fees will be approximately $680 million. The proposed settlement covers all claims relating to *Vioxx* by settlement class members who purchased Merck securities between May 21, 1999, and October 29, 2004. The settlement is not an admission of wrongdoing and, as part of the settlement agreement, defendants continue to deny the allegations. The proposed settlement, including any award of attorneys' fees and expenses, is subject to final court approval. On February 8, 2016, the parties filed the stipulation of settlement, which the court preliminarily approved on February 11, 2016. The court has set a final approval hearing for June 28, 2016. The proposed settlement does not resolve the individual securities lawsuits discussed below.

As previously disclosed, 13 individual securities lawsuits filed by foreign and domestic institutional investors also are consolidated with the *Vioxx* Securities Lawsuits. The allegations in the individual securities lawsuits are substantially similar to the allegations in the *Vioxx* Securities Lawsuits. Discovery has been completed in those actions. The proposed settlement in the Class Action, discussed above, does not resolve the individual securities lawsuits,

although each individual plaintiff has the right, at its option, to join the settlement class at no additional cost to Merck. In light of the proposed settlement in the Class Action, the court adjourned the previously-scheduled trial date of March 1, 2016, for all cases in the consolidated action. The court has scheduled a conference on February 26, 2016, to discuss a pretrial schedule for any parties in the individual lawsuits for whom no settlement has been reached.

Insurance

As a result of the previously disclosed insurance arbitration, the Company will receive insurance proceeds of approximately $380 million in connection with the settlement of the Class Action. The Company also has Directors and Officers insurance coverage applicable to the *Vioxx* Securities Lawsuits with remaining stated upper limits of approximately $145 million. There are disputes with the insurers about the availability of some or all of the Company's Directors and Officers insurance coverage for these claims. The amounts actually recovered under the Directors and Officers policies discussed in this paragraph may be less than the stated upper limits.

International Lawsuits

As previously disclosed, in addition to the lawsuits discussed above, Merck has been named as a defendant in litigation relating to *Vioxx* in Brazil and Europe (collectively, the *Vioxx* International Lawsuits). As previously disclosed, in January 2012, the Company entered into an agreement to resolve all claims related to *Vioxx* in Canada and, in April 2013, the Company paid approximately $21 million into a settlement fund. The agreement was approved by courts in Canada's provinces and, during December 2015, the claims administrator finalized claimant eligibility determinations and the Company made a final payment of approximately $5 million into the settlement fund.

Reserves

In connection with the settlement of the Class Action, which remains subject to final court approval, the Company established a net reserve of $680 million in the fourth quarter of 2015. The Company believes that it has meritorious defenses to the remaining *Vioxx* Product Liability Lawsuits, *Vioxx* Securities Lawsuits and *Vioxx* International Lawsuits (collectively, the Remaining *Vioxx* Litigation) and will vigorously defend against them. In view of the inherent difficulty of predicting the outcome of litigation, particularly where there are many claimants and the claimants seek indeterminate damages, the Company is unable to predict the outcome of these matters and, at this time, cannot reasonably estimate the possible loss or range of loss with respect to the Remaining *Vioxx* Litigation. The Company has established a reserve with respect to certain *Vioxx* Product Liability Lawsuits. The Company also has an immaterial remaining reserve relating to the previously disclosed *Vioxx* investigation for the non-participating states with which litigation is continuing. The Company has established no other liability reserves with respect to the Remaining *Vioxx* Litigation.

Other 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, 2015, approximately 4,675 cases had been filed and were pending against Merck in either federal or state court, including one case which seeks class action certification, as well as damages and/or medical monitoring. In approximately 210 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*; however, a large majority of those actions are subject to the settlement discussed below. In addition, plaintiffs in approximately 4,460 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. As a condition to the settlement, 100% of the state and federal ONJ plaintiffs had to agree to participate in the settlement plan or Merck could either terminate the ONJ Master Settlement Agreement, or waive the 100% participation requirement and agree to a lesser funding amount for the settlement fund. On July 14, 2014, Merck elected to proceed with the ONJ Master Settlement Agreement at a reduced funding level since the participation level was approximately 95%. Merck has fully funded the ONJ Master Settlement Agreement and the escrow agent under the agreement has begun making settlement payments to qualifying plaintiffs. Approximately 40 non-participants' cases will remain once the settlement is complete. The ONJ Master Settlement Agreement has no effect on the cases alleging Femur Fractures discussed below.

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 (the Femur Fracture MDL). Judge Pisano presided over the Femur Fracture MDL until March 10, 2015, at which time the Femur Fracture MDL was reassigned from Judge Pisano to Judge Freda L. Wolfson following Judge Pisano's retirement. 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, on June 27, 2013, the Femur Fracture MDL court granted Merck's motion for judgment as a matter of law in the *Glynn* case and held that the plaintiff's failure to warn claim was preempted by federal law.

In August 2013, the Femur Fracture MDL court entered an order requiring plaintiffs in the Femur Fracture MDL to show cause why those cases asserting claims for a femur fracture injury that took place prior to September 14, 2010, should not be dismissed based on the court's preemption decision in the *Glynn* case. Pursuant to the show cause order, on March 26, 2014, the Femur Fracture MDL court dismissed with prejudice approximately 650 cases on preemption grounds. Plaintiffs in approximately 500 of those cases are appealing that decision to the U.S. Court of Appeals for the Third Circuit. In June 2015, the Femur Fracture MDL court dismissed without prejudice another approximately 520 cases pending plaintiffs' appeal of the preemption ruling to the Third Circuit.

On June 17, 2014, Judge Pisano 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* have appealed Judge Pisano's decision to the Third Circuit. In August 2014, Merck filed a motion requesting that Judge Pisano 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.

As of December 31, 2015, approximately 30 cases were pending in the Femur Fracture MDL, excluding the 500 cases dismissed with prejudice on preemption grounds that are pending appeal and the 520 cases dismissed without prejudice that are also pending the aforementioned appeal.

As of December 31, 2015, approximately 3,100 cases alleging Femur Fractures have been filed in New Jersey state court and are pending before Judge Jessica Mayer in Middlesex County. The parties selected an initial group of 30 cases to be reviewed through fact discovery. Two additional groups of 50 cases each to be reviewed through fact discovery were selected in November 2013 and March 2014, respectively. A further group of 25 cases to be reviewed through fact discovery was selected by Merck in July 2015.

As of December 31, 2015, approximately 305 cases alleging Femur Fractures have been filed and are pending in California state court. A petition was filed seeking to coordinate all Femur Fracture cases filed in California state court before a single judge in Orange County, California. The petition was granted and Judge Thierry Colaw is currently presiding over the coordinated proceedings. 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 on February 17, 2015 and the jury returned a verdict in Merck's favor on April 3, 2015, and plaintiff has appealed that verdict to the California appellate court. The next Femur Fracture trial in California is scheduled to be held on April 11, 2016, and is currently set to include several plaintiffs.

Additionally, there are six 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, 2015, approximately 785 product user claims have been served on Merck 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). There are 13 cases pending against Merck in state courts other than the California State Court.

On November 9, 2015, the MDL granted summary judgment on the grounds of preemption as to all claims alleging injury due to pancreatic cancer. Based on that ruling, on November 30, 2015, the MDL entered final judgment resulting in the dismissal of the pancreatic cancer claims against Merck relating to approximately 665 product users.

On November 16, 2015, the California State Court likewise granted summary judgment on preemption grounds as to claims alleging injury due to pancreatic cancer, which will result in the dismissal of the pancreatic cancer claims against Merck relating to approximately 350 product users.

Plaintiffs are appealing the MDL preemption ruling, and are expected to do likewise with respect to the California State Court ruling once that court enters final judgment.

In addition to the claims noted above, the Company has agreed, as of December 31, 2015, to toll the statute of limitations for approximately 20 additional claims. The Company intends to continue defending against these lawsuits.

NuvaRing

As previously disclosed, beginning in May 2007, a number of product liability complaints were filed in various jurisdictions asserting claims against the Company and its subsidiaries relating to *NuvaRing*, a combined hormonal contraceptive vaginal ring. The plaintiffs contended the Company, among other things, failed to adequately design and manufacture *NuvaRing* and failed to adequately warn of the alleged increased risk of venous thromboembolism (VTE) posed by *NuvaRing*, and/or downplayed the risk of VTE. The plaintiffs sought damages for injuries allegedly sustained from their product use, including some alleged deaths, heart attacks and strokes. The majority of the cases were pending in a federal multidistrict litigation venued in Missouri.

Pursuant to a settlement agreement between Merck and negotiating plaintiffs' counsel, which became effective as of June 4, 2014, Merck paid a lump total settlement of $100 million to resolve more than 95% of the cases filed and under retainer by counsel as of February 7, 2014. Plaintiffs in approximately 3,700 cases joined the settlement program. Each filed case is to be dismissed with prejudice once the settlement administration process is completed. Those dismissals began in the second quarter and continued on a rolling basis throughout 2015. The Company has certain insurance coverage available to it, which is currently being used to partially fund the Company's legal fees. This insurance coverage was also used to fund the settlement.

As of December 31, 2015, there were 16 cases pending outside of the settlement program, inclusive of cases filed after the settlement program closed. Of these cases, 15 are pending in the multidistrict litigation and are subject to individual case management orders requiring plaintiffs to meet various discovery and evidentiary requirements. As of December 31, 2015, these 15 plaintiffs were meeting those requirements and continuing to prosecute their cases.

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, 2015, approximately 1,400 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 60 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 John Gleeson of the Eastern District of New York. The matters pending in state court in New Jersey have been consolidated before Judge Jessica Mayer in Middlesex County. In addition, there is one matter pending in state court in Massachusetts and one matter pending in state court in New York. The Company intends to defend against these lawsuits.

Governmental Proceedings

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 (the DOJ) which 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 government.

As previously disclosed, the Company has received a civil investigative demand from the U.S. Attorney's Office, Eastern District of Pennsylvania which requests information relating to the Company's contracting and pricing of *Dulera* Inhalation Aerosol with certain pharmacy benefit managers and Medicare Part D plans. The Company is cooperating with the investigation.

As previously disclosed, the Company has received letters from the DOJ and the SEC that seek information about activities in a number of countries and reference the Foreign Corrupt Practices Act. The Company has cooperated with the agencies in their requests and believes that this inquiry is part of a broader review of pharmaceutical industry practices in foreign countries. As previously disclosed, the Company has been advised by the DOJ that, based on the information that it has received, it has closed its inquiry into this matter as it relates to the Company. In the future, the Company may receive additional requests for information from either or both of the DOJ and the SEC.

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.

Commercial and Other Litigation

K-DUR Antitrust Litigation

As previously disclosed, in June 1997 and January 1998, Schering-Plough settled patent litigation with Upsher-Smith, Inc. (Upsher-Smith) and ESI Lederle, Inc. (Lederle), respectively, relating to generic versions of K‑DUR, Schering-Plough's long-acting potassium chloride product supplement used by cardiac patients, for which Lederle and Upsher-Smith had filed Abbreviated New Drug Applications (ANDAs). Following the commencement of an administrative proceeding by the U.S. Federal Trade Commission (the FTC) in 2001 alleging anti-competitive effects from those settlements (which has been resolved in Schering-Plough's favor), putative class and non-class action suits were 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. These suits claimed violations of federal and state antitrust laws, as well as other state statutory and common law causes of action, and sought unspecified damages. In April 2008, the indirect purchasers voluntarily dismissed their case. In March 2010, the District Court granted summary judgment to the defendants on the remaining lawsuits and dismissed the matter in its entirety. In July 2012, the Third Circuit Court of Appeals reversed the District Court's grant of summary judgment and remanded the case for further proceedings. At the same time, the Third Circuit upheld a December 2008 decision by the District Court certifying certain direct purchaser plaintiffs' claims as a class action.

In August 2012, the Company filed a petition for certiorari with the U.S. Supreme Court seeking review of the Third Circuit's decision. In June 2013, the Supreme Court granted that petition, vacated the judgment of the Third Circuit, and remanded the case for further consideration in light of its decision in *FTC v. Actavis, Inc.* That decision held that whether a so-called "reverse payment" — i.e., a payment from the holder of a pharmaceutical patent to a party challenging the patent made in connection with a settlement of their dispute — violates the antitrust laws should be

determined on the basis of a "rule of reason" analysis. In September 2013, the Third Circuit returned the case to the District Court for further proceedings in accordance with the *Actavis* standard. In April 2015, the Company filed motions for summary judgment. On February 25, 2016, the District 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. No trial date has yet been set.

Sales Force Litigation

As previously disclosed, in May 2013, Ms. Kelli Smith filed a complaint against the Company in the United States District Court for the District of New Jersey on behalf of herself and a putative class of female sales representatives and a putative sub-class of female sales representatives with children, claiming (a) discriminatory policies and practices in selection, promotion and advancement, (b) disparate pay, (c) differential treatment, (d) hostile work environment and (e) retaliation under federal and state discrimination laws. In November 2013, the Company filed a motion to dismiss the class claims. Plaintiffs sought and were granted leave to file an amended complaint. In January 2014, plaintiffs filed an amended complaint adding four additional named plaintiffs. On October 8, 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, which are currently pending before the court.

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, 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. On September 4, 2014, the court denied Merck's motion to dismiss the False Claims Act suit and granted in part and denied in part its motion to dismiss the then-pending antitrust suit. As a result, both the False Claims Act suit and the antitrust suits have proceeded into discovery. 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 United Kingdom (UK) and Germany 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. To date, KGaA has not taken steps to appeal the decision. 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. This decision reflects one step in a litigation process taking place in a number of countries and will be appealed.

Patent Litigation

From time to time, generic manufacturers of pharmaceutical products file ANDAs with the U.S. Food and Drug Administration (FDA) seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned by the Company. To protect its patent rights, the Company may file patent infringement lawsuits against such generic companies. Certain products of the Company (or products marketed via agreements with other companies) currently involved in such patent infringement litigation in the United States include: *Cancidas*, *Cubicin,*

Emend for Injection, *Invanz*, *Nasonex*, *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 generic 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.

Cancidas — In February 2014, a patent infringement lawsuit was filed in the United States against Xellia Pharmaceuticals ApS (Xellia) with respect to Xellia's application to the FDA seeking pre-patent expiry approval to market a generic version of *Cancidas*. In June 2015, the district court found that Xellia infringed the Company's patent and ordered that Xellia's application not be approved until the patent expires in September 2017 (including pediatric exclusivity). Xellia has appealed this decision, and the appeal will be heard in March 2016. In August 2014, a patent infringement lawsuit was filed in the United States against Fresenius Kabi USA, LLC (Fresenius) in respect of Fresenius's application to the FDA seeking pre-patent expiry approval to market a generic version of *Cancidas*. The lawsuit automatically stays FDA approval of Fresenius's application until December 2016 or until an adverse court decision, if any, whichever may occur earlier.

Cubicin — In March 2012, a patent infringement lawsuit was filed in the United States against Hospira, Inc. (Hospira), with respect to Hospira's application to the FDA seeking pre-patent expiry approval to market a generic version of *Cubicin*. A trial was held in February 2014, and in December 2014 the district court found the composition patent, which expires in June 2016, to be valid and infringed. Later patents, expiring in September 2019 and November 2020, were found to be invalid. Hospira appealed the finding that the composition patent is not invalid and the Company cross-appealed the finding that the later patents are invalid. In November 2015, the U.S. Court of Appeals for the Federal Circuit affirmed the lower court decision. Hospira's application will not be approved until at least June 2016.

In October 2013, a patent infringement lawsuit was filed in the United States against Strides, Inc. and Agila Specialties Private Limited (Strides/Agila), with respect to Strides/Agila's application to the FDA seeking pre-patent expiry approval to market a generic version of *Cubicin.* As a result of the Hospira decision, Strides/Agila's application will not be approved until at least June 2016.

In July 2014, a patent infringement lawsuit was filed in the United States against Fresenius, with respect to Fresenius's application to the FDA seeking pre-patent expiry approval to market a generic version of *Cubicin.* As a result of the Hospira decision, Fresenius's application will not be approved until at least June 2016.

In December 2015, a patent infringement lawsuit was filed in the United States against Sagent Pharmaceuticals, Inc. (Sagent), with respect to Sagent's application to the FDA seeking pre-patent expiry approval to market a generic version of *Cubicin.* As a result of the Hospira decision, Sagent's application will not be approved until at least June 2016.

In December 2015, a patent infringement lawsuit was filed in the United States against Actavis LLC (Actavis), with respect to Actavis's application to the FDA seeking pre-patent expiry approval to market a generic version of *Cubicin.* As a result of the Hospira decision, Actavis's application will not be approved until at least June 2016.

In January 2016, a patent infringement lawsuit was filed in the United States against Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (Dr. Reddy), with respect to Dr. Reddy's application to the FDA seeking pre-patent expiry approval to market a generic version of *Cubicin.* As a result of the Hospira decision, Dr. Reddy's application will not be approved until at least June 2016.

An earlier district court action against Teva Parenteral Medicines Inc., Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, Teva) resulted in a settlement whereby Teva can launch a generic version of *Cubicin* at the latest in December 2017, or earlier under certain conditions, but in no event before June 2016.

In October 2014, Agila Specialties Inc. and Mylan Pharmaceuticals Inc. (Agila/Mylan) filed petitions for *Inter Partes* Review (IPR) at the United States Patent and Trademark Office (USPTO) seeking the invalidity of the September 2019 and November 2020 patents. In April 2015, Agila/Mylan withdrew its petitions for IPR in exchange for the Company agreeing to narrow the issues in the Strides/Agila lawsuit referenced above. In November 2014, Fresenius filed petitions for IPR at the USPTO seeking the invalidity of the September 2019 patents. In May 2015, the

USPTO granted Fresenius's petition for an IPR on the September 2019 patents. The IPR hearing was held in February 2016. In July 2015, Fresenius filed petitions for IPR seeking invalidity of the November 2020 patents. In January 2016, the USPTO granted Fresenius's petition for an IPR on the November 2020 patents.

Emend for Injection — In May 2012, a patent infringement lawsuit was filed in the United States against Sandoz Inc. (Sandoz) in respect of Sandoz's application to the FDA seeking pre-patent expiry approval to market a generic version of *Emend* for Injection. A trial in the lawsuit against Sandoz was held and, in August 2015, the court found that the Company's patent was infringed and not invalid. The court ordered that Sandoz's application not be approved until the expiration of the Company's patent in 2019. In December 2015, Sandoz dropped its appeal of the court's decision. In June 2012, a patent infringement lawsuit was filed in the United States against Accord Healthcare, Inc. US, Accord Healthcare, Inc. and Intas Pharmaceuticals Ltd (collectively, Intas) in respect of Intas's application to the FDA seeking pre-patent expiry approval to market a generic version of *Emend* for Injection. The Company agreed with Intas to stay the lawsuit until the outcome of the lawsuit with Sandoz. In October 2015, following the Sandoz decision, the court found that the Company's patent was infringed and not invalid. The court ordered that Intas's application not be approved until the expiration of the Company's patent in 2019. In July 2014, a patent infringement lawsuit was filed in the United States against Fresenius in respect of Fresenius's application to the FDA seeking pre-patent expiry approval to market a generic version of *Emend* for Injection. In January 2016, the parties settled this matter. Under the terms of the settlement, Fresenius will not be entitled to enter the market pre-patent expiry except under certain conditions. In December 2014, Apotex Inc. (Apotex) filed a petition for IPR at the USPTO seeking the invalidity of claims in the compound patent covering *Emend* for Injection. The USPTO rejected Apotex's petition in June 2015.

Invanz — In July 2014, a patent infringement lawsuit was filed in the United States against Hospira in respect of Hospira's application to the FDA seeking pre-patent expiry approval to market a generic version of *Invanz*. The lawsuit automatically stays FDA approval of Hospira's application until November 2016 or until an adverse court decision, if any, whichever may occur earlier. Since Hospira did not challenge an earlier patent covering *Invanz*, its application to the FDA will not be approved until at least that patent expires in May 2016. The trial in this matter is scheduled to begin in April 2016. In August 2015, a patent infringement lawsuit was filed in the United States against Savior Lifetec Corporation (Savior) in respect of Savior's application to the FDA seeking pre-patent expiry approval to market a generic version of *Invanz*. The lawsuit automatically stays FDA approval of Savior's application until November 2017 or until an adverse court decision, if any, whichever may occur earlier. Since Savior did not challenge an earlier patent covering *Invanz*, its application to the FDA will not be approved until at least that patent expires in May 2016.

Nasonex — In July 2014, a patent infringement lawsuit was filed in the United States against Teva Pharmaceuticals USA, Inc. (Teva Pharma) in respect of Teva Pharma's application to the FDA seeking pre-patent expiry approval to market a generic version of *Nasonex*. The lawsuit automatically stays FDA approval of Teva Pharma's application until November 2016 or until an adverse court decision, if any, whichever may occur earlier. The trial in this matter is scheduled to begin in May 2016. In March 2015, a patent infringement lawsuit was filed in the United States against Amneal Pharmaceuticals LLC (Amneal), in respect of Amneal's application to the FDA seeking pre-patent expiry approval to market a generic version of *Nasonex*. The lawsuit automatically stays FDA approval of Amneal's application until August 2017 or until an adverse court decision, if any, whichever may occur earlier. The trial in this matter is scheduled to begin in June 2016.

A previous decision, issued in June 2013, held that the Merck patent in the Teva Pharma and Amneal lawsuits covering mometasone furoate monohydrate was valid, but that it was not infringed by Apotex Corp.'s proposed product. In April 2015, a patent infringement lawsuit was filed against Apotex Inc. and Apotex Corp. (Apotex) in respect of Apotex's application to the FDA seeking pre-patent expiry approval to market a generic version of *Nasonex* that allegedly differs from the generic version in the previous lawsuit.

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*. The lawsuit automatically stays FDA approval of Actavis's application until December 2017 or until an adverse court decision, if any, whichever may occur earlier.

NuvaRing — In December 2013, the Company filed a lawsuit against a subsidiary of Allergan 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 and the Company is awaiting the court's decision. 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*.

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. The Company believes that the '878 patent is invalid and filed an opposition in the European Patent Office (EPO) seeking its revocation. In June 2014, the Opposition Division of the EPO found the claims in the '878 patent are valid. The Company received the Opposition Division's written opinion in September 2014 and the Company submitted its substantive appeal in February 2015. In April 2014, the Company, and three other companies, opposed another European patent (EP 2 161 336) ('336) owned by BMS and Ono that it believes is invalid. The '336 patent, if valid, broadly claims anti-PD-1 antibodies that could include *Keytruda*. BMS and Ono recently submitted a request to amend the claims of the '336 patent. If the EPO allows this amendment, the claims of the '336 patent would no longer broadly claim anti-PD-1 antibodies such as *Keytruda*.

In May 2014, the Company filed a lawsuit in the UK seeking revocation of the UK national versions of both the '878 and '336 patents. In July 2014, Ono and BMS sued the Company seeking a declaration that the '878 patent would be infringed in the UK by the marketing of *Keytruda*. The Company has sought a declaration from the UK court that *Keytruda* will not infringe the '336 patent in the UK. BMS and Ono notified the Company of their request to amend the claims of the EPO '336 patent and of their intention to seek permission from the court to similarly amend the UK national version so that the claims of the '336 patent would no longer broadly claim anti-PD-1 antibodies such as *Keytruda*. A trial was held in the UK in July 2015. At that trial, the issues of validity and infringement of the '878 patent were heard at the same time by the court. In October 2015, the court issued its judgment, finding the '878 patent valid and infringed. Merck appealed this judgment.

In February 2015, the Company filed lawsuits in the Netherlands seeking revocation of the Dutch national versions of both the '878 and '336 patents. BMS and Ono amended the claims of the '336 patent so that the claims of the '336 patent no longer broadly claim anti-PD-1 antibodies such as *Keytruda*. Trial regarding the validity and infringement of the '878 patent was held in January 2016 and the Company is anticipating a decision in April 2016.

In December 2015, BMS and Ono filed lawsuits against the Company in France, Ireland, Switzerland and Germany alleging infringement of the '878 patent. In January 2016, BMS and Ono filed a lawsuit against the Company in Spain alleging infringement of the '878 patent. In France, BMS and Ono have filed for preliminary relief seeking payment of damages in France while the case is pending. A hearing on this preliminary relief is set for February 2016. Dates for trials regarding the validity and infringement of the Irish, French, Swiss and Spanish national versions of the '878 patent have not yet been scheduled. A trial concerning the infringement of the German version of the '878 patent is currently scheduled to begin in March 2017.

The Company continues to believe the '878 patent is invalid.

The Company can file lawsuits seeking revocation of the '336 and '878 patents in other national courts in Europe at any time, and Ono and BMS can file patent infringement actions against the Company in other national courts in Europe at or around the time the Company launches *Keytruda*. If a national court determines that the Company infringed a valid claim in the '878 or '336 patent, Ono and BMS may be entitled to monetary damages, including royalties on future sales of *Keytruda*, and potentially could seek an injunction to prevent the Company from marketing *Keytruda* in that country.

The USPTO granted US Patent Nos. 8,728,474 to Ono and 8,779,105 to Ono and BMS. These patents are equivalent to the '878 and '336 patents, respectively. In September 2014, BMS and Ono filed a lawsuit in the United States alleging that, by marketing *Keytruda*, the Company will infringe US Patent No. 8,728,474. BMS and Ono are not seeking to prevent or stop the marketing of *Keytruda* in the United States. The trial in this matter is currently scheduled to begin in April 2017. The Company believes that the 8,728,474 patent and the 8,779,105 patent are both invalid. Recently, Ono filed lawsuits in the United States alleging that, by marketing *Keytruda*, the Company will

infringe US Patent Nos. 9,067,999 and 9,073,994, which are patents related to the 8,728,474 patent. The Company believes the 9,067,999 and 9,073,994 patents are also invalid.

In September 2014, the Company filed a lawsuit in Australia seeking the revocation of Australian Patent No. 2011203119, which is equivalent to the '336 patent. In March 2015, BMS and Ono counterclaimed in this matter alleging that the Company's manufacture and supply of *Keytruda* to the Australian market will infringe Australian Patent No. 2011203119.

Ono and BMS have similar and other patents and applications, which the Company is closely monitoring, pending in the United States, Japan and other countries.

The Company is confident that it will be able to market *Keytruda* in any country in which it is approved and that it will not be prevented from doing so by the Ono or BMS patents or any pending applications.

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, 2015 and December 31, 2014 of approximately $245 million and $215 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 (the 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 conducted an air compliance evaluation of the Company's pharmaceutical manufacturing facility in Elkton, Virginia. As a result of the investigation, the Company was recently issued a Notice of Noncompliance and Show Cause Notification relating to certain federally enforceable requirements applicable to the Elkton facility. The Company is attempting to resolve these alleged violations by way of settlement but will defend itself if settlement cannot be reached.

The Company and its subsidiaries are parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund, and other federal and state equivalents. These proceedings seek to require the operators of hazardous waste disposal facilities, transporters of waste to the sites and generators of hazardous waste disposed of at the sites to clean up the sites or to reimburse the government

for cleanup costs. The Company has been made a party to these proceedings as an alleged generator of waste disposed of at the sites. In each case, the government alleges that the defendants are jointly and severally liable for the cleanup costs. Although joint and several liability is alleged, these proceedings are frequently resolved so that the allocation of cleanup costs among the parties more nearly reflects the relative contributions of the parties to the site situation. The Company's potential liability varies greatly from site to site. For some sites the potential liability is *de minimis* and for others the final costs of cleanup have not yet been determined. While it is not feasible to predict the outcome of many of these proceedings brought by federal or state agencies or private litigants, in the opinion of the Company, such proceedings should not ultimately result in any liability which would have a material adverse effect on the financial position, results of operations, liquidity or capital resources of the Company. The Company has taken an active role in identifying and accruing for these costs and such amounts do not include any reduction for anticipated recoveries of cleanup costs from former site owners or operators or other recalcitrant potentially responsible parties.

In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $109 million and $125 million at December 31, 2015 and 2014, 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 $57 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.

11. Equity

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

Capital Stock

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

	2015		2014		2013	
	Common Stock	**Treasury Stock**	Common Stock	Treasury Stock	Common Stock	Treasury Stock
Balance January 1	**3,577**	**739**	3,577	650	3,577	550
Purchases of treasury stock	**—**	**75**	—	134	—	139
Issuances [(1)]	**—**	**(18)**	—	(45)	—	(39)
Balance December 31	**3,577**	**796**	3,577	739	3,577	650

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

Noncontrolling Interests

In connection with the 1998 restructuring of AMI, Merck assumed $2.4 billion par value preferred stock with a dividend rate of 5% per annum, which was carried by KBI and included in *Noncontrolling interests*. In 2014, AstraZeneca exercised its option to acquire Merck's interest in AZLP (see Note 8) and this preferred stock obligation was retired.

12. Share-Based Compensation Plans

The Company has share-based compensation plans under which the Company grants restricted stock units (RSUs) and performance share units (PSUs) to certain management level employees. The Company also issues RSUs to employees of certain of the Company's equity method investees. 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, 2015, 134 million shares collectively were authorized for future grants under the Company's share-based compensation plans. These awards are settled primarily with treasury shares.

Employee stock options are granted to purchase shares of Company stock at the fair market value at the time of grant. These awards generally vest one-third each year over a three-year period, with a contractual term of 7-10 years. RSUs are stock awards that are granted to employees and entitle the holder to shares of common stock as the awards vest. The fair value of the stock option and RSU awards is determined and fixed on the grant date based on the Company's stock price. PSUs are stock awards where the ultimate number of shares issued will be contingent on the Company's performance against a pre-set objective or set of objectives. The fair value of each PSU is determined on the date of grant based on the Company's stock price. For RSUs and certain PSUs granted before December 31, 2009 employees participate in dividends on the same basis as common shares and such dividends are nonforfeitable by the holder. For RSUs and PSUs issued on or after January 1, 2010, 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, generally three years, subject to the terms applicable to such awards.

Total pretax share-based compensation cost recorded in 2015, 2014 and 2013 was $299 million, $278 million and $276 million, respectively, with related income tax benefits of $93 million, $86 million and $84 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 2015, 2014 and 2013 was $59.73, $58.14 and $45.01 per option, respectively. The weighted average fair value of options granted in 2015, 2014 and 2013 was $6.46, $6.79 and $6.21 per option, respectively, and were determined using the following assumptions:

Years Ended December 31	**2015**	2014	2013
Expected dividend yield	**4.1%**	4.3%	4.2%
Risk-free interest rate	**1.7%**	2.0%	1.2%
Expected volatility	**19.9%**	22.0%	25.0%
Expected life (years)	**6.2**	6.4	7.0

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

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2015	76,135	$ 39.05		
Granted	**5,565**	**59.73**		
Exercised	**(13,779)**	**35.23**		
Forfeited	**(3,253)**	**39.10**		
Outstanding December 31, 2015	**64,668**	**$ 41.64**	**3.71**	**$ 785**
Exercisable December 31, 2015	**54,990**	**$ 39.12**	**2.87**	**$ 765**

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

Years Ended December 31	**2015**	2014	2013
Total intrinsic value of stock options exercised	**$ 332**	$ 626	$ 374
Fair value of stock options vested	**30**	35	42
Cash received from the exercise of stock options	**485**	1,560	1,210

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

	RSUs		PSUs	
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested January 1, 2015	15,634	$ 46.66	1,882	$ 52.81
Granted	**4,562**	**59.66**	**909**	**51.84**
Vested	**(5,774)**	**39.45**	**(743)**	**44.58**
Forfeited	**(1,022)**	**52.64**	**(164)**	**55.66**
Nonvested December 31, 2015	**13,400**	**$ 53.73**	**1,884**	**$ 55.33**

At December 31, 2015, there was $407 million of total pretax unrecognized compensation expense related to nonvested stock options, RSU and PSU awards which will be recognized over a weighted average period of 1.9 years. For segment reporting, share-based compensation costs are unallocated expenses.

13. Pension and Other Postretirement Benefit Plans

The Company has defined benefit pension plans covering eligible employees in the United States and in certain of its international subsidiaries. Beginning on January 1, 2013, active participants in Merck's primary U.S. defined benefit pension plans are accruing pension benefits using cash balance formulas based on age, service, pay and interest. However, during a transition period from January 1, 2013 through December 31, 2019, participants will earn the greater of the benefit as calculated under the employee's legacy final average pay formula or their cash balance formula. For all years of service after December 31, 2019, participants will earn future benefits under only the cash balance formula. 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 for pension and other postretirement benefit plans consisted of the following components:

	Pension Benefits								
	U.S.			International			Other Postretirement Benefits		
Years Ended December 31	**2015**	2014	2013	**2015**	2014	2013	**2015**	2014	2013
Service cost	**$ 307**	$ 300	$ 386	**$ 251**	$ 266	$ 296	**$ 80**	$ 78	$ 102
Interest cost	**434**	425	402	**206**	269	263	**110**	115	107
Expected return on plan assets	**(819)**	(782)	(721)	**(379)**	(416)	(376)	**(143)**	(139)	(126)
Net amortization	**158**	74	251	**104**	59	85	**(59)**	(71)	(50)
Termination benefits	**22**	53	51	**1**	11	7	**7**	22	50
Curtailments	**(12)**	(69)	(22)	**(9)**	(4)	(1)	**(19)**	(39)	(11)
Settlements	**1**	11	1	**12**	6	22	**—**	—	—
Net periodic benefit cost (credit)	**$ 91**	$ 12	$ 348	**$ 186**	$ 191	$ 296	**$ (24)**	$ (34)	$ 72

The changes in net periodic benefit cost for pension and other postretirement benefit plans year over year are largely attributable to changes in the discount rate affecting net amortization.

In connection with restructuring actions (see Note 3), termination charges were recorded in 2015, 2014 and 2013 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 in 2015, 2014 and 2013 on pension and other postretirement benefit plans.

In addition, settlements were recorded in 2015, 2014 and 2013 on certain U.S. and international pension plans.

Obligations and Funded Status

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

	Pension Benefits				Other Postretirement Benefits	
	U.S.		International			
	2015	2014	**2015**	2014	**2015**	2014
Fair value of plan assets January 1	**$ 9,984**	$ 10,007	**$ 7,724**	$ 7,428	**$ 1,984**	$ 1,913
Actual return on plan assets	**(226)**	484	**138**	1,099	**(34)**	114
Company contributions	**66**	92	**163**	276	**63**	67
Effects of exchange rate changes	**—**	—	**(568)**	(816)	**(1)**	—
Benefits paid	**(523)**	(535)	**(196)**	(245)	**(99)**	(110)
Settlements	**(35)**	(64)	**(66)**	(31)	**—**	—
Other	**—**	—	**9**	13	**—**	—
Fair value of plan assets December 31	**$ 9,266**	$ 9,984	**$ 7,204**	$ 7,724	**$ 1,913**	$ 1,984
Benefit obligation January 1	**$ 10,632**	$ 8,666	**$ 8,331**	$ 7,389	**$ 2,638**	$ 2,329
Service cost	**307**	300	**251**	266	**80**	78
Interest cost	**434**	425	**206**	269	**110**	115
Actuarial (gains) losses	**(1,102)**	1,857	**(127)**	1,605	**(384)**	212
Benefits paid	**(523)**	(535)	**(196)**	(245)	**(99)**	(110)
Effects of exchange rate changes	**—**	—	**(647)**	(864)	**(11)**	(6)
Plan amendments	**—**	—	**(1)**	(4)	**(531)**	—
Curtailments	**(14)**	(70)	**(15)**	(76)	**(3)**	3
Termination benefits	**22**	53	**1**	11	**7**	22
Settlements	**(35)**	(64)	**(66)**	(31)	**—**	—
Other	**2**	—	**(4)**	11	**3**	(5)
Benefit obligation December 31	**$ 9,723**	$ 10,632	**$ 7,733**	$ 8,331	**$ 1,810**	$ 2,638
Funded status December 31	**$ (457)**	$ (648)	**$ (529)**	$ (607)	**$ 103**	$ (654)
Recognized as:						
Other assets	**$ 179**	$ 68	**$ 567**	$ 565	**$ 359**	$ 1
Accrued and other current liabilities	**(48)**	(41)	**(7)**	(11)	**(10)**	(11)
Other noncurrent liabilities	**(588)**	(675)	**(1,089)**	(1,161)	**(246)**	(644)

At December 31, 2015 and 2014, the accumulated benefit obligation was $16.7 billion and $17.9 billion, respectively, for all pension plans, of which $9.4 billion and $10.1 billion, respectively, related to U.S. pension plans.

Actuarial gains in 2015 reflect a change in the discount rate. Actuarial losses in 2014 reflect a change in the discount rate and, for U.S. plans, also reflect an impact for the Company's adoption of new retirement plan mortality assumptions issued by the Society of Actuaries in October 2014.

The decline in the benefit obligation for other postretirement benefits in 2015 resulting from plan amendments primarily reflects changes to Merck's retiree medical benefits approved by the Company in December 2015. The changes provide that, beginning in 2017, Merck will provide access to retiree health insurance coverage that supplements government-sponsored Medicare through a private insurance marketplace. This new approach will allow Medicare-eligible retirees to choose insurance with the terms, cost and coverage that best fits their needs, while still receiving financial support as determined by Merck. The Company's subsidy for these retirees for medical coverage

in 2017 is expected to be comparable to 2016. Future changes in support, if any, will be based on a number of factors such as business conditions, government actions, marketplace changes and the general consumer inflation rate.

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

	U.S.		International	
	2015	2014	**2015**	2014
Pension plans with a projected benefit obligation in excess of plan assets				
Projected benefit obligation	**$ 1,310**	$ 3,963	**$ 5,093**	$ 5,513
Fair value of plan assets	**674**	3,247	**3,996**	4,341
Pension plans with an accumulated benefit obligation in excess of plan assets				
Accumulated benefit obligation	**$ 611**	$ 810	**$ 4,812**	$ 2,749
Fair value of plan assets	**—**	138	**3,964**	1,870

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, 2015 and 2014, $516 million and $580 million, respectively, or approximately 3% of the Company's pension investments at each year end, were categorized as Level 3 assets.

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

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

	Fair Value Measurements Using				Fair Value Measurements Using			
	Quoted Prices In Active Markets for Identical Assets (Level 1)	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**	**Total**	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
	2015				2014			
U.S. Pension Plans								
Assets								
Cash and cash equivalents	**$ —**	**$ 189**	**$ —**	**$ 189**	$ 2	$ 234	$ —	$ 236
Investment funds								
Developed markets equities	**566**	**3,704**	**—**	**4,270**	540	4,518	—	5,058
Emerging markets equities	**87**	**632**	**—**	**719**	107	718	—	825
Government and agency obligations	**—**	**181**	**—**	**181**	—	31	—	31
Fixed income obligations	**—**	**134**	**—**	**134**	—	132	—	132
Equity securities								
Developed markets	**2,444**	**—**	**—**	**2,444**	2,169	—	—	2,169
Fixed income securities								
Government and agency obligations	**—**	**391**	**—**	**391**	—	516	—	516
Corporate obligations	**—**	**679**	**—**	**679**	—	722	—	722
Mortgage and asset-backed securities	**—**	**236**	**—**	**236**	—	245	—	245
Other investments								
Derivatives	**—**	**—**	**—**	**—**	1	31	—	32
Other	**—**	**—**	**23**	**23**	—	—	28	28
Liabilities								
Derivatives	**—**	**—**	**—**	**—**	—	10	—	10
	$ 3,097	**$ 6,146**	**$ 23**	**$ 9,266**	$ 2,819	$ 7,137	$ 28	$ 9,984
International Pension Plans								
Assets								
Cash and cash equivalents	**$ 63**	**$ 9**	**$ —**	**$ 72**	$ 208	$ 13	$ —	$ 221
Investment funds								
Developed markets equities	**184**	**3,024**	**—**	**3,208**	217	2,991	—	3,208
Emerging markets equities	**21**	**228**	**—**	**249**	31	256	—	287
Government and agency obligations	**305**	**1,269**	**—**	**1,574**	317	1,410	—	1,727
Corporate obligations	**173**	**159**	**—**	**332**	183	170	—	353
Fixed income obligations	**8**	**10**	**—**	**18**	9	16	—	25
Real estate [1]	**—**	**3**	**10**	**13**	—	8	29	37
Equity securities								
Developed markets	**496**	**—**	**—**	**496**	509	—	—	509
Fixed income securities								
Government and agency obligations	**2**	**465**	**—**	**467**	28	448	—	476
Corporate obligations	**—**	**161**	**—**	**161**	2	190	1	193
Mortgage and asset-backed securities	**—**	**68**	**—**	**68**	—	90	—	90
Other investments								
Insurance contracts [2]	**—**	**60**	**481**	**541**	—	69	521	590
Other	**—**	**3**	**2**	**5**	3	4	1	8
	$ 1,252	**$ 5,459**	**$ 493**	**$ 7,204**	$ 1,507	$ 5,665	$ 552	$ 7,724

[1] *The plans' Level 3 investments in real estate funds are generally valued by market appraisals of the underlying investments in the funds.*

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

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

	2015				2014			
	Insurance Contracts	**Real Estate**	**Other**	**Total**	Insurance Contracts	Real Estate	Other	Total
U.S. Pension Plans								
Balance January 1	**$ —**	**$ —**	**$ 28**	**$ 28**	$ —	$ —	$ 31	$ 31
Actual return on plan assets:								
Relating to assets still held at December 31	**—**	**—**	**(3)**	**(3)**	—	—	1	1
Relating to assets sold during the year	**—**	**—**	**5**	**5**	—	—	4	4
Purchases	**—**	**—**	**1**	**1**	—	—	1	1
Sales	**—**	**—**	**(8)**	**(8)**	—	—	(9)	(9)
Balance December 31	**$ —**	**$ —**	**$ 23**	**$ 23**	$ —	$ —	$ 28	$ 28
International Pension Plans								
Balance January 1	**$ 521**	**$ 29**	**$ 2**	**$ 552**	$ 540	$ 49	$ 2	$ 591
Actual return on plan assets:								
Relating to assets still held at December 31	**(23)**	**(3)**	**—**	**(26)**	(35)	(4)	—	(39)
Relating to assets sold during the year	**—**	**—**	**—**	**—**	—	—	—	—
Purchases	**20**	**—**	**—**	**20**	22	—	—	22
Sales	**(31)**	**(16)**	**—**	**(47)**	(3)	(10)	—	(13)
Transfers out of Level 3	**(6)**	**—**	**—**	**(6)**	(3)	(6)	—	(9)
Balance December 31	**$ 481**	**$ 10**	**$ 2**	**$ 493**	$ 521	$ 29	$ 2	$ 552

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

	Fair Value Measurements Using				Fair Value Measurements Using			
	Quoted Prices In Active Markets for Identical Assets (Level 1)	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**	**Total**	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
	2015				2014			
Assets								
Cash and cash equivalents	**$ 65**	**$ 17**	**$ —**	**$ 82**	$ 60	$ 20	$ —	$ 80
Investment funds								
Developed markets equities	**53**	**540**	**—**	**593**	51	613	—	664
Emerging markets equities	**29**	**82**	**—**	**111**	36	93	—	129
Government and agency obligations	**2**	**16**	**—**	**18**	3	2	—	5
Fixed income obligations	**—**	**12**	**—**	**12**	—	12	—	12
Equity securities								
Developed markets	**229**	**—**	**—**	**229**	204	—	—	204
Fixed income securities								
Government and agency obligations	**—**	**339**	**—**	**339**	—	333	—	333
Corporate obligations	**—**	**311**	**—**	**311**	—	336	—	336
Mortgage and asset-backed securities	**—**	**218**	**—**	**218**	—	219	—	219
Other investments								
Derivatives	**—**	**—**	**—**	**—**	—	2	—	2
	$ 378	**$ 1,535**	**$ —**	**$ 1,913**	$ 354	$ 1,630	$ —	$ 1,984

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 40% to 60% in U.S. equities, 20% to 40% in international equities, 15% to 25% 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 2016 are approximately $50 million for U.S. pension plans, approximately $150 million for international pension plans and approximately $60 million for other postretirement benefit plans.

Expected Benefit Payments

Expected benefit payments are as follows:

	U.S. Pension Benefits	International Pension Benefits	Other Postretirement Benefits
2016	$ 528	$ 206	$ 101
2017	532	188	100
2018	555	198	104
2019	596	201	108
2020	610	211	111
2021 — 2025	3,414	1,179	624

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 pension and other postretirement benefit cost over the average remaining service life of employees. The following amounts were reflected as components of *OCI*:

	Pension Plans						Other Postretirement Benefit Plans		
	U.S.			International					
Years Ended December 31	**2015**	2014	2013	**2015**	2014	2013	**2015**	2014	2013
Net gain (loss) arising during the period	**$ 73**	$ (2,085)	$ 2,676	**$ (66)**	$ (779)	$ 513	**$ 209**	$ (223)	$ 499
Prior service (cost) credit arising during the period	**(13)**	(59)	(23)	**(4)**	(8)	226	**511**	(42)	26
	$ 60	$ (2,144)	$ 2,653	**$ (70)**	$ (787)	$ 739	**$ 720**	$ (265)	$ 525
Net loss amortization included in benefit cost	**$ 214**	$ 135	$ 318	**$ 118**	$ 74	$ 89	**$ 5**	$ 1	$ 23
Prior service (credit) cost amortization included in benefit cost	**(56)**	(61)	(67)	**(14)**	(15)	(4)	**(64)**	(72)	(73)
	$ 158	$ 74	$ 251	**$ 104**	$ 59	$ 85	**$ (59)**	$ (71)	$ (50)

The estimated net loss (gain) and prior service cost (credit) amounts that will be amortized from *AOCI* into net pension and postretirement benefit cost during 2016 are $202 million and $(67) million, respectively, for pension

plans (of which $115 million and $(55) million, respectively, relates to U.S. pension plans). The estimated prior service cost (credit) amounts that will be amortized from *AOCI* into net pension and postretirement benefit cost during 2016 for other postretirement benefit plans is $(106) million.

Actuarial Assumptions

The Company reassesses its benefit plan assumptions on a regular basis. The weighted average assumptions used in determining U.S. pension and other postretirement benefit plan and international pension plan information are as follows:

	U.S. Pension and Other Postretirement Benefit Plans			International Pension Plans		
December 31	**2015**	2014	2013	**2015**	2014	2013
Net periodic benefit cost						
Discount rate	**4.20%**	4.90%	4.10%	**2.70%**	3.80%	3.60%
Expected rate of return on plan assets	**8.50%**	8.50%	8.50%	**5.70%**	6.00%	5.80%
Salary growth rate	**4.40%**	4.50%	4.50%	**2.90%**	3.10%	3.30%
Benefit obligation						
Discount rate	**4.80%**	4.20%	5.10%	**2.80%**	2.70%	3.80%
Salary growth rate	**4.30%**	4.40%	4.50%	**2.90%**	2.90%	3.10%

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. In developing the expected rate of return within each plan, long-term historical returns data are considered as well as actual returns on the plan assets and other capital markets experience. 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 2016, the Company's expected rate of return will range from 7.30% to 8.75%, the same range as in 2015 for its U.S. pension and other postretirement benefit plans.

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

December 31	**2015**	2014
Health care cost trend rate assumed for next year	**6.8%**	6.9%
Rate to which the cost trend rate is assumed to decline	**4.5%**	4.6%
Year that the trend rate reaches the ultimate trend rate	**2027**	2027

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

	One Percentage Point	
	Increase	Decrease
Effect on total service and interest cost components	**$ 34**	**$ (27)**
Effect on benefit obligation	**75**	**(64)**

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 2015, 2014 and 2013 were $125 million, $124 million and $138 million, respectively.

14. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

Years Ended December 31	**2015**	2014	2013
Interest income	**$ (289)**	$ (266)	$ (264)
Interest expense	**672**	732	801
Exchange losses	**1,277**	180	290
Equity income from affiliates	**(205)**	(257)	(404)
Other, net	**72**	(12,002)	(12)
	$ 1,527	$ (11,613)	$ 411

The increase in exchange losses in 2015 was driven by Venezuela. During the second quarter of 2015, upon evaluation of evolving economic conditions in Venezuela and volatility in the country, the Company determined it was unlikely that all outstanding net monetary assets would be settled at the official rate of 6.30 VEF (Bolívar Fuertes) per U.S. dollar. Accordingly, during the second quarter of 2015, the Company recorded a charge of $715 million to devalue its net monetary assets in Venezuela to an amount that included the Company's estimate of the U.S. dollar amount that would ultimately be collected. During the third quarter of 2015, the Company recorded additional exchange losses of $138 million in the aggregate reflecting the ongoing effect of translating transactions and net monetary assets consistent with the second quarter. In the fourth quarter of 2015, as a result of the further deterioration of economic conditions in Venezuela, and continued declines in transactions which were settled at the official rate, the Company began using the SIMADI rate to report its Venezuelan operations. The Company also revalued its remaining net monetary assets at the SIMADI rate, which resulted in an additional charge in the fourth quarter of 2015 of $161 million. Exchange losses in 2013 reflect $140 million of losses due to a Venezuelan currency devaluation. In February 2013, the Venezuelan government devalued its currency from 4.30 VEF per U.S. dollar to 6.30 VEF per U.S. dollar. The Company recognized losses due to exchange of approximately $140 million in 2013 resulting from the remeasurement of the local monetary assets and liabilities at the new rate. 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 2015 and 2014 as compared with 2013 was driven primarily by the termination of the Company's relationship with AZLP on June 30, 2014 (see Note 8). In 2015, the lower equity income from AZLP was partially offset by higher equity income from certain research investment funds.

Other, net (as presented in the table above) in 2015 includes a $680 million net charge related to the settlement of *Vioxx* shareholder class action litigation (see Note 10) 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 4), a $147 million gain on the divestiture of Merck's remaining ophthalmics business in international markets (see Note 4), and the recognition of $182 million of deferred income related to AstraZeneca's option exercise (see Note 8). Other, net in 2014 includes an $11.2 billion gain on the divestiture of MCC (see Note 4), a gain of $741 million related to AstraZeneca's option exercise (see Note 8), a $480 million gain on the divestiture of certain ophthalmic products in several international markets (see Note 4), a gain of $204 million related to the divestiture of Sirna (see Note 4) and the recognition of $140 million of deferred income related to AstraZeneca's option exercise, partially offset by a $628 million loss on extinguishment of debt (see Note 9) and a $93 million goodwill impairment charge related to the Company's joint venture with Supera (see Note 7).

Interest paid was $653 million in 2015, $852 million in 2014 and $922 million in 2013.

15. Taxes on Income

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

	2015		2014		2013	
	Amount	**Tax Rate**	Amount	Tax Rate	Amount	Tax Rate
U.S. statutory rate applied to income before taxes	**$ 1,890**	**35.0%**	$ 6,049	35.0%	$ 1,941	35.0%
Differential arising from:						
Foreign earnings	**(2,105)**	**(39.0)**	(1,367)	(7.9)	(1,296)	(23.4)
Tax settlements	**(417)**	**(7.7)**	(89)	(0.5)	(497)	(9.0)
AstraZeneca option exercise	**—**	**—**	(774)	(4.5)	—	—
Sale of Sirna Therapeutics, Inc.	**—**	**—**	(357)	(2.1)	—	—
The American Taxpayer Relief Act of 2012	**—**	**—**	—	—	(269)	(4.8)
Impact of purchase accounting adjustments, including amortization	**797**	**14.8**	1,013	5.9	990	17.8
Foreign currency devaluation related to Venezuela	**321**	**5.9**	—	—	27	0.5
Unremitted foreign earnings	**260**	**4.8**	(209)	(1.2)	(81)	(1.5)
Restructuring	**167**	**3.1**	289	1.7	224	4.0
State taxes	**159**	**2.9**	7	—	44	0.8
U.S. health care reform legislation	**66**	**1.2**	134	0.8	65	1.2
Divestiture of Merck Consumer Care	**—**	**—**	440	2.5	—	—
Other [(1)]	**(196)**	**(3.6)**	213	1.2	(120)	(2.1)
	$ 942	**17.4%**	$ 5,349	30.9%	$ 1,028	18.5%

[(1)] *Other includes the tax effect of contingency reserves, research credits, tax rate changes and miscellaneous items.*

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, where the earnings have been indefinitely reinvested, thereby yielding a favorable impact on the effective tax rate as compared with the 35.0% 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 35.0% 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. The Company's 2014 effective tax rate reflects the impact of the Tax Increase Prevention Act, which was signed into law on December 19, 2014, extending the research credit and the controlled foreign corporation look-through provisions for one year only. The American Taxpayer Relief Act of 2012 was signed into law on January 2, 2013, extending the research credit and the controlled foreign corporation look-through provisions for two years retroactively from January 1, 2012 through December 31, 2013. The Company recorded the entire 2012 benefit of $269 million in 2013, the financial statement period that included the date of enactment.

Income before taxes consisted of:

Years Ended December 31	**2015**	2014	2013
Domestic	**$ 2,247**	$ 15,730	$ 3,513
Foreign	**3,154**	1,553	2,032
	$ 5,401	$ 17,283	$ 5,545

Taxes on income consisted of:

Years Ended December 31	**2015**	2014	2013
Current provision			
Federal	**$ 732**	$ 7,136	$ 568
Foreign	**844**	438	923
State	**130**	375	(133)
	1,706	7,949	1,358
Deferred provision			
Federal	**(552)**	(2,162)	30
Foreign	**(163)**	(201)	(398)
State	**(49)**	(237)	38
	(764)	(2,600)	(330)
	$ 942	$ 5,349	$ 1,028

Deferred income taxes at December 31 consisted of:

	2015		2014	
	Assets	**Liabilities**	Assets	Liabilities
Intangibles	**$ —**	**$ 4,962**	$ —	$ 3,358
Inventory related	**49**	**752**	56	699
Accelerated depreciation	**43**	**910**	58	892
Unremitted foreign earnings	**—**	**2,124**	—	2,016
Pensions and other postretirement benefits	**435**	**131**	778	156
Compensation related	**535**	**—**	578	—
Unrecognized tax benefits	**412**	**—**	401	—
Net operating losses and other tax credit carryforwards	**565**	**—**	379	—
Other	**1,217**	**—**	1,535	65
Subtotal	**3,256**	**8,879**	3,785	7,186
Valuation allowance	**(304)**		(265)	
Total deferred taxes	**$ 2,952**	**$ 8,879**	$ 3,520	$ 7,186
Net deferred income taxes		**$ 5,927**		$ 3,666
Recognized as:				
Other assets	**$ 608**		$ 801	
Deferred income taxes		**$ 6,535**		$ 4,467

As discussed in Note 2, the Company elected to retrospectively early adopt new accounting guidance that requires that all deferred tax assets and liabilities, along with any related valuation allowance, be classified as noncurrent on the balance sheet. The adoption of this standard had the following impact on the 2014 Consolidated Balance Sheet amounts as previously reported: *Other current assets* reduced by $568 million, *Other assets* increased by $400 million, *Accrued and other current liabilities* reduced by $369 million, *Deferred income taxes* increased by $201 million. Total assets and total liabilities as previously reported at December 31, 2014 were each reduced by $168 million.

The Company has net operating loss (NOL) carryforwards in several jurisdictions. As of December 31, 2015, $257 million of deferred taxes on NOL carryforwards relate to foreign jurisdictions, none of which are individually significant. Valuation allowances of $304 million have been established on these foreign NOL carryforwards and other foreign deferred tax assets. In addition, the Company has $308 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 2015, 2014 and 2013 were $1.8 billion, $7.9 billion and $2.3 billion, respectively. Income taxes paid in 2014 reflects approximately $5.0 billion of taxes paid on the divestiture of MCC. Tax benefits relating to stock option exercises were $109 million in 2015, $202 million in 2014 and $70 million in 2013.

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

	2015	2014	2013
Balance January 1	**$ 3,534**	$ 3,503	$ 4,425
Additions related to current year positions	**198**	389	320
Additions related to prior year positions	**53**	23	177
Reductions for tax positions of prior years [(1)]	**(59)**	(156)	(747)
Settlements [(1)]	**(184)**	(161)	(603)
Lapse of statute of limitations	**(94)**	(64)	(69)
Balance December 31	**$ 3,448**	$ 3,534	$ 3,503

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

If the Company were to recognize the unrecognized tax benefits of $3.4 billion at December 31, 2015, the income tax provision would reflect a favorable net impact of $3.2 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, 2015 could decrease by up to $1.2 billion 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. However, there is one item that is currently under discussion with the Internal Revenue Service (IRS) relating to the 2006 through 2008 examination. The Company has concluded that its position should be sustained upon audit. However, if this item were to result in an unfavorable outcome or settlement, it could have a material adverse impact on the Company's financial position, liquidity and results of operations.

Interest and penalties associated with uncertain tax positions amounted to an expense of $102 million in 2015 and $9 million in 2014 and a benefit of $319 million in 2013. These amounts reflect the beneficial impacts of various tax settlements, including those discussed below. Liabilities for accrued interest and penalties were $766 million and $659 million as of December 31, 2015 and 2014, respectively.

The IRS is currently conducting examinations of the Company's tax returns for the years 2006 through 2008, as well as 2010 and 2011. 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.

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 2015.

In 2013, IRS finalized its examination of Schering-Plough's 2007-2009 tax years. The Company's unrecognized tax benefits for the years under examination exceeded the adjustments related to this examination period and therefore the Company recorded a net $165 million tax provision benefit in 2013.

In 2013, the Company recorded an out-of-period net tax benefit of $160 million related to an open issue originally raised during the 2003-2006 IRS examination. That issue was settled in the fourth quarter of 2012, with final resolution relating to interest owed being reached in the first quarter of 2013. The Company's unrecognized tax benefits related to this issue exceeded the settlement amount. Management concluded that the exclusion of this benefit was not material to prior year financial statements.

At December 31, 2015, foreign earnings of $59.2 billion have been retained indefinitely by subsidiary companies for reinvestment; therefore, no provision has been made for income taxes that would be payable upon the distribution of such earnings and it would not be practicable to determine the amount of the related unrecognized deferred income tax liability. In addition, the Company has subsidiaries operating in Puerto Rico and Singapore under tax incentive grants that begin to expire in 2022.

16. Earnings per Share

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

Years Ended December 31	**2015**	2014	2013
Net income attributable to Merck & Co., Inc.	**$ 4,442**	$ 11,920	$ 4,404
Average common shares outstanding	**2,816**	2,894	2,963
Common shares issuable [1]	**25**	34	33
Average common shares outstanding assuming dilution	**2,841**	2,928	2,996
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	**$ 1.58**	$ 4.12	$ 1.49
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	**$ 1.56**	$ 4.07	$ 1.47

[1] *Issuable primarily under share-based compensation plans.*

In 2015, 2014 and 2013, 9 million, 4 million and 25 million, respectively, of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

17. Other Comprehensive Income (Loss)

Changes in *AOCI* by component are as follows:

	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance January 1, 2013, net of taxes	$ (97)	$ 73	$ (3,667)	$ (991)	$ (4,682)
Other comprehensive income (loss) before reclassification adjustments, pretax	335	33	3,917	(383)	3,902
Tax	(132)	(23)	(1,365)	(100)	(1,620)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	203	10	2,552	(483)	2,282
Reclassification adjustments, pretax	42 [1]	(39) [2]	286 [3]	—	289
Tax	(16)	10	(80)	—	(86)
Reclassification adjustments, net of taxes	26	(29)	206	—	203
Other comprehensive income (loss), net of taxes	229	(19)	2,758	(483)	2,485
Balance December 31, 2013, net of taxes	132	54	(909)	(1,474)	(2,197)
Other comprehensive income (loss) before reclassification adjustments, pretax	778	48	(3,196)	(412)	(2,782)
Tax	(285)	(17)	1,067	(92)	673
Other comprehensive income (loss) before reclassification adjustments, net of taxes	493	31	(2,129)	(504)	(2,109)
Reclassification adjustments, pretax	(146) [1]	43 [2]	62 [3]	—	(41)
Tax	51	(17)	(10)	—	24
Reclassification adjustments, net of taxes	(95)	26	52	—	(17)
Other comprehensive income (loss), net of taxes	398	57	(2,077)	(504)	(2,126)
Balance December 31, 2014, net of taxes	530	111	(2,986) [4]	(1,978)	(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)** [1]	**(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**	**(208)**	**175**
Balance December 31, 2015, net of taxes	**$ 404**	**$ 41**	**$ (2,407)** [4]	**$ (2,186)**	**$ (4,148)**

[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 13).*

[4] *Includes pension plan net loss of $3.3 billion and $3.5 billion at December 31, 2015 and 2014, respectively, and other postretirement benefit plan net loss of $86 million and $228 million at December 31, 2015 and in 2014, respectively, as well as pension plan prior service credit of $414 million and $473 million at December 31, 2015 and 2014, respectively, and other postretirement benefit plan prior service credit of $547 million and $257 million at December 31, 2015 and 2014.*

18. Segment Reporting

The Company's operations are principally managed on a products basis and are comprised of four operating segments – Pharmaceutical, Animal Health, Alliances and Healthcare Services. The Animal Health, Alliances and Healthcare Services segments are not material for separate reporting and are included in all other in the table below. The Pharmaceutical segment includes human health pharmaceutical and vaccine products marketed either directly by the Company or through joint ventures. 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 vaccines is sold to the U.S. Centers for Disease Control and Prevention Vaccines for Children program, which is funded by the U.S. government. Additionally, the Company sells vaccines to the Federal government for placement into vaccine stockpiles. The Company also has animal health operations that discover, develop, manufacture and market animal health products, including vaccines, which the Company sells to veterinarians, distributors and animal producers. Merck's Alliances segment primarily includes results from the Company's relationship with AstraZeneca LP until the termination of that relationship on June 30, 2014. 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. On October 1, 2014, the Company divested its Consumer Care segment (see Note 4) that developed, manufactured and marketed over-the-counter, foot care and sun care products.

The accounting policies for the segments described above are the same as those described in Note 2.

Sales of the Company's products were as follows:

Years Ended December 31	**2015**	2014	2013
Primary Care and Women's Health			
Cardiovascular			
Zetia	**$ 2,526**	$ 2,650	$ 2,658
Vytorin	**1,251**	1,516	1,643
Diabetes			
Januvia	**3,863**	3,931	4,004
Janumet	**2,151**	2,071	1,829
General Medicine and Women's Health			
NuvaRing	**732**	723	686
Implanon/Nexplanon	**588**	502	403
Dulera	**536**	460	324
Follistim AQ	**383**	412	481
Hospital and Specialty			
Hepatitis			
PegIntron	**182**	381	496
HIV			
Isentress	**1,511**	1,673	1,643
Hospital Acute Care			
Cubicin [(1)]	**1,127**	25	24
Cancidas	**573**	681	660
Invanz	**569**	529	488
Noxafil	**487**	402	309
Bridion	**353**	340	288
Primaxin	**313**	329	335
Immunology			
Remicade	**1,794**	2,372	2,271
Simponi	**690**	689	500
Oncology			
Keytruda	**566**	55	—
Emend	**535**	553	507
Temodar	**312**	350	708
Diversified Brands			
Respiratory			
Singulair	**931**	1,092	1,196
Nasonex	**858**	1,099	1,335
Clarinex	**187**	232	235
Other			
Cozaar/Hyzaar	**667**	806	1,006
Arcoxia	**471**	519	484
Fosamax	**359**	470	560
Zocor	**217**	258	301
Propecia	**183**	264	283
Vaccines [(2)]			
Gardasil/Gardasil 9	**1,908**	1,738	1,831
ProQuad/M-M-R II/Varivax	**1,505**	1,394	1,306
Zostavax	**749**	765	758
RotaTeq	**610**	659	636
Pneumovax 23	**542**	746	653
Other pharmaceutical [(3)]	**4,553**	5,356	6,596
Total Pharmaceutical segment sales	**34,782**	36,042	37,437
Other segment sales [(4)]	**3,659**	5,758	6,397
Total segment sales	**38,441**	41,800	43,834
Other [(5)]	**1,057**	437	199
	$ 39,498	$ 42,237	$ 44,033

[(1)] *Sales of* Cubicin *in 2015 represent sales subsequent to the Cubist acquisition date. Sales of* Cubicin *in 2014 and 2013 reflect sales in Japan pursuant to a previously existing licensing agreement.*

[(2)] *These amounts do not reflect sales of vaccines sold in most major European markets through the Company's joint venture, Sanofi Pasteur MSD, the results of which are reflected in equity income from affiliates which is included in* Other (income) expense, net. *These amounts do, however, reflect supply sales to Sanofi Pasteur MSD.*

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

[(4)] *Represents the non-reportable segments of Animal Health, Alliances and Healthcare Services, as well as Consumer Care until its divestiture on October 1, 2014 (see Note 4). The Alliances segment includes revenue from the Company's relationship with AZLP until termination on June 30, 2014 (see Note 8).*

[(5)] *Other revenues are primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, as well as third-party manufacturing sales. Other revenues in 2014 also include $232 million received by Merck in connection with the sale of the U.S. marketing rights to* Saphris *(see Note 4). Other revenues in 2013 reflect $50 million of revenue for the out-license of a pipeline compound.*

Consolidated revenues by geographic area where derived are as follows:

Years Ended December 31	**2015**	2014	2013
United States	**$ 17,519**	$ 17,071	$ 18,246
Europe, Middle East and Africa	**10,677**	13,174	13,140
Asia Pacific	**3,820**	3,951	3,845
Japan	**2,673**	3,471	4,044
Latin America	**2,823**	3,151	3,203
Other	**1,986**	1,419	1,555
	$ 39,498	$ 42,237	$ 44,033

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

Years Ended December 31	**2015**	2014	2013
Segment profits:			
Pharmaceutical segment	**$ 21,658**	$ 22,164	$ 22,983
Other segments	**1,659**	2,458	3,049
Total segment profits	**23,317**	24,622	26,032
Other profits	**810**	627	63
Unallocated:			
Interest income	**289**	266	264
Interest expense	**(672)**	(732)	(801)
Equity income from affiliates	**135**	59	(159)
Depreciation and amortization	**(1,573)**	(2,452)	(2,250)
Research and development	**(5,871)**	(5,823)	(6,381)
Amortization of purchase accounting adjustments	**(4,856)**	(4,182)	(4,690)
Restructuring costs	**(619)**	(1,013)	(1,709)
Gain on sale of certain migraine clinical development programs	**250**	—	—
Gain on the divestiture of certain ophthalmic products	**147**	480	—
Foreign currency devaluation related to Venezuela	**(876)**	—	(140)
Net charge related to the settlement of *Vioxx* shareholder class action litigation	**(680)**	—	—
Gain on divestiture of Merck Consumer Care	**—**	11,209	—
Gain on AstraZeneca option exercise	**—**	741	—
Loss on extinguishment of debt	**—**	(628)	—
Other unallocated, net	**(4,400)**	(5,891)	(4,684)
	$ 5,401	$ 17,283	$ 5,545

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 product intangible asset impairment charges, gains or losses on sales of businesses 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, 2015			
Included in segment profits:			
Equity income from affiliates	**$ 70**	**$ —**	**$ 70**
Depreciation and amortization	**(82)**	**(18)**	**(100)**
Year Ended December 31, 2014			
Included in segment profits:			
Equity income from affiliates	$ 90	$ 108	$ 198
Depreciation and amortization	(39)	(18)	(57)
Year Ended December 31, 2013			
Included in segment profits:			
Equity income from affiliates	$ 88	$ 475	$ 563
Depreciation and amortization	(27)	(22)	(49)

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

December 31	**2015**	2014	2013
United States	**$ 8,467**	$ 8,727	$ 10,076
Europe, Middle East and Africa	**2,844**	3,120	3,346
Asia Pacific	**842**	897	1,001
Latin America	**182**	207	242
Japan	**164**	172	211
Other	**8**	13	97
	$ 12,507	$ 13,136	$ 14,973

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.:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of income, comprehensive income, equity and cash flows present fairly, in all material respects, the financial position of Merck & Co., Inc. and its subsidiaries at December 31, 2015 and December 31, 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015 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, 2015, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these 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 under Item 9a. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note 15 to the consolidated financial statements, the Company changed the manner in which it classifies deferred taxes in 2015 and 2014 due to the adoption of Accounting Standards Update 2015-17, *Balance Sheet Classification of Deferred Taxes*.

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

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

PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 26, 2016

(b) Supplementary Data

Selected quarterly financial data for 2015 and 2014 are contained in the Condensed Interim Financial Data table below.

Condensed Interim Financial Data (Unaudited)

($ in millions except per share amounts)	4th Q [1]	3rd Q [2]	2nd Q [3]	1st Q [4]
2015 [5]				
Sales	**$ 10,215**	**$ 10,073**	**$ 9,785**	**$ 9,425**
Materials and production	**3,850**	**3,761**	**3,754**	**3,569**
Marketing and administrative	**2,615**	**2,472**	**2,624**	**2,601**
Research and development	**1,797**	**1,500**	**1,670**	**1,737**
Restructuring costs	**233**	**113**	**191**	**82**
Other (income) expense, net	**905**	**(170)**	**739**	**55**
Income before taxes	**815**	**2,397**	**807**	**1,381**
Net income attributable to Merck & Co., Inc.	**976**	**1,826**	**687**	**953**
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	**$ 0.35**	**$ 0.65**	**$ 0.24**	**$ 0.34**
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	**$ 0.35**	**$ 0.64**	**$ 0.24**	**$ 0.33**
2014 [5]				
Sales	$ 10,482	$ 10,557	$ 10,934	$ 10,264
Materials and production	3,749	4,223	4,893	3,903
Marketing and administrative	2,924	2,975	2,973	2,734
Research and development	2,283	1,659	1,664	1,574
Restructuring costs	349	376	163	125
Other (income) expense, net	(10,634)	(166)	(650)	(163)
Income before taxes	11,811	1,490	1,891	2,091
Net income attributable to Merck & Co., Inc.	7,316	895	2,004	1,705
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	$ 2.57	$ 0.31	$ 0.69	$ 0.58
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	$ 2.54	$ 0.31	$ 0.68	$ 0.57

[1] *Amounts for 2015 reflect a net charge related to the settlement of* Vioxx *shareholder class action litigation (see Note 10), foreign exchange losses related to Venezuela (see Note 14) and a gain on the sale of the Company's remaining ophthalmics business in international markets (see Note 4). Amounts for 2014 reflect the divestiture of Merck's Consumer Care business on October 1, 2014 (see Note 4), including an $11.2 billion gain on the sale. Amounts for 2014 also include a loss on extinguishment of debt (see Note 9).*

[2] *Amounts for 2015 include a gain on the sale of certain migraine clinical development programs (see Note 4). Amounts for 2014 include gains on sales of businesses (see Note 4) and an additional year of expense for the health care reform fee.*

[3] *Amounts for 2015 include foreign exchange losses related to the devaluation of the Company's net monetary assets in Venezuela (see Note 14). Amounts for 2014 include a gain on AstraZeneca's option exercise (see Note 8).*

[4] *Amounts for 2014 include a tax benefit relating to the sale of Sirna Therapeutics, Inc. (see Note 4).*

[5] *Amounts for 2015 and 2014 reflect acquisition and divestiture-related costs (see Note 7) and the impact of restructuring actions (see Note 3).*

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

Not applicable.

Item 9A. Controls and Procedures.

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, 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.

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, 2015. 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.

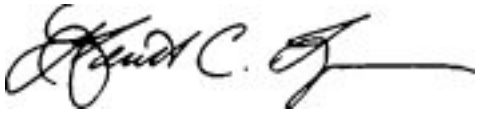
The financial statements and other financial information included in the Annual Report on Form 10-K fairly present, in all material respects, the Company's financial condition, results of operations and cash flows. Our formal certification to the Securities and Exchange Commission is included in this 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, 2015.

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, 2015, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.



Kenneth C. Frazier
Chairman, President and Chief Executive Officer

Robert M. Davis
Executive Vice President and Chief Financial Officer

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The required information on directors and nominees is incorporated by reference from the discussion under Proposal 1. Election of Directors of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2016. Information on executive officers is set forth in Part I of this document on pages 29 through 30.

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 24, 2016.

The Company has a Code of Conduct — *Our Values and Standards* applicable to all employees, including the principal executive officer, principal financial officer, principal accounting officer and Controller. The Code of Conduct is available on the Company's website at *www.merck.com/about/code_of_conduct.pdf*. The Company intends to disclose future amendments to certain provisions of the Code of Conduct, and waivers of the Code of Conduct granted to executive officers and directors, if any, on the website within four business days following the date of any amendment or waiver. Every Merck employee is responsible for adhering to business practices that are in accordance with the law and with ethical principles that reflect the highest standards of corporate and individual behavior. 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 24, 2016.

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 24, 2016.

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 24, 2016.

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 24, 2016.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information with respect to security ownership of certain beneficial owners and management is incorporated by reference from the discussion under the heading "Stock Ownership Information" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2016.

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, 2015. 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]	64,668,238[2]	$ 41.64	133,513,514
Equity compensation plans not approved by security holders	—	—	—
Total	64,668,238	$ 41.64	133,513,514

(1) *Includes options to purchase shares of Company Common Stock and other rights under the following shareholder-approved plans: the Merck Sharp & Dohme 2004, 2007 and 2010 Incentive Stock Plans, the Merck & Co., Inc. 2006 and 2010 Non-Employee Directors Stock Option Plans, and the Merck & Co., Inc. Schering-Plough 2002 and 2006 Stock Incentive Plans.*

(2) *Excludes approximately 13,399,881 shares of restricted stock units and 1,883,597 performance share units (assuming maximum payouts) under the Merck Sharp & Dohme 2004, 2007 and 2010 Incentive Stock Plans. Also excludes 279,862 shares of phantom stock deferred under the MSD Employee Deferral Program and 528,142 shares of phantom stock deferred under the Merck & Co., Inc. Plan for Deferred Payment of Directors' Compensation.*

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The required information on transactions with related persons is incorporated by reference from the discussion under the heading "Related Person Transactions" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2016.

The required information on director independence is incorporated by reference from the discussion under the heading "Independence of Directors" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 24, 2016.

Item 14. Principal Accountant Fees and Services.

The information required for this item is incorporated by reference from the discussion under Proposal 3, Ratification of Appointment of Independent Registered Public Accounting Firm for 2016beginning 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 24, 2016.

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, 2015, 2014 and 2013

Consolidated statement of comprehensive income for the years ended December 31, 2015, 2014 and 2013

Consolidated balance sheet as of December 31, 2015 and 2014

Consolidated statement of equity for the years ended December 31, 2015, 2014 and 2013

Consolidated statement of cash flows for the years ended December 31, 2015, 2014 and 2013

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 (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 Merck & Co., Inc.'s Form 10-Q Quarterly Report for the quarter year 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	—	First Supplemental Indenture to the 2003 Indenture (including Form of Note), dated November 26, 2003 — Incorporated by reference to Exhibit 4.2 to Schering-Plough's Current Report on Form 8‑K filed November 28, 2003 (No. 1-6571)
4.7	—	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)
4.8	—	Third Supplemental Indenture to the 2003 Indenture (including Form of Note), dated September 17, 2007 — Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8‑K filed September 17, 2007 (No. 1-6571)
4.9	—	Fourth Supplemental Indenture to the 2003 Indenture (including Form of Note), dated October 1, 2007 — Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8‑K filed October 2, 2007 (No.1-6571)
4.10	—	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)
4.11	—	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)
4.12	—	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 January 1, 2013) — Incorporated by reference to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2012 (No. 1-6571)
*10.3	—	Merck Sharp & Dohme Corp. 2004 Incentive Stock Plan (amended and restated as of November 3, 2009) — Incorporated by reference to Exhibit 10.8 to Merck & Co., Inc.'s Current Report on Form 8‑K filed November 4, 2009 (No. 1-6571)

Exhibit Number		Description
*10.4	—	Merck Sharp & Dohme Corp. 2007 Incentive Stock Plan (effective as amended and restated as of November 3, 2009) — Incorporated by reference to Exhibit 10.7 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
*10.5	—	Amendment One to the Merck Sharp & Dohme Corp. 2007 Incentive Stock Plan (effective February 15, 2010) — Incorporated by reference to Exhibit 10.2 to Merck & Co., Inc.'s Current Report on Form 8-K filed February 18, 2010 (No. 1-6571)
*10.6	—	Merck & Co., Inc. 2010 Incentive Stock Plan (as amended and restated June 1, 2015) — Incorporated by reference to Merck & Co., Inc.'s Schedule 14A filed April 13, 2015 (No. 1-6571)
*10.7	—	Form of stock option terms for a non-qualified stock option under the Merck Sharp & Dohme Corp. 2007 Incentive Stock Plan and the Schering-Plough 2006 Stock Incentive Plan — Incorporated by reference to Exhibit 10.3 to Merck & Co., Inc.'s Current Report on Form 8-K filed February 15, 2010 (No. 1-6571)
*10.8	—	Form of stock option terms for 2011 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Merck & Co., Inc.'s Form 10‑Q Quarterly Report for the period ended March 31, 2011 (No. 1-6571)
*10.9	—	Form of stock option terms for 2012 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Merck & Co., Inc.'s Form 10‑K Annual Report for the fiscal year ended December 31, 2011 (No. 1-6571)
*10.10	—	Form of restricted stock unit terms for 2012 quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2011 (No. 1-6571)
*10.11	—	Form of performance share unit terms for 2012 grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the period ended March 31, 2012 (No. 1-6571)
*10.12	—	Form of stock option terms for 2013 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2012 (No. 1-6571)
*10.13	—	Form of restricted stock unit terms for 2013 quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2012 (No. 1-6571)
*10.14	—	Form of performance share unit terms for 2013 grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2014 (No. 1-6571)
*10.15	—	Form of stock option terms for 2014 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2014 (No. 1-6571)
*10.16	—	Form of restricted stock unit terms for 2014 quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2014 (No. 1-6571)
*10.17	—	Form of performance share unit terms for 2014 grants under the Merck & Co., Inc. 2010 Stock Incentive Plan — Incorporated by reference to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2014 (No. 1-6571)
*10.18	—	Form of stock option terms for 2015 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan
*10.19	—	Form of restricted stock unit terms for 2015 quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan
*10.20	—	Form of performance share unit terms for 2015 grants under the Merck & Co., Inc. 2010 Stock Incentive Plan

Exhibit Number		Description
*10.21	—	Merck & Co., Inc. Change in Control Separation Benefits Plan (Effective as Amended and Restated, as of January 1, 2013) — Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8‑K dated November 29, 2012 (No. 1-6571)
*10.22	—	Merck & Co., Inc. U.S. Separation Benefits Plan (effective as of January 1, 2013) (amended and restated as of October 1, 2013) — Incorporated by reference to Merck & Co., Inc.'s Form 10‑Q Quarterly Report for the period ended September 30, 2013 (No. 1-6571)
*10.23	—	Merck & Co., Inc. U.S. Separation Benefits Plan (amended and restated effective as of November 15, 2014) — Incorporated by reference to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2014 (No. 1-6571)
*10.24	—	Merck & Co., Inc. 2006 Non-Employee Directors Stock Option Plan (amended and restated as of November 3, 2009) — Incorporated by reference to Exhibit 10.5 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
*10.25	—	Merck & Co., Inc. 2010 Non-Employee Directors Stock Option Plan (amended and restated as of December 1, 2010) — Incorporated by reference to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2010 (No. 1-6571)
*10.26	—	Retirement Plan for the Directors of Merck & Co., Inc. (amended and restated June 21, 1996) — Incorporated by reference to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1996 (No. 1-3305)
*10.27	—	Merck & Co., Inc. Plan for Deferred Payment of Directors' Compensation (effective as amended and restated as of December 1, 2010) — Incorporated by reference to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2010 (No. 1-6571)
*10.28	—	Offer Letter between Merck & Co., Inc. and Robert Davis, dated March 17, 2014 — Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K dated March 27, 2014 (No. 1-6571)
*10.29	—	Agreement Letter between Merck & Co., Inc. and Bruce N. Kuhlik, dated July 21, 2015 — Incorporated by reference to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the period ended September 30, 2015 (No. 1-6571)
*10.30	—	Form of employment agreement effective upon a change of control between Schering-Plough and certain executives for new agreements beginning in January 1, 2008 — Incorporated by reference to Exhibit 10(e)(xv) to Schering-Plough's 10-K for the year ended December 31, 2008 (No. 1-6571)
10.31	—	Distribution agreement between Schering-Plough and Centocor, Inc., dated April 3, 1998 — Incorporated by reference to Exhibit 10(u) to Schering-Plough's Amended 10-K for the year ended December 31, 2003, filed May 3, 2004 (No. 1-6571)†
10.32	—	Amendment Agreement to the Distribution Agreement between Centocor, Inc., CAN Development, LLC, and Schering-Plough (Ireland) Company — Incorporated by reference to Exhibit 10.1 to Schering-Plough's Current Report on Form 8-K filed December 21, 2007 (No. 1-6571)†
10.33	—	Accelerated Share Purchase Agreement between Merck & Co., Inc. and Goldman, Sachs & Co., dated May 20, 2013 — Incorporated by reference to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the period ended June 30, 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
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

Exhibit Number		Description
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, 2015, 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.

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* *Management contract or compensatory plan or arrangement.*

† *Certain portions of the exhibit have been omitted pursuant to a request for confidential treatment. The non-public information has been filed separately with the Securities and Exchange Commission pursuant to rule 24b-2 under the Securities Exchange Act of 1934, as amended.*

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: February 26, 2016

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 26, 2016
ROBERT M. DAVIS	Executive Vice President and Chief Financial Officer; Principal Financial Officer	February 26, 2016
RITA A. KARACHUN	Senior Vice President Finance-Global Controller; Principal Accounting Officer	February 26, 2016
LESLIE A. BRUN	Director	February 26, 2016
THOMAS R. CECH	Director	February 26, 2016
PAMELA J. CRAIG	Director	February 26, 2016
THOMAS H. GLOCER	Director	February 26, 2016
WILLIAM B. HARRISON, JR.	Director	February 26, 2016
C. ROBERT KIDDER	Director	February 26, 2016
ROCHELLE B. LAZARUS	Director	February 26, 2016
CARLOS E. REPRESAS	Director	February 26, 2016
PAUL B. ROTHMAN	Director	February 26, 2016
PATRICIA F. RUSSO	Director	February 26, 2016
CRAIG B. THOMPSON	Director	February 26, 2016
WENDELL P. WEEKS	Director	February 26, 2016
PETER C. WENDELL	Director	February 26, 2016

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)