

Merck & Co., Inc.  
Form 10-K  
February 27, 2015

As filed with the Securities and Exchange Commission on February 27, 2015

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, 2014

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

Number of shares of Common Stock (\$0.50 par value) outstanding as of January 31, 2015: 2,838,192,933.

Aggregate market value of Common Stock (\$0.50 par value) held by non-affiliates on June 30, 2014 based on closing price on June 30, 2014: \$167,695,000,000.

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

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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 26, 2015, 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 three operating segments, which are the Pharmaceutical, Animal Health and Alliances segments, and one reportable segment, which is the Pharmaceutical 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. 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.

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## Product Sales

Sales of the Company’s top pharmaceutical products, as well as total sales of animal health and consumer care products, were as follows:

(\$ in millions)	2014	2013	2012
Total Sales	\$42,237	\$44,033	\$47,267
Pharmaceutical	36,042	37,437	40,601
Januvia	3,931	4,004	4,086
Zetia	2,650	2,658	2,567
Remicade	2,372	2,271	2,076
Janumet	2,071	1,829	1,659
Gardasil	1,738	1,831	1,631
Isentress	1,673	1,643	1,515
ProQuad/M-M-R II/Varivax	1,394	1,306	1,273
Nasonex	1,099	1,335	1,268
Singulair	1,092	1,196	3,853
Animal Health	3,454	3,362	3,399
Consumer Care <sup>(1)</sup>	1,547	1,894	1,952
Other Revenues <sup>(2)</sup>	1,194	1,340	1,315

(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.

Other revenues are primarily comprised of alliance revenue, miscellaneous corporate revenues and third-party manufacturing sales. On October 1, 2013, the Company divested a substantial portion of its third-party manufacturing sales.



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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: PegIntron (peginterferon alpha-2b) and Victrelis (boceprevir), medicines for the treatment of chronic hepatitis C virus ("HCV").

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

Acute Care: 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; Primaxin (imipenem and cilastatin sodium), an anti-bacterial product. The Company acquired the following products pursuant to the Cubist Pharmaceuticals, Inc. ("Cubist") acquisition that was consummated in January 2015: Cubicin (daptomycin for injection), an I.V. antibiotic for complicated skin and skin structure infections or bacteremia, when caused by designated susceptible organisms; and Zerbaxa (ceftolozane/tazobactam), an I.V. combination product for the treatment of complicated intra-abdominal infections or complicated urinary tract infections, when caused by designated susceptible organisms.

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

Other: Cosopt (dorzolamide hydrochloride-timolol maleate ophthalmic solution), which the Company markets outside the United States, and Trusopt (dorzolamide hydrochloride ophthalmic solution), ophthalmic products.

Oncology

Emend (aprepitant) for the prevention of chemotherapy-induced and post-operative nausea and vomiting; Temodar (temozolomide) (marketed as Temodal outside the United States), a treatment for certain types of brain tumors; and Keytruda (pembrolizumab) for the treatment of advanced melanoma in patients whose disease has progressed after other therapies.

Diversified Brands

Respiratory: Nasonex (mometasone furoate monohydrate), an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms; Singulair (montelukast), a medicine indicated for the chronic treatment of asthma and the relief of symptoms of allergic rhinitis; 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; Propecia (finasteride), a product for the treatment of male pattern hair loss; Zocor (simvastatin), a statin for modifying cholesterol; and Remeron (mirtazapine), an antidepressant.

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### Vaccines

Gardasil (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant), a vaccine to help prevent certain diseases caused by four 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); Pneumovax 23 (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease; and RotaTeq (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children.

### 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; Regumate/Matrix fertility management for swine and horses; 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; M+Pac swine pneumonia vaccine; and Porcilis vaccine line for infectious diseases in swine.

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

Companion Animal Products: 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; Activyl/Scalibor/Exspot for protecting against bites from fleas, ticks, mosquitoes and sandflies; and Bravecto (fluralaner), a chewable tablet that kills fleas and ticks in dogs for up to 12 weeks, which was approved by the U.S. Food and Drug Administration (the “FDA”) in 2014 and launched in approximately 30 countries.

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 September 2014, Merck announced that 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. Keytruda is the first anti-PD-1 (programmed death receptor-1) therapy approved in the United States.

In August 2014, Merck announced that the FDA approved Belsomra (suvorexant) for the treatment of adults with insomnia who have difficulty falling asleep and/or staying asleep. Belsomra became available in the United States in early 2015. Following receipt of marketing approval, Belsomra was launched in Japan in November 2014. The Company is continuing with plans to seek approval for suvorexant in other countries around the world.

In December 2014, the Company announced that the FDA approved Gardasil 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), Merck’s 9-valent HPV vaccine, for use in girls and young women 9 to 26 years of age for the prevention of cervical, vulvar, vaginal, and anal cancers caused by HPV types 16, 18, 31, 33, 45, 52 and 58, pre-cancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58, and genital warts caused by HPV types 6 and 11. Gardasil 9 is also approved for use in boys 9 to 15 years of age for the prevention of anal cancer caused by HPV types 16, 18, 31, 33, 45, 52 and 58, precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58, and genital warts caused by HPV types 6 and 11. Gardasil 9 includes the greatest number of HPV types in any available HPV vaccine.





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In April 2014, Merck announced that the FDA approved Grastek (Timothy Grass Pollen Allergen Extract) and Ragwitek (Short Ragweed Pollen Allergen Extract) tablets for sublingual use. Grastek is an allergen extract indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy Grass or cross-reactive grass pollens. Grastek is approved for use in persons 5 through 65 years of age. Ragwitek is an allergen extract indicated as immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen. Ragwitek is approved for use in adults 18 through 65 years of age. Neither Grastek nor Ragwitek is indicated for the immediate relief of allergic symptoms. The prescribing information for Grastek and Ragwitek includes a boxed warning regarding severe allergic reactions.

In May 2014, Merck announced that the FDA approved Zontivity (vorapaxar) 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 European Commission (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 launch Zontivity in the European Union (the “EU”) in late 2015 or early 2016.

In September 2014, Vanihep (vaniprevir), an oral twice-daily protease inhibitor for the treatment of chronic HCV was approved in Japan. Vanihep will be available only in Japan.

Additionally, as part of its acquisition of Cubist, the Company acquired Zerbaxa (ceftolozane/tazobactam), a combination product approved by the FDA in December 2014 to treat complicated intra-abdominal infections or complicated urinary tract infections, when caused by designated susceptible organisms.

### Joint Ventures

#### AstraZeneca LP

On June 30, 2014, AstraZeneca Group Plc (“AstraZeneca”) exercised its option to purchase Merck’s interest in Merck’s joint venture with AstraZeneca. As a result of AstraZeneca’s exercise of its option, 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.) 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 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.). 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 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 exclusive 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 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. The Company previously lost market exclusivity for Remicade in certain smaller European markets and experienced biosimilar competition and a decline in sales in those markets. In February

2015,

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the Company lost market exclusivity in major European markets and the Company anticipates a more substantial decline in Remicade sales. Additionally, the Company anticipates mandatory price reductions in certain European markets. All profits derived from Merck's exclusive 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 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, and generic drug and animal health care manufacturers. 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 positions 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. The effect on operations of competitive factors and patent disputes cannot be predicted.

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 joint ventures and licenses, 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 \$430 million, \$280 million and \$210 million was recorded by Merck as a reduction to revenue in 2014, 2013 and 2012, 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 2014 and will remain \$3.0 billion in 2015. 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 \$390 million, \$151 million and \$190 million of costs within Marketing and administrative expenses in 2014,

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2013 and 2012, respectively, for the annual health care reform fee. The increase in expenses in 2014 reflects final regulations on the annual health care reform fee issued by the Internal Revenue Service (the “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. The full impact of U.S. health care reform cannot be predicted at this time.

The Company also faces increasing pricing pressure globally from managed care organizations, government agencies and programs that could negatively affect the Company’s sales and profit margins. In the United States, these include (i) practices of managed care groups, 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 2014 and the Company anticipates the austerity measures will continue to negatively affect revenue performance in 2015. 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. 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 2015 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

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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. 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 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.

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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.



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

Product	Year of Expiration (in the U.S.) <sup>(1)</sup>
Integrilin <sup>(2)</sup>	2015 (use/formulation)
Emend	2015
Follistim AQ	2015
Invanz	2016 (compound)/2017 (composition)
Cubicin <sup>(3)</sup>	2016 (composition)
Zostavax	2016 (use)
Dulera	2017 (formulation)/2020 (combination)
Zetia <sup>(4)</sup> /Vytorin	2017
Asmanex	2018 (formulation)
Nasonex <sup>(5)</sup>	2018(formulation)
NuvaRing	2018 (delivery system)
Emend for Injection	2019
Noxafil	2019
RotaTeq	2019
Intron A	2020
Recombivax	2020 (method of making/vectors)
Januvia/Janumet/Janumet XR	2022 (compound)/2026 (salt)
Isentress	2023
Nexplanon	2026 (device)/2027 (device with applicator)
Grastek	2026 (use)
Ragwitek	2026 (use)
Zontivity	2027 (with pending Patent Term Restoration)
Gardasil/Gardasil 9	2028
Keytruda	2028
Zerbaxa	2028 (with pending Patent Term Restoration)
Sivextro	2028 (with Patent Term Restoration)
Belsomra	2029

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

(1) Item 8. “Financial Statements and Supplementary Data,” Note 10. “Contingencies and Environmental Liabilities” below.

(2) By agreement, certain generic manufacturers may launch a generic version of Integrilin in June 2015.

(3) 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. Hospira has appealed the lack of invalidity of the June 2016 patent and the Company has cross-appealed on the invalidity of the later patents.

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

(5) A district court decision (upheld on appeal to the Court of Appeals for the Federal Circuit) 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.

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

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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.)
MK-8962 (corifollitropin alfa injection)	2018 (formulation/use)
V419 (pediatric hexavalent combination vaccine)	2020 (method of making/vectors)
MK-8616 (sugammadex) Injection	2021
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)
MK-0822 (odanacatib)	2024
MK-8228 (letermovir)	2025
MK-2402 (bevenopran)	2025
MK-8237 (allergy, house dust mites)	2026 (use)
MK-0859 (anacetrapib)	2027
MK-3415A (actoxumab/bezlotoxumab)	2028
MK-5172A (grazoprevir/elbasvir)	2030
MK-3102 (omarigliptin)	2030
MK-8931 (BACE Inhibitor)	2030
MK-8835 (ertugliflozin)	2031
MK-1439 (doravirine)	2031
MK-4261 (surotomycin)	2031

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 2014 on patent and know-how licenses and other rights amounted to \$274 million. Merck also incurred royalty expenses amounting to \$1.1 billion in 2014 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 11,400 people are employed in the Company’s research activities. Research and development expenses were \$7.2 billion in 2014, \$7.5 billion in 2013 and \$8.2 billion in 2012 (which included restructuring costs and acquisition-related costs in all years). The Company



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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. Further, Merck has moved to diversify its portfolio through a collaboration on the development of biosimilars, which have the potential to harness the market opportunity presented by biological medicine patent expiries by delivering high quality biosimilars to enhance access for patients worldwide. 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 is evaluating certain late-stage clinical development and platform technology assets to determine their out-licensing or sale potential. In 2014, the Company entered into an agreement to divest its Sirna Therapeutics, Inc. subsidiary and related RNAi technology assets and out-licensed an investigational therapeutic antibody candidate to Sun Pharmaceutical Industries Ltd. ("Sun Pharma").

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

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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, 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 review 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 Pharmaceutical Medical Devices Agency in Japan, Health Canada, Agencia



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Nacional de Vigilancia in Brazil, Korea Food and Drug Administration in South Korea, and Therapeutic Goods Administration in Australia. Each country has a separate and independent review process and timeline. In many markets, approval times can be longer as the regulatory authority requires approval in a major market, such as the 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 anti-PD-1 (programmed death receptor-1) therapy under review by the EMA for the treatment of advanced melanoma. In September 2014, the FDA approved 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. Keytruda is the first anti-PD-1 therapy approved in the United States.

The Keytruda clinical development program also includes studies in more than 30 cancers including: bladder, colorectal, gastric, head and neck, melanoma, non-small-cell lung, renal, triple negative breast and hematological malignancies. In addition, the Company has announced a number of collaborations with other pharmaceutical companies to evaluate novel combination regimens with Keytruda. In October 2014, Keytruda was granted Breakthrough Therapy Designation by the FDA for the treatment of patients with Epidermal Growth Factor Receptor mutation-negative, and Anaplastic Lymphoma Kinase rearrangement-negative non-small-cell lung cancer whose disease has progressed on or following platinum-based chemotherapy. The Company anticipates submitting a supplemental BLA to the FDA in mid-2015 for Keytruda.

MK-8616, Bridion (sugammadex) Injection, is an investigational agent for the reversal of neuromuscular blockade induced by rocuronium or vecuronium (neuromuscular blocking agents). Neuromuscular blockade is used in anesthesiology to induce muscle relaxation during surgery. In September 2013, Merck announced that it had received a CRL from the FDA for the resubmission of the NDA for Bridion. To address the CRL, the Company conducted a new hypersensitivity study and, in October 2014, resubmitted the NDA to the FDA. The Company anticipates an FDA advisory committee meeting will be held on March 18, 2015 to review Bridion. If approved, the Company expects to launch Bridion in the United States later in 2015. Bridion is approved and has been launched in many countries outside of the United States.

V419, DTaP5-IPV-Hib-HepB, is an investigational pediatric hexavalent vaccine that the Company is developing in partnership with Sanofi Pasteur under review by the FDA and the EMA. If approved, V419 would be the first pediatric combination vaccine in the United States 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. If approved, V419 will be co-promoted in the United States via a partnership with Sanofi Pasteur and marketed via the SPMSD joint venture in Europe.

MK-3102, omarigliptin, is an investigational once-weekly dipeptidyl peptidase-4 (“DPP-4”) inhibitor in development for the treatment of type 2 diabetes. In November 2014, Merck announced that the Company has submitted a new drug application for omarigliptin to the Japanese Pharmaceuticals and Medical Devices Agency. Omarigliptin is in Phase 3 clinical development in the United States.

MK-1986, Sivextro (tedizolid phosphate), a once-daily oxazolidinone antibiotic developed for both intravenous and oral administration for the treatment of acute bacterial skin and skin structuring infections (“ABSSSI”) caused by certain Gram-positive organisms, is under review by the EMA. In January 2015, Merck announced that the Committee for Medicinal Products for Human Use (the “CHMP”) of the EMA has adopted a positive opinion recommending approval of Sivextro for the treatment of ABSSSI in adults. Merck acquired Sivextro as a part of its purchase of Cubist. If the EC affirms the CHMP opinion, it will grant a centralized marketing authorization with unified labeling that is valid in the 28 countries that are members of the EU, as well as European Economic Area members, Iceland, Liechtenstein and Norway. Sivextro is approved in the United States and is indicated for the treatment of adults with ABSSSI caused by designated susceptible Gram-positive organisms. The Company is conducting a Phase 3 clinical trial to assess the safety and efficacy of Sivextro in adult patients with ventilated nosocomial pneumonia, including ventilator-associated bacterial pneumonia (“VABP”) and ventilated hospital-acquired bacterial pneumonia (“ventilated

HABP”). In 2013, the FDA designated Sivextro as a QIDP for its now approved indication in ABSSSI, as well as for

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its potential indication in ventilated nosocomial pneumonia, including VABP and ventilated HABP, in each of the I.V. and oral dosage forms.

MK-7625A, Zerbaxa, a combination product for the treatment of certain serious bacterial infections in adults, is under review by the EMA. Merck acquired Zerbaxa as a part of its purchase of Cubist. In December 2014, Zerbaxa was approved by the FDA 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. The Company is conducting a Phase 3 clinical trial to assess the safety and efficacy of Zerbaxa in adult patients with ventilated nosocomial pneumonia, including VABP and ventilated HABP. The FDA designated Zerbaxa as a QIDP for its now approved indications as well as for its potential indication in ventilated nosocomial pneumonia, including VABP and ventilated HABP.

V503, Gardasil 9, the Company's nine-valent HPV vaccine that helps protect against certain HPV-related diseases, is under review by the EMA. V503 incorporates antigens against five additional cancer-causing HPV types as compared with Gardasil. Gardasil 9 was approved by the FDA in December 2014.

MK-8962, corifollitropin alfa injection, is an investigational fertility treatment under review by the FDA 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 is reviewing its options with respect to this drug candidate in response to the CRL. Corifollitropin alfa injection is marketed as Elonva in certain markets outside of the United States.

In addition to the candidates under regulatory review, the Company has several drug candidates in Phase 3 development. The Company anticipates filing an NDA or a BLA, as applicable, with the FDA with respect to certain of these candidates in 2015.

MK-5172A, a once daily, fixed-dose, combination, chronic HCV treatment regimen consisting of MK-5172, grazoprevir, an investigational HCV NS3/4A protease inhibitor, and MK-8742, elbasvir, an investigational HCV NS5A replication complex inhibitor, began Phase 3 clinical trials in June 2014. MK-5172A is being investigated in a broad clinical program that includes studies in patients with multiple HCV genotypes who are treatment-naïve, treatment failures, or who fit into other important HCV subpopulations such as patients with cirrhosis and those co-infected with HIV. The Company expects to file an NDA with the FDA in the first half of 2015 for MK-5172A. On January 30, 2015, the Company received notification from the FDA of its intent to rescind Breakthrough Therapy Designation status for this combination treatment regimen, citing the availability of other recently approved treatments for Genotype 1 patients. The Company is discussing this matter with the FDA and does not expect that it will impact its ability to file an NDA for this combination regimen or the timing of that filing.

The Company has started the Phase 2 C-CREST studies to study combination regimens of grazoprevir and MK-3682 (formerly IDX21437) with either elbasvir or MK-8408 for the treatment of HCV infection. The Company expects to begin Phase 3 studies in 2015.

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

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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, in support of regulatory submissions. Merck plans to submit an NDA to the FDA for odanacatib in 2015. Merck also plans to submit applications to the EMA and the Ministry of Health, Labour, and Welfare in Japan.

MK-8237 is an investigational allergy immunotherapy tablet for house dust mite allergy. In 2014, the FDA approved Grastek, a Timothy grass pollen allergen extract sublingual immunotherapy tablet, and Ragwitek, a short ragweed pollen allergen extract sublingual immunotherapy tablet. Both Grastek and Ragwitek, as well as the ongoing program for MK-8237, are part of a North America partnership between Merck and ALK-Abello.

MK-8931 is Merck's novel investigational oral  $\beta$ -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 amnesic mild cognitive impairment due to Alzheimer's disease, also known as prodromal Alzheimer's disease. MK-8931 is also being studied in another Phase 3 trial versus placebo in patients with mild-to-moderate Alzheimer's disease (EPOCH).

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 large, event-driven cardiovascular clinical outcomes trial, REVEAL (Randomized EVALuation of the Effects of Anacetrapib Through Lipid-modification), involving patients with preexisting vascular disease that is predicted to be completed in 2017.

MK-3415A, actoxumab/bezlotoxumab, an investigational candidate for the prevention of Clostridium difficile infection recurrence, is a combination of two monoclonal antibodies used to treat patients with a single infusion.

MK-4261, surotomycin, is an investigational oral antibiotic in development for the treatment of Clostridium difficile associated diarrhea. Merck acquired surotomycin as part of its purchase of Cubist. The FDA has designated surotomycin as a QIDP.

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-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.

MK-1293 is an insulin glargine candidate for the treatment of patients with type 1 and type 2 diabetes. In February 2014, the Company announced that it had expanded its collaboration with Samsung Bioepis to develop, manufacture and commercialize MK-1293. Under the terms of the agreement, the companies will collaborate on clinical development, regulatory filings and manufacturing. If approved, Merck will commercialize this candidate.

V212 is an inactivated 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.

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. In September 2014, Merck and 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.



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In May 2014, Merck and Endocyte, Inc. (“Endocyte”) (the Company’s collaboration partner) announced the withdrawal of the conditional MAA from the EMA for vintafolide for the treatment of adult patients with folate receptor-positive, platinum-resistant ovarian cancer, in combination with pegylated liposomal doxorubicin (“PLD”). The companies’ decision was based on review of interim data from the PROCEED trial. The PROCEED trial has been terminated based on the Data Safety Monitoring Board’s (the “DSMB”) recommendation that the study be stopped because vintafolide in combination with PLD versus PLD alone did not meet the pre-specified criteria for progression-free survival to allow continuation of the study. The DSMB did not identify any safety concerns for the patients enrolled in the PROCEED trial. In June 2014, Merck returned worldwide rights for vintafolide in all indications to Endocyte. The chart below reflects the Company’s research pipeline as of February 20, 2015. 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	Allergy	Acute Bacterial Skin & Skin Structure Infections (ABSSSI)
MK-7622	MK-8237, House Dust Mite (March 2014) <sup>(1,2)</sup>	MK-1986 Sivextro (EU)
Asthma	Alzheimer’s Disease	Complicated Intra-Abdominal Infections (cIAI) & Complicated Urinary Tract Infections (cUTI)
MK-1029	MK-8931 (December 2013)	MK-7625A Zerbaxa (EU)
Bacterial Infection	Atherosclerosis	Diabetes Mellitus
MK-7655 (relebactam)	MK-0859 (anacetrapib) (May 2008)	MK-3102 (omarigliptin) (Japan)
Cancer	Bladder Cancer	Fertility
MK-2206	MK-3475 Keytruda (October 2014)	MK-8962 (corifollitropin alfa injection) (U.S.) <sup>(3)</sup>
MK-8628	Clostridium difficile Infection	HPV-Related Cancers
Contraception, Medicated IUS	MK-3415A (actoxumab/bezlotoxumab) (November 2011)	V503 Gardasil 9 (EU)
MK-8342	MK-4261 (surotomycin) (July 2012)	Melanoma
Contraception, Next Generation Ring	CMV Prophylaxis in Transplant Patients	MK-3475 Keytruda (EU)
MK-8342B	MK-8228 (letermovir) (June 2014)	Neuromuscular Blockade Reversal
Ebola Vaccine	Diabetes Mellitus	MK-8616 Bridion (U.S.) <sup>(4)</sup>
V920	MK-3102 (omarigliptin) (September 2012)	Pediatric Hexavalent Combination Vaccine
Gastric Cancer	MK-8835 (ertugliflozin) (November 2013) <sup>(1)</sup>	V419 (U.S./EU) <sup>(5)</sup>
MK-3475 Keytruda	MK-1293 (February 2014) <sup>(1)</sup>	
Heart Failure	Head and Neck Cancer	Footnotes:
MK-1242 (vericiguat) <sup>(1)</sup>	MK-3475 Keytruda (November 2014)	<sup>(1)</sup> Being developed in a collaboration.
Hepatitis C	Hepatitis C	<sup>(2)</sup> North American rights only.
MK-3682/MK-8742 (elbasvir)/MK-5172 (grazoprevir)	MK-5172A (grazoprevir/elbasvir) (June 2014)	<sup>(3)</sup> In July 2014, Merck received a CRL from the FDA for corifollitropin alfa injection (MK-8962). Merck is reviewing its options with respect to this drug candidate in response to the CRL.
MK-3682/MK-8408/MK-5172 (grazoprevir)	Herpes Zoster	<sup>(4)</sup> In September 2013, Merck received a CRL from the FDA for the resubmission
Pneumoconjugate Vaccine	V212 (inactivated VZV vaccine) (December 2010)	
V114	HIV	
	MK-1439 (doravirine) (December 2014)	
	Non-Small-Cell Lung Cancer	

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MK-3475 Keytruda (September 2014) Opioid-Induced Constipation	of the NDA for Bridion (MK-8616). To address the CRL, the Company conducted a new hypersensitivity study and has resubmitted the NDA to the FDA.
MK-2402 (bevenopran) (October 2012) Osteoporosis	
MK-0822 (odanacatib) (September 2007)	<sup>(5)</sup> V419 is being developed in partnership with Sanofi Pasteur and, if approved, will be co-promoted via a U.S. partnership and marketed via the SPMSD joint venture in Europe.

Employees

As of December 31, 2014, the Company had approximately 70,000 employees worldwide, with approximately 26,800 employed in the United States, including Puerto Rico. Approximately 31% of worldwide employees of the Company are represented by various collective bargaining groups.



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### 2013 Restructuring Program

In 2013, the Company announced a global restructuring program (the “2013 Restructuring Program”) as part of its global initiative to sharpen its commercial and research and development focus. As part of the program, the Company expects to reduce its total workforce by approximately 8,500 positions. These workforce reductions will primarily come from the elimination of positions in sales, administrative and headquarters organizations, as well as research and development. The Company will also reduce its global real estate footprint and continue to improve the efficiency of its manufacturing and supply network. Since inception of the 2013 Restructuring Program through December 31, 2014, Merck has eliminated approximately 6,095 positions comprised of employee separations, as well as the elimination of contractors and vacant positions. The remaining actions under the 2013 Restructuring Program are expected to be substantially completed by the end of 2015.

### Merger Restructuring Program

The global restructuring program (the “Merger Restructuring Program”) that was initiated in 2010 subsequent to the Merck and Schering-Plough merger (the “Merger”) is intended to streamline the cost structure of the combined company. Further actions under this program were initiated in 2011. The workforce reductions associated with this plan relate to the elimination of positions in sales, administrative and headquarters organizations, as well as from 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, 2014, Merck has eliminated approximately 28,410 positions comprised of employee separations, as well as the elimination of contractors and vacant positions. Approximately 3,440 position eliminations remain pending under this program and an older program as of December 31, 2014. The non-manufacturing related restructuring actions under the Merger Restructuring Program were substantially completed by the end of 2013. The remaining actions under this program relate to ongoing manufacturing facility rationalizations, which are expected to be substantially completed by 2016.

### 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 \$12 million in 2014, and are estimated at \$53 million in the aggregate for the years 2015 through 2019. These amounts do not consider potential recoveries from other parties. The Company has taken an active role in identifying and providing 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 \$125 million and \$213 million at December 31, 2014 and 2013, 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 \$66 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 were 60% of sales in 2014, 59% of sales in 2013 and 57% of sales in 2012. 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.



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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](http://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](http://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.



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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 the Company's major marketed products 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, made by Apotex, a generic manufacturer, does not infringe the Company's U.S. patent for Nasonex. If Apotex receives approval to market in the United States its generic form of Nasonex, the Company will experience a loss of Nasonex sales.

In addition, in September 2013, the EC approved a biosimilar for Remicade. While the Company experienced biosimilar competition in certain smaller European markets, the Company anticipates a more substantial decline in Remicade sales following loss of market exclusivity in major European markets in February 2015. Additionally, the Company anticipates mandatory price reductions in certain European markets. 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, Remicade, Janumet, Gardasil, Isentress, Vytorin, and Nasonex. 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.



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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 FDA 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 increasing 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 mergers and 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





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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 is conducting the TECOS study involving sitagliptin and the results of that study could have a material adverse effect on the sales of Januvia and Janumet.

The Trial Evaluating Cardiovascular Outcomes with Sitagliptin ("TECOS"), an event-driven, cardiovascular outcomes study with sitagliptin, began in 2008 and enrolled over 14,000 patients. TECOS will evaluate the impact of sitagliptin on cardiovascular outcomes when added to usual care compared to usual care without sitagliptin in a large, high-risk type 2 diabetes population across multiple countries. TECOS is expected to be completed in the first quarter of 2015 and the Company expects that the results of TECOS will be presented at the annual scientific sessions meeting of the American Diabetes Association in June 2015.

The Company sells sitagliptin as Januvia, and as Janumet and Janumet XR (sitagliptin combined with metformin immediate-release and extended release, respectively), for the treatment of adult patients with type 2 diabetes. The Januvia/Janumet/Janumet XR franchise is the Company's largest with combined 2014 worldwide sales of \$6.0 billion.

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If the results of the TECOS trial show a negative effect on cardiovascular outcomes or reveal another safety issue related to the use of sitagliptin, that could have a material, adverse effect on the sales of Januvia and Janumet/Janumet XR. If sales of such products are materially adversely affected, the Company's business, cash flows, results of operations, financial position and prospects could also be materially adversely affected.

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 mergers and 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.

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.

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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, major health care reform was adopted into law and important market reforms have begun and continued through its implementation in 2014. The law is expected to expand access to health care to about 32 million Americans by the end of the decade. In 2010, the minimum rebate to states participating in the Medicaid program increased from 15.1% to 23.1% on the Company's branded prescription drugs; the Medicaid rebate was extended to Medicaid Managed Care Organizations; and eligibility for the federal 340B drug discount program was extended to rural referral centers, sole community hospitals, critical access hospitals, certain free standing cancer hospitals, and certain additional children's hospitals.

In addition, the law 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, the Company is required to pay an annual health care reform fee, which is assessed on all branded prescription drug manufacturers and importers. The fee is calculated based on the industry's total sales of branded prescription drugs to specified government programs. The percentage of a manufacturer's sales that are included is determined by a tiered scale based on the manufacturer's individual revenues. Each manufacturer's portion of the total annual fee is based on the manufacturer's proportion of the total includable sales in the prior year. The annual industry fee for 2014 was \$3.0 billion and will remain \$3.0 billion in 2015.

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, including the biennial price reductions in Japan, negatively affected the Company's revenue performance in 2014. The Company anticipates these pricing actions and other austerity measures will continue to negatively affect revenue performance in 2015.

The Company continues to monitor the credit and economic conditions within Greece, Spain, Italy and Portugal, among other members of the EU. These economic conditions, as well as inherent variability of timing of cash receipts, have resulted in, and may continue to result in, an increase in the average length of time that it takes to collect on the accounts receivable outstanding in these countries and may also impact the likelihood of collecting 100% of outstanding accounts receivable. As of December 31, 2014, the Company's accounts receivable in Greece, Italy, Spain and Portugal totaled approximately \$600 million. Of this amount, hospital and public sector receivables were approximately \$330 million in the aggregate, of which approximately 14%, 27%, 46% and 13% related to Greece, Italy, Spain and Portugal, respectively. As of December 31, 2014, the Company's total net accounts receivable outstanding for more than one year were approximately \$100 million, of which approximately 31% related to accounts receivable in Greece, Italy, Spain and Portugal, mostly comprised of hospital and public sector receivables. If credit and economic conditions in Europe worsen, the resulting economic and currency impacts in the affected markets and globally could have a material adverse effect on the Company's results.

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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.

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.

The Company faces significant litigation related to Vioxx.

On September 30, 2004, Merck voluntarily withdrew Vioxx, its arthritis and acute pain medication, from the market worldwide. Although Merck has settled the major portion of the U.S. Product Liability litigation, the Company still faces material litigation arising from the voluntary withdrawal of Vioxx.

In addition to the Vioxx Product Liability Lawsuits and lawsuits from certain states that did not participate in a previously-disclosed settlement, various purported class actions and individual lawsuits have been brought against Merck and several current and former officers and directors of Merck alleging that Merck made false and misleading statements regarding Vioxx in violation of the federal securities laws and state laws (all of these suits are referred to as the "Vioxx Securities Lawsuits"). The Vioxx Securities Lawsuits have been transferred by the Judicial Panel on Multidistrict Litigation to the U.S. District Court for the District of New Jersey before District Judge Stanley R. Chesler for inclusion in a nationwide multidistrict litigation, and have been consolidated for all purposes. Merck has also been named as a defendant in actions in various countries outside the United States. (All of these suits are referred to as the "Vioxx International Lawsuits".)

The Vioxx litigation is discussed more fully in Item 8. "Financial Statements and Supplementary Data," Note 10. "Contingencies and Environmental Liabilities" below. The Company believes that it has meritorious defenses to the Vioxx Product Liability Lawsuits, Vioxx Securities Lawsuits and Vioxx International Lawsuits (collectively, the "Vioxx Litigation") and will vigorously defend against them. The Company's insurance coverage with respect to the Vioxx Litigation will not be adequate to cover its defense costs and any losses.

The Company is not currently able to estimate any additional amounts that it may be required to pay in connection with the Vioxx Litigation. These proceedings are still expected to continue for years and the Company cannot

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predict the course the proceedings will take. In view of the inherent difficulty of predicting the outcome of litigation, 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 not established any material reserves for any potential liability relating to the remaining Vioxx Litigation although it has established reserves related to the settlement of certain Vioxx International Lawsuits and with respect to certain other Vioxx Product Liability Lawsuits, all of which are discussed in Item 8. “Financial Statements and Supplementary Data,” Note 10. “Contingencies and Environmental Liabilities” below.

Unfavorable outcomes in the Vioxx Litigation resulting in the payment of substantial damages could have a material adverse effect on the Company’s business, cash flow, results of operations, financial position and prospects.

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 presence in emerging markets. However, there is no guarantee that the Company’s efforts to expand sales in emerging 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.

For instance, in February 2013, the Venezuelan government devalued its currency. As a result of that devaluation, the Company recognized losses due to exchange. If the Venezuelan government were to devalue its currency again in 2015, the Company would recognize additional losses due to exchange and the Company expects that the impact would be greater than in 2013.

In addition, in China, recent governmental investigations involving other multinational pharmaceutical companies and domestic health care companies and medical institutes adversely affected 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, as such, 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 in Venezuela in 2013.

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

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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.

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.

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 industrial 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



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or the Company's third party providers' databases or systems that could result in financial, legal, business or reputational harm to the Company.

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, there might not be structured processes in place to secure and protect information. Identifying new points of entry as social media continues to expand presents new challenges.

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.

In 2013, the Company voluntarily suspended sales of Zilmax, an animal feed supplement, in the United States and Canada after concerns were raised about cattle that had been fed Zilmax. The suspension materially reduced the sales of Zilmax. The Company can give no assurances as to when sales of Zilmax in the United States and Canada will resume.

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



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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.

### 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.

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- 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 litigation related to Vioxx.
- 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 the Netherlands, 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 10 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 Australia, Canada, Japan, Singapore, South Africa, and other countries in Western Europe, Central and South America, and Asia.

Capital expenditures were \$1.3 billion in 2014, \$1.5 billion in 2013 and \$2.0 billion in 2012. In the United States, these amounted to \$873 million in 2014, \$902 million in 2013 and \$1.3 billion in 2012. Abroad, such expenditures amounted to \$444 million in 2014, \$646 million in 2013 and \$662 million in 2012.

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

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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, 2015)

At the time of the Merger, November 3, 2009, certain executive officers assumed their position in the merged company as noted below.

KENNETH C. FRAZIER — Age 60

December 2011 — Chairman, President and Chief Executive Officer, Merck & Co., Inc.

January 2011 — President and Chief Executive Officer, Merck & Co., Inc.

May 2010 — President, Merck & Co., Inc. — 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, Merck & Co., Inc. from 2007 to 2010.

ADELE D. AMBROSE — Age 58

November 2009 — Senior Vice President and Chief Communications Officer, Merck & Co., Inc. — responsible for the Global Communications organization

ROBERT M. DAVIS — Age 48

April 2014 — Executive Vice President and Chief Financial Officer, Merck & Co., Inc. — 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 59

November 2009 — Executive Vice President and President, Merck Manufacturing Division, Merck & Co., Inc. — responsible for the Company’s global manufacturing, procurement, and distribution and logistics functions

RICHARD R. DELUCA, JR. — Age 52

September 2011 — Executive Vice President and President, Merck Animal Health, Merck & Co., Inc. — 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.

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JULIE GERBERDING — Age 59

January 2015 — Executive Vice President for Strategic Communications, Global Public Policy and Population Health, Merck & Co., Inc. — responsible for Merck’s Global Public Policy, Corporate Responsibility and Global Communications functions

January 2010 — President, Merck Vaccines, Merck & Co., Inc. — 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 48

December 2012 — Executive Vice President and Chief Information Officer, Merck & Co., Inc. — responsible for the Company’s global information technology (IT) organization

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

MIRIAN M. GRADDICK-WEIR — Age 60

November 2009 — Executive Vice President, Human Resources, Merck & Co., Inc. — responsible for the Global Human Resources organization

MICHAEL J. HOLSTON — Age 52

June 2012 — Executive Vice President and Chief Ethics and Compliance Officer, Merck & Co., Inc. — 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 51

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

November 2009 — Assistant Controller, Merck & Co., Inc. - responsible for the global consolidation of the Company’s entities as well as acting as controller for the U.S.-based entities

BRUCE N. KUHLIK — Age 58

November 2009 — Executive Vice President and General Counsel, Merck & Co., Inc. — responsible for the Company’s legal function

ROGER M. PERLMUTTER — Age 62

April 2013 — Executive Vice President and President, Merck Research Laboratories, Merck & Co., Inc. — 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.

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MICHAEL ROSENBLATT, M.D. — Age 67

December 2009 — Executive Vice President and Chief Medical Officer, Merck & Co., Inc. — 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 50

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

November 2009 — President, Global Human Health, U.S. Market-Integration Leader, Merck & Co., Inc. — 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.

As previously announced by the Company, effective July 1, 2015, Michael J. Holston will succeed Bruce N. Kuhlik as the Company's General Counsel.

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.

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## PART II

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

The principal market for trading of the Company's Common Stock is the New York Stock Exchange ("NYSE") under the symbol MRK. 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
2014	\$1.76	\$0.44	\$0.44	\$0.44	\$0.44
2013	\$1.72	\$0.43	\$0.43	\$0.43	\$0.43

## Common Stock Market Prices

	4th Q	3rd Q	2nd Q	1st Q
2014				
High	\$62.20	\$61.33	\$59.84	\$57.65
Low	\$52.49	\$55.57	\$54.40	\$49.30
2013				
High	\$50.42	\$49.08	\$50.16	\$45.42
Low	\$44.62	\$46.03	\$43.77	\$40.83

As of January 31, 2015, there were approximately 141,500 shareholders of record.

Issuer purchases of equity securities for the three months ended December 31, 2014 were as follows:

## Issuer Purchases of Equity Securities

Period	Total Number of Shares Purchased <sup>(1)</sup>	Average Price Paid Per Share	(\$ in millions)
			Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs <sup>(1)</sup>
October 1 — October 31	10,694,800	\$57.07	\$3,685
November 1 — November 30	7,974,000	\$58.88	\$3,215
December 1 — December 31	9,111,700	\$59.28	\$2,675
Total	27,780,500	\$58.31	\$2,675

<sup>(1)</sup> All shares purchased during the period were made as part of a plan approved by the Board of Directors in May 2013 to purchase up to \$15 billion in Merck shares.

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## Performance Graph

The following graph assumes a \$100 investment on December 31, 2009, 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: Abbott Laboratories / AbbVie Inc., Bristol-Myers Squibb Company, Johnson & Johnson, Eli Lilly and Company, and Pfizer Inc.

## Comparison of Five-Year Cumulative Total Return

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

		End of Period Value	2014/2009 CAGR**	
MERCK		\$ 189	14	%
PEER GRP.**		220	17	%
S&P 500		205	15	%

  

	2009	2010	2011	2012	2013	2014
MERCK	100.00	102.86	112.67	127.46	161.63	189.02
PEER GRP.	100.00	99.55	121.01	137.44	187.80	220.29
S&P 500	100.00	115.08	117.49	136.27	180.37	205.00

\*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.

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## Item 6. Selected Financial Data.

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

Merck & Co., Inc. and Subsidiaries

(\$ in millions except per share amounts)

	2014 <sup>(1)</sup>	2013	2012 <sup>(2)</sup>	2011 <sup>(3)</sup>	2010 <sup>(4)</sup>
Results for Year:					
Sales	\$42,237	\$44,033	\$47,267	\$48,047	\$45,987
Materials and production	16,768	16,954	16,446	16,871	18,396
Marketing and administrative	11,606	11,911	12,776	13,733	13,125
Research and development	7,180	7,503	8,168	8,467	11,111
Restructuring costs	1,013	1,709	664	1,306	985
Equity income from affiliates	(257 )	(404 )	(642 )	(610 )	(587 )
Other (income) expense, net	(11,356 )	815	1,116	946	1,304
Income before taxes	17,283	5,545	8,739	7,334	1,653
Taxes on income	5,349	1,028	2,440	942	671
Net income	11,934	4,517	6,299	6,392	982
Less: Net income attributable to noncontrolling interests	14	113	131	120	121
Net income attributable to Merck & Co., Inc.	11,920	4,404	6,168	6,272	861
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	\$4.12	\$1.49	\$2.03	\$2.04	\$0.28
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	\$4.07	\$1.47	\$2.00	\$2.02	\$0.28
Cash dividends declared	5,156	5,132	5,173	4,818	4,730
Cash dividends declared per common share	\$1.77	\$1.73	\$1.69	\$1.56	\$1.52
Capital expenditures	1,317	1,548	1,954	1,723	1,678
Depreciation	2,471	2,225	1,999	2,351	2,638
Average common shares outstanding (millions)	2,894	2,963	3,041	3,071	3,095
Average common shares outstanding assuming dilution (millions)	2,928	2,996	3,076	3,094	3,120
Year-End Position:					
Working capital	\$14,407	\$17,817	\$16,509	\$16,936	\$13,423
Property, plant and equipment, net	13,136	14,973	16,030	16,297	17,082
Total assets	98,335	105,645	106,132	105,128	105,781
Long-term debt	18,699	20,539	16,254	15,525	15,482
Total equity	48,791	52,326	55,463	56,943	56,805
Year-End Statistics:					
Number of stockholders of record	142,000	149,400	157,400	166,100	171,000
Number of employees	70,000	77,000	83,000	86,000	94,000

Amounts for 2014 reflect the divestiture of Merck’s Consumer Care (“MCC”) business on October 1, 2014, including

- (1) 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.
- (2) Amounts for 2012 include a net charge recorded in connection with the settlement of certain shareholder litigation.
- (3) Amounts for 2011 include an arbitration settlement charge.
- (4) Amounts for 2010 include a reserve related to Vioxx litigation and a gain recognized on AstraZeneca’s exercise of its option to acquire certain assets from the Company.





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

Description of Merck's Business

Merck & Co., Inc. ("Merck" or the "Company") is a global health care company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies and animal health products, which it markets directly and through its joint ventures. The Company's operations are principally managed on a products basis and are comprised of three operating segments, which are the Pharmaceutical, Animal Health and Alliances segments, and one reportable segment, which is the Pharmaceutical 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. 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 2014, Merck continued to execute its multi-year initiative to sharpen its commercial and research and development focus, redesign its operating model and reduce its cost base while remaining focused on innovation. The Company received approval for six products in the United States in 2014, including U.S. Food and Drug Administration ("FDA") approval for Keytruda for the treatment of advanced melanoma in patients whose disease has progressed after other therapies, Belsomra for the treatment of insomnia, and Gardasil 9, a nine-valent human papillomavirus ("HPV") vaccine. Merck also enhanced its pipeline with external innovation, including the 2014 acquisitions of Idenix Pharmaceuticals, Inc. ("Idenix"), a company engaged in the discovery and development of next-generation treatments for hepatitis C virus ("HCV"), and OncoEthix, a privately held biotechnology company specializing in oncology drug development. In addition, Merck announced the acquisition of 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, which closed in January 2015. Also, in 2014, Merck entered into a worldwide collaboration with Bayer AG ("Bayer") to market and develop novel therapies for cardiovascular disease and other therapeutic indications.

As part of Merck's prioritization efforts, the Company continued to review its assets to determine whether they could provide the best short- and longer-term value with Merck or elsewhere. As a result, the Company divested its Consumer Care ("MCC") business to Bayer, which provided capital to the Company to better resource its core areas of focus and return cash to shareholders. Merck determined that its Animal Health business remains a key growth driver and is committed to looking for ways to augment this business. As part of its intensified portfolio assessment process, the Company sold the U.S. marketing rights for Saphris, an antipsychotic indicated for the treatment of schizophrenia and bipolar I disorder in adults, and divested certain ophthalmic products in Japan and markets in Europe and Asia Pacific. The Company's portfolio assessment process is ongoing and future divestitures may occur.

Worldwide sales were \$42.2 billion in 2014, a decline of 4% compared with 2013, including a 1% unfavorable effect from foreign exchange. The decline reflects lower revenue resulting from the ongoing impacts of product divestitures and the loss of market exclusivity for several products, as well as the termination of the Company's relationship with AstraZeneca LP ("AZLP") and the divestiture of MCC. In addition, lower sales of products for the treatment of HCV also contributed to the sales decline. These declines were partially offset by growth in immunology, acute care, diabetes, and vaccine products, as well as higher sales from Merck's Animal Health business.

Within the core human pharmaceutical and vaccine business, Merck will continue to support its in-line portfolio, as well as ongoing and upcoming product launches. In 2014, the FDA granted accelerated approval for Keytruda, the Company's anti-PD-1 (programmed death receptor-1) therapy for the treatment of patients with unresectable or

metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor. Keytruda is currently under review in the European Union (the “EU”) for the treatment of

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advanced melanoma. Merck expects to submit a supplemental Biologics License Application (“sBLA”) to the FDA for Keytruda for the treatment of patients with Epidermal Growth Factor Receptor mutation-negative, and Anaplastic Lymphoma Kinase rearrangement-negative non-small-cell lung cancer whose disease has progressed on or following platinum-based chemotherapy in mid-year 2015. Keytruda continues to be studied in more than 30 cancers and in 20 combination settings, and Merck has presented data in a number of different tumor types (see “Research and Development” below).

In addition, the FDA approved Belsomra for the treatment of adults with insomnia who have difficulty falling asleep and/or staying asleep, Gardasil 9, a nine-valent HPV vaccine, and Zontivity, a protease-activated receptor-1 (PAR-1) antagonist for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction or with peripheral arterial disease. Also, in December 2014 prior to the Company’s acquisition of Cubist, the FDA approved Cubist’s Zerbaxa, a new combination product 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.

Additionally, the Company currently has candidates under review with the FDA: MK-8616, Bridion (sugammadex) Injection, a medication for the reversal of two types of neuromuscular blocking agents used during surgery; and V419, an investigational pediatric hexavalent vaccine that the Company is developing in partnership with Sanofi Pasteur designed to help protect against six important diseases - diphtheria, tetanus, pertussis (whooping cough), polio (poliovirus types 1, 2, and 3), invasive disease caused by Haemophilus influenzae type b (Hib), and hepatitis B. In addition, Zerbaxa is under review in the EU.

As a result of prioritizing its research efforts, Merck is focused 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. In 2014, Merck accelerated several of its key clinical programs, positioning the Company for long-term growth. The Company now has more than 10 candidates in Phase 3 clinical development in its core therapeutic areas, as well as other areas with significant potential. MK-5172A, an all-oral combination regimen consisting of MK-5172, grazoprevir, an investigational HCV NS3/4A protease inhibitor, and MK-8742, elbasvir, an investigational HCV NS5A replication complex inhibitor, is currently in Phase 3 clinical trials. The Company expects to file a New Drug Application (“NDA”) with the FDA in the first half of 2015 for MK-5172A. As a result of portfolio prioritization, the Company is out-licensing or discontinuing selected late-stage clinical development assets and reducing its focus on platform technologies. During 2014, the Company out-licensed MK-3222 (tildrakizumab), an investigational treatment for chronic plaque psoriasis, and divested its Sirna Therapeutics, Inc. subsidiary and related RNAi technology assets.

The Company made strong progress in 2014 redesigning its operating model and reducing its cost base. As a result of disciplined cost management, Merck remains on track to achieve its overall savings goal by the end of 2015. As noted above, these savings have enabled the Company to better target its resources to key priorities across the enterprise. Marketing and administrative expenses and Research and development costs were down in 2014 as compared with 2013 reflecting lower selling and promotional spending and lower costs as a result of portfolio prioritization.

In 2013, the Company announced a global restructuring program (the “2013 Restructuring Program”) as part of its global initiative to sharpen its commercial and research and development focus. As part of the program, the Company expects to reduce its total workforce by approximately 8,500 positions. These workforce reductions will primarily come from the elimination of positions in sales, administrative and headquarters organizations, as well as research and development. The Company will also reduce its global real estate footprint and continue to improve the efficiency of its manufacturing and supply network. The Company recorded total pretax costs of \$1.2 billion in both 2014 and 2013 related to this restructuring program. The actions under the 2013 Restructuring Program are expected to be substantially completed by the end of 2015 with the cumulative pretax costs estimated to be approximately \$3.0 billion. The Company expects the actions under the 2013 Restructuring Program to result in annual net cost savings of approximately \$2.0 billion by the end of 2015. The Company anticipates that the actions under the 2013 Restructuring Program, combined with remaining actions under the Merger Restructuring Program (discussed below), will result in annual net cost savings of \$2.5 billion by the end of 2015 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

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streamline the cost structure of the combined company. The workforce reductions associated with this plan relate to the elimination of positions in sales, administrative and headquarters organizations, as well as from 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 \$730 million in 2014, \$1.1 billion in 2013 and \$951 million in 2012 related to this restructuring program. The non-manufacturing related restructuring actions under the Merger Restructuring Program were substantially completed by the end of 2013. The remaining actions under this program relate to ongoing manufacturing facility rationalizations, which are expected to be substantially completed by 2016. The Company expects the estimated total cumulative pretax costs for this program to be approximately \$8.5 billion and to yield annual savings upon completion of the program of approximately \$4.0 billion to \$4.6 billion.

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 of the projected costs associated with the above mentioned restructuring programs, 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 2014, Merck's Board of Directors raised the Company's quarterly dividend to \$0.45 per share from \$0.44 per share. During 2014, the Company returned nearly \$13 billion to shareholders through dividends and share repurchases.

Earnings per common share assuming dilution attributable to common shareholders ("EPS") for 2014 were \$4.07 compared with \$1.47 in 2013. 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 includes an \$11.2 billion gain recognized in connection with the divestiture of MCC. Non-GAAP EPS, which excludes these items, were \$3.49 in both 2014 and 2013 (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 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, and generic drug and animal health care manufacturers. 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 positions 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. The effect on operations of competitive factors and patent disputes cannot be predicted.

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 joint ventures and licenses, 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.

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## 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 \$430 million, \$280 million and \$210 million was recorded by Merck as a reduction to revenue in 2014, 2013 and 2012, 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 2014 and will remain \$3.0 billion in 2015. 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 \$390 million, \$151 million and \$190 million of costs within Marketing and administrative expenses in 2014, 2013 and 2012, respectively, for the annual health care reform fee. The increase in expenses in 2014 reflects final regulations on the annual health care reform fee issued by the Internal Revenue Service (the “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. The full impact of U.S. health care reform cannot be predicted at this time.

The Company also faces increasing pricing pressure globally from managed care organizations, government agencies and programs that could negatively affect the Company’s sales and profit margins. In the United States, these include (i) practices of managed care groups, 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 2014 and the Company anticipates the austerity measures will continue to negatively affect revenue performance in 2015. 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.

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In addition, in Japan, the pharmaceutical industry is subject to government-mandated biennial price reductions of pharmaceutical products and certain vaccines. 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 2015 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.



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### 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. 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 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.

### Operating Results

#### Sales

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, treatments for hypertension. 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 on October 1, 2014. The revenue decline was also driven by lower sales of Victrelis and PegIntron, medicines for the treatment of chronic HCV, Nasonex, an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, and Vytorin, a cholesterol modifying product. These declines were partially offset by growth in Remicade and Simponi, treatments for inflammatory diseases, the diabetes franchise of Januvia/Janumet, Dulera Inhalation Aerosol, a combination medicine for the treatment of asthma, Implanon/Nexplanon, a single-rod subdermal contraceptive implant, as well as higher sales from 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.

Sales in the United States were \$17.1 billion in 2014, a decline of 6% compared with \$18.2 billion in 2013. The sales decrease was driven primarily by the termination of the Company's relationship with AZLP, the divestiture of MCC and the ongoing impact of product divestitures. In addition, the decline reflects lower sales of Temodar, Victrelis, Vytorin and Nasonex, partially offset by higher sales of Dulera Inhalation Aerosol, the Januvia/Janumet franchise and Implanon/Nexplanon, as well as by the revenue recognized in connection with the sale of the U.S. marketing rights to Saphris.

International sales were \$25.2 billion in 2014, a decline of 2% compared with \$25.8 billion in 2013. Foreign exchange unfavorably affected international sales performance by 2% in 2014. The sales decrease reflects the divestiture of MCC. The decline was also driven by lower sales in the Pharmaceutical segment, reflecting declines in Japan, Europe and Canada. Sales in Japan declined 14% in 2014, to \$3.4 billion, of which 8% was due to the unfavorable effect of foreign exchange. The sales decline was largely driven by the biennial price reductions and repricings that occurred in 2014, product divestitures and the ongoing impacts of the loss of the market exclusivity for several products, including

Cozaar and Hyzaar, as well as lower sales of Gardasil, a vaccine to help prevent certain diseases caused by four types of HPV, reflecting the Japanese government's decision in 2013 to suspend proactive recommendation of HPV vaccines, partially offset by higher sales of Pneumovax 23, a vaccine to help prevent pneumococcal disease. Sales in Europe and

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Canada declined 2% in 2014, to \$10.4 billion, including a 1% favorable effect from foreign exchange reflecting lower sales of Singulair, Nasonex and Victrelis, as well as from product divestitures and ongoing generic erosion and fiscal austerity measures in this region, partially offset by growth in Simponi, Remicade, Janumet and Januvia. Sales in the emerging markets were \$7.8 billion in 2014, essentially flat compared with 2013, including a 5% unfavorable effect from foreign exchange, reflecting higher sales of vaccine, acute care, and diabetes products, offset by lower sales of HCV products, as well from product divestitures. Total international sales represented 60% and 59% of total sales in 2014 and 2013, 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 2014. The Company anticipates these pricing actions and other austerity measures will continue to negatively affect revenue performance in 2015.

In October 2013, the Company sold its active pharmaceutical ingredient ("API") manufacturing business in the Netherlands 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 and divested certain ophthalmic products in several international markets (most of which closed on July 1, 2014). On October 1, 2014, the Company sold its MCC business to Bayer including the prescription rights to Claritin and Afrin. 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, as discussed in Note 8 to the consolidated financial statements, 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 which resulted in a sales decline of approximately \$450 million in the Alliances segment.

Worldwide sales totaled \$44.0 billion in 2013, a decline of 7% compared with \$47.3 billion in 2012. The sales decline was driven primarily by lower sales of Singulair. The patents that provided U.S. market exclusivity and market exclusivity in a number of major European markets for Singulair expired in August 2012 and February 2013, respectively, and the Company experienced a significant and rapid decline in Singulair sales in those markets thereafter. Foreign exchange unfavorably affected global sales performance by 2% in 2013. The revenue decline in 2013 was also driven by lower sales of Maxalt, a product for the acute treatment of migraine, Cozaar and Hyzaar, Temodar, Clarinex, a non-sedating antihistamine, PegIntron, Propecia, a product for male pattern hair loss, Fosamax, for the treatment osteoporosis, and Vytarin. These declines were partially offset by growth in Gardasil, Remicade, Simponi, Janumet, Isentress, a treatment for HIV-1 infection, Dulera Inhalation Aerosol, and Zostavax, a vaccine to help prevent shingles (herpes zoster).

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Sales of the Company's products were as follows:

(\$ in millions)	2014	2013	2012
Primary Care and Women's Health			
Cardiovascular			
Zetia	\$2,650	\$2,658	\$2,567
Vytorin	1,516	1,643	1,747
Diabetes			
Januvia	3,931	4,004	4,086
Janumet	2,071	1,829	1,659
General Medicine and Women's Health			
NuvaRing	723	686	623
Implanon/Nexplanon	502	403	348
Dulera	460	324	207
Follistim AQ	412	481	468
Hospital and Specialty			
Hepatitis			
PegIntron	381	496	653
Vitreolis	153	428	502
HIV			
Isentress	1,673	1,643	1,515
Acute Care			
Cancidas	681	660	619
Invanz	529	488	445
Noxafil	402	309	258
Bridion	340	288	261
Primaxin	329	335	384
Immunology			
Remicade	2,372	2,271	2,076
Simponi	689	500	331
Other			
Cosopt/Trusopt	257	416	444
Oncology			
Emend	553	507	489
Temodar	350	708	917
Keytruda	55	—	—
Diversified Brands			
Respiratory			
Nasonex	1,099	1,335	1,268
Singulair	1,092	1,196	3,853
Clarinet	232	235	393
Other			
Cozaar/Hyzaar	806	1,006	1,284
Arcoxia	519	484	453
Fosamax	470	560	676
Propecia	264	283	424
Zocor	258	301	383
Remeron	193	206	232
Vaccines <sup>(1)</sup>			
Gardasil	1,738	1,831	1,631

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ProQuad/M-M-R II/Varivax	1,394	1,306	1,273
Zostavax	765	758	651
Pneumovax 23	746	653	580
RotaTeq	659	636	601
Other pharmaceutical <sup>(2)</sup>	4,778	5,570	6,300
Total Pharmaceutical segment sales	36,042	37,437	40,601
Other segment sales <sup>(3)</sup>	5,585	6,325	6,412
Total segment sales	41,627	43,762	47,013
Other <sup>(4)</sup>	610	271	254
	\$42,237	\$44,033	\$47,267

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. These amounts do, however, reflect supply sales to Sanofi Pasteur MSD.

<sup>(2)</sup> Other pharmaceutical primarily reflects sales of other human health pharmaceutical products, including products within the franchises not listed separately.

<sup>(3)</sup> Represents the non-reportable segments of Animal Health and Alliances, 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.

Other revenues are primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, sales related to divested products or businesses, and other supply sales not included in segment results. Other <sup>(4)</sup> revenues in 2014 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. Other revenues also include third-party manufacturing sales, a substantial portion of which was divested in October 2013.



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## 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 \$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 Zetia in Canada where it lost market exclusivity. Combined worldwide sales of Zetia and Vytorin were \$4.3 billion in 2013, essentially flat as compared with 2012 including a 1% unfavorable impact from foreign exchange, reflecting higher sales of Zetia in the United States due to pricing, partially offset by lower volumes of Vytorin in the United States.

In November 2014, Merck announced that the investigational IMPROVE-IT study met its primary and all secondary composite efficacy endpoints. In IMPROVE-IT, patients taking Vytorin - which combines simvastatin with Zetia (ezetimibe) - 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. Merck plans to submit the data from IMPROVE-IT to the FDA in mid-2015 to support a new indication for reduction of major 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.

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 Zetia 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 Vytorin in those markets until April 2019.

For business reasons, the Company has no plans at this time to reintroduce Liptruzet to the U.S. market. The Company has not supplied Liptruzet in the United States since its January 2014 voluntary recall of that product due to packaging defects. The two active ingredients in Liptruzet remain available: Zetia from Merck, and atorvastatin as a generic from multiple manufacturers.

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 European Commission (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 launch Zontivity in the EU in late 2015 or early 2016.

## 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 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 dipeptidyl peptidase-4 ("DPP-4") inhibitors, including Januvia, were subject to repricing in Japan. Combined global sales of Januvia and Janumet were \$5.8 billion in 2013, an increase of 2% compared with 2012 including a 3% unfavorable effect from foreign exchange. The sales growth reflects higher volumes outside of the United States.

The Trial Evaluating Cardiovascular Outcomes with Sitagliptin ("TECOS"), an event-driven, cardiovascular outcomes study with sitagliptin, began in 2008 and enrolled over 14,000 patients. TECOS will evaluate the impact of sitagliptin on cardiovascular outcomes when added to usual care compared to usual care without sitagliptin in a large, high-risk type 2 diabetes population across multiple countries. TECOS is expected to be completed in the first quarter of 2015

and the Company expects that the results of TECOS will be presented at the annual scientific meeting of the

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American Diabetes Association in June 2015. If the results of the TECOS trial show a negative effect on cardiovascular outcomes or reveal another safety issue related to the use of sitagliptin, that could have a material adverse effect on the sales of Januvia and Janumet/Janumet XR.

### General Medicine and Women's Health

Worldwide sales of NuvaRing, a vaginal contraceptive product, were \$723 million in 2014, an increase of 5% compared with 2013 including a 1% unfavorable impact from foreign exchange, largely reflecting higher pricing in the United States. Global sales of NuvaRing were \$686 million in 2013, an increase of 10% compared with 2012, primarily reflecting volume growth and favorable pricing in the United States.

Worldwide sales of Implanon/Nexplanon, a single-rod subdermal contraceptive implant, grew 25% to \$502 million in 2014 compared with 2013 driven primarily by higher demand in the United States. Implanon/Nexplanon sales increased 16% to \$403 million in 2013 compared with 2012 driven primarily by volume growth in the United States that was partially offset by declines in the emerging markets from pricing pressures.

Global sales of Dulera Inhalation Aerosol, a combination medicine for the treatment of asthma, were \$460 million in 2014, \$324 million in 2013 and \$207 million in 2012 reflecting higher demand in the United States. Dulera Inhalation Aerosol was approved by the FDA in June 2010.

Global sales of Follistim AQ (marketed in most countries outside the United States as Puregon), a fertility treatment, 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. Sales of Follistim AQ grew 3% to \$481 million in 2013 compared with 2012 driven largely by positive performance in the United States. The patent that provides market exclusivity for Follistim AQ in the United States expires in June 2015.

In August 2014, Merck announced that the FDA approved Belsomra (suvorexant) for the treatment of adults with insomnia who have difficulty falling asleep and/or staying asleep. Belsomra became available in the United States in early 2015. Following receipt of marketing approval, Belsomra was launched in Japan in November 2014. The Company is continuing with plans to seek approval for suvorexant in other countries around the world.

In April 2014, Merck announced that the FDA approved Grastek and Ragwitek tablets for sublingual use. Grastek is an allergen extract indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy Grass or cross-reactive grass pollens. Grastek is approved for use in persons 5 through 65 years of age. Ragwitek is an allergen extract indicated as immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen. Ragwitek is approved for use in adults 18 through 65 years of age. Neither Grastek nor Ragwitek is indicated for the immediate relief of allergic symptoms. The prescribing information for Grastek and Ragwitek includes a boxed warning regarding severe allergic reactions. Both Grastek and Ragwitek, as well as an ongoing Phase 3 program for sublingual immunotherapy tablets for allergic rhinitis associated with house dust mites, are part of a North America partnership between Merck and ALK-Abello.

### Hospital and Specialty

#### Hepatitis

Worldwide sales of PegIntron, a treatment for chronic HCV, were \$381 million in 2014, a decline of 23% compared with 2013, driven by lower volumes in most regions as the availability of new therapeutic options has resulted in loss of market share or led to patient treatment delays in markets anticipating the availability of new therapeutic options. Foreign exchange unfavorably affected global sales performance by 3% in 2014. Global sales of PegIntron declined 24% to \$496 million in 2013 compared with 2012 reflecting declines in all regions that were attributable in part to patient treatment being delayed by health care providers in anticipation of new therapeutic options becoming available. Foreign exchange unfavorably affected global sales performance by 3% in 2013.

Global sales of Victrelis, an oral medicine for the treatment of chronic HCV, 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 new therapeutic options has resulted in loss of market share or led to patient treatment delays in markets anticipating the availability of new therapeutic options. Worldwide sales of Victrelis were \$428 million in 2013, a

decline of 15% compared with 2012 including a 1% unfavorable effect from foreign exchange. Sales declines

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in the United States, Europe and Canada were partially offset by growth across the emerging markets. The sales declines in the United States, Europe and Canada were attributable in part to patient treatment being delayed by health care providers in anticipation of new therapeutic options becoming available.

Sales of the Company's products indicated for treatment of chronic HCV including Victrelis and PegIntron discussed above, as well as Rebetol, continue to be adversely affected by new therapeutic options becoming available. During 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 impairment charges of \$793 million related to PegIntron, \$244 million related to Victrelis and \$35 million related to Rebetol recorded within Materials and production costs in 2014. Sales of these products were adversely affected in 2013 by patient treatment being delayed by health care providers in anticipation of new therapeutic options becoming available. Sales of Rebetol, a product sold almost entirely in international markets, were particularly adversely affected by this trend given the markets where Rebetol is sold, as well as from generic competition. During 2013, the Company recorded an impairment charge of \$156 million on the Rebetol intangible asset. In the event future circumstances arise that significantly reduce current cash flow projections for these products, the Company may record additional intangible asset impairment charges in the future. The carrying value of the intangible assets related to these products was \$96 million in the aggregate at December 31, 2014.

Following receipt of market approval, Vanihep, an oral twice-daily protease inhibitor for the treatment of chronic HCV was launched in Japan in November 2014. Vanihep will be available only in Japan.

**HIV**

Worldwide sales of Isentress, an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, 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. Global sales of Isentress grew 8% to \$1.6 billion in 2013 compared with 2012 driven primarily by volume growth in the United States and Europe. Foreign exchange unfavorably affected global sales performance by 1% in both 2014 and 2013.

**Acute Care**

Global sales of Cancidas, an anti-fungal product, increased 3% in 2014 to \$681 million compared with 2013 largely reflecting volume growth in the Asia Pacific region, particularly in China. Sales of Cancidas increased 7% to \$660 million in 2013 compared with 2012 reflecting growth in most emerging markets, as well as in Europe and Japan. Worldwide sales of Noxafil, for the prevention of invasive fungal infections, grew 30% in 2014 to \$402 million and increased 20% in 2013 to \$309 million driven by volume growth in the United States and Europe reflecting a positive impact from the approval of new formulations.

Bridion, for the reversal of two types of neuromuscular blocking agents used during surgery, is approved and has been launched in many countries outside of the United States. Sales of Bridion rose 18% in 2014 to \$340 million compared with 2013 driven by volume growth in all markets. Foreign exchange unfavorably affected global sales performance by 6% in 2014. Sales of Bridion were \$288 million in 2013, an increase of 10% compared with 2012. The sales growth was driven by volume growth in Europe, the emerging markets and Japan, partially offset by a 13% unfavorable effect of foreign exchange primarily on sales in Japan. In September 2013, the Company received a CRL from the FDA for the resubmission of the NDA for Bridion. To address the CRL, the Company conducted a new hypersensitivity study and, in October 2014, resubmitted the NDA to the FDA. The Company anticipates an FDA advisory committee meeting will be held on March 18, 2015 to review Bridion. If approved, the Company expects to launch Bridion in the United States later in 2015.

In January 2015, Merck acquired 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. Cubist's products include Cubicin, an I.V. antibiotic for complicated skin and skin structure infections or bacteremia, when caused by



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designated susceptible organisms, Zerbaxa, a combination product recently approved by the FDA 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 for the treatment of acute bacterial skin and skin structure infections (“ABSSSI”) in adults caused by designated susceptible Gram-positive organisms. Both Zerbaxa and Sivextro are under review in the EU.

**Immunology**

Sales of Remicade, a treatment for inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), 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 Remicade were \$2.3 billion in 2013, an increase of 9% compared with 2012 including a 2% favorable effect from foreign exchange. Sales growth reflects volume growth in Europe, as well as Russia. In September 2013, the EC approved an infliximab biosimilar. While the Company is experiencing biosimilar competition in certain smaller European markets, the Company anticipates a more substantial decline in Remicade sales following loss of market exclusivity in major European markets in February 2015. Additionally, the Company anticipates mandatory price reductions in certain European markets.

Sales of Simponi, a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), 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. In September 2013, the EC approved Simponi for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy or who are intolerant to or have medical contraindications for such therapies. Sales of Simponi were \$500 million in 2013 compared with \$331 million in 2012 driven by continued launch activities.

**Other**

Worldwide sales of ophthalmic products Cosopt and Trusopt declined 38% in 2014 to \$257 million compared with 2013 driven largely by the divestiture of Cosopt and Trusopt in many international markets in 2014 and the sale of the U.S. rights to Cosopt and Cosopt PF in 2013 as discussed below. Sales of Cosopt and Trusopt were \$416 million in 2013, a decline of 6% compared with 2012, reflecting a 7% unfavorable effect from foreign exchange and lower sales in Europe and Canada due to generic competition, partially offset by volume growth in Japan.

In November 2013, Merck sold the U.S. rights to ophthalmic products Cosopt and Cosopt PF (as well as AzaSite through the sale of its Inspire Pharmaceuticals, Inc. subsidiary) to Akorn, Inc (“Akorn”). Also, as noted above, in May 2014, Merck entered into an agreement to sell certain ophthalmic products, including Cosopt and Trusopt, to Santen in Japan and markets in Europe and Asia Pacific. The transaction closed in most markets on July 1, 2014. The remaining markets closed on October 1, 2014. Merck continues to sell its ophthalmic products in markets not included in the transactions with Santen and Akorn.

Merck’s sales of Saphris (asenapine), an antipsychotic indicated for the treatment of schizophrenia and bipolar I disorder in adults, were \$84 million in 2014, \$158 million in 2013 and \$166 million in 2012. In January 2014, Merck sold the U.S. marketing rights to Saphris to Forest Laboratories, Inc. (“Forest”). Under the terms of the agreement, Forest made upfront payments of \$232 million, which are reflected in Sales in 2014, and will make additional payments to Merck based on defined sales milestones. In addition, as part of this transaction, Merck has agreed to supply product to Forest (subsequently acquired by Actavis plc) until patent expiry. Asenapine, sold under the brand name Sycrest, is also approved in the EU for the treatment of bipolar I disorder in adults. Under a commercialization agreement for Sycrest sublingual tablets (5 mg, 10 mg), H. Lundbeck A/S makes product supply payments in exchange for exclusive commercial rights to Sycrest in all markets outside the United States, China and Japan. During 2013, the Company recorded an impairment charge on the Saphris/Sycrest intangible asset (see Note 7 to the consolidated financial statements).

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

**Oncology**

Global sales of Emend, for the prevention of chemotherapy-induced and post-operative nausea and vomiting, 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. Sales of Emend were \$507 million in 2013, an increase



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of 4% compared with 2012 including a 1% unfavorable effect from foreign exchange, largely reflecting volume growth in the United States and the emerging markets, partially offset by a decline in Japan.

Sales of Temodar (marketed as Temodal outside the United States), a treatment for certain types of brain tumors, declined 51% to \$350 million in 2014 and decreased 23% to \$708 million in 2013. Foreign exchange unfavorably affected global sales performance by 3% in both 2014 and 2013. The sales declines were driven primarily by generic competition in the United States, as well as in Europe. As previously disclosed, 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. Temodar lost patent exclusivity in the EU in 2009. Accordingly, the Company is experiencing sales declines due to the loss of exclusivity in these markets and the Company expects these declines to continue.

In September 2014, Merck announced that 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. Keytruda is the first anti-PD-1 (programmed death receptor-1) therapy approved in the United States. In June 2014, Merck announced the European Medicines Agency (the “EMA”) accepted for review a Marketing Authorization Application (“MAA”) for Keytruda for the treatment of advanced melanoma. The Company has made additional regulatory filings in other countries and further filings are planned. In December 2014, the Company estimates 2,000 patients were receiving treatment with Keytruda. Sales of Keytruda were \$55 million in 2014.

The Keytruda clinical development program also includes studies across a broad range of cancer types (see “Research and Development” below). In October 2014, Keytruda was granted Breakthrough Therapy Designation by the FDA for the treatment of patients with Epidermal Growth Factor Receptor mutation-negative, and Anaplastic Lymphoma Kinase rearrangement-negative non-small-cell lung cancer whose disease has progressed on or following platinum-based chemotherapy. The Company anticipates submitting an sBLA to the FDA in mid-2015 for Keytruda.

#### 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

Global sales of Nasonex, an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, declined 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 from generic competition. 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 several of these markets. Accordingly, the Company experienced a rapid decline in Nasonex sales in Europe in 2014 and expects the decline to continue. Sales of Nasonex increased 5% to \$1.3 billion in 2013 compared with 2012 driven primarily by increases in the United States, reflecting net favorable adjustments to indirect customer discounts, as well as by volume growth in Japan, partially offset by declines in Latin America, Canada and Europe. Foreign exchange unfavorably affected global sales performance by 3% in 2013. 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. If Apotex’s generic version becomes available, significant losses of U.S. Nasonex sales could occur and the Company may take a non-cash impairment charge with respect to the carrying value of the Nasonex intangible asset, which was \$719 million at December 31, 2014. If the Nasonex intangible asset is determined to be impaired, the impairment charge could be material. U.S. sales of Nasonex were \$577 million in 2014.

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 \$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.

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The patents that provided market exclusivity for Singulair expired in a number of major European markets in February 2013 and the Company experienced significant and rapid declines in sales of Singulair in those markets following the patent expiries and expects the declines to continue. Global sales of Singulair fell 69% to \$1.2 billion in 2013 compared with 2012 driven primarily by lower sales in the United States and Europe as a result of generic competition. The patent that provided U.S. market exclusivity for Singulair expired in August 2012. The patent that provides market exclusivity for Singulair in Japan will expire in 2016. Singulair sales in Japan were \$537 million in 2014.

Global sales of Cozaar and its companion agent Hyzaar (a combination of Cozaar and hydrochlorothiazide), treatments for hypertension, declined 20% in 2014 to \$806 million and decreased 22% in 2013 to \$1.0 billion. Foreign exchange unfavorably affected global sales performance by 4% and 8% in 2014 and 2013, 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 significant declines in Cozaar and Hyzaar sales and expects the declines to continue.

Worldwide sales of 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, decreased 16% in 2014 to \$470 million and declined 17% in 2013 to \$560 million driven by declines in all regions. These medicines have lost market exclusivity in the United States and in most major international markets. The Company expects the sales declines within the Fosamax product franchise to continue.

Other products contained in Diversified Brands include among others, Clarinex, a non-sedating antihistamine; Arcoxia for the treatment of arthritis and pain; Propecia, a product for the treatment of male pattern hair loss, Zocor, a statin for modifying cholesterol; and Remeron, an antidepressant.

**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 (see “Selected Joint Venture and Affiliate Information” below). Supply sales to SPMSD, however, are included.

Merck’s sales of Gardasil, a vaccine to help prevent certain diseases caused by four types of HPV, 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. Merck’s sales of Gardasil grew 12% to \$1.8 billion in 2013 compared with 2012 driven primarily by volume growth in the United States, reflecting continued uptake in both males and females, and volume growth in Latin America, partially offset by lower volumes in Japan. Sales in 2014, 2013 and 2012 included \$56 million, \$37 million and \$44 million, respectively, of purchases for the U.S. Centers for Disease Control and Prevention (“CDC”) Pediatric Vaccine Stockpile. In June 2013, the Japanese Health Ministry issued an advisory to suspend active promotion of HPV vaccines. The Company is a party to certain third-party license agreements with respect to Gardasil (including a cross-license and settlement agreement with GlaxoSmithKline). As a result of these agreements, the Company pays royalties on worldwide Gardasil sales of 19% to 27% which vary by country and are included in Materials and production costs. In December 2014, the Company announced that the FDA approved Gardasil 9, Merck’s 9-valent HPV vaccine, for use in girls and young women 9 to 26 years of age for the prevention of cervical, vulvar, vaginal, and anal cancers caused by HPV types 16, 18, 31, 33, 45, 52 and 58, pre-cancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58, and genital warts caused by HPV types 6 and 11. Gardasil 9 is also approved for use in boys 9 to 15 years of age for the prevention of anal cancer caused by HPV types 16, 18, 31, 33, 45, 52 and 58, precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58, and genital warts caused by HPV types 6 and 11. Gardasil 9 includes the greatest number of HPV types in any available HPV vaccine.

Merck’s sales of ProQuad, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, were \$395 million in 2014, \$314 million in 2013 and \$61 million in 2012. 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. Sales of ProQuad in 2012 were affected by supply

constraints. ProQuad became available again in the United States for ordering in October 2012.

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Merck's sales of Varivax, a vaccine to help prevent chickenpox (varicella), were \$672 million in 2014, \$684 million in 2013 and \$846 million in 2012. Sales performance in 2014 reflects lower sales in the United States largely offset by growth in the emerging markets. Merck's sales of M-M-R II, a vaccine to help protect against measles, mumps and rubella, were \$326 million in 2014, \$307 million in 2013 and \$365 million in 2012. Sales of Varivax and M M R II declined in 2013 as compared with 2012 due to the availability of ProQuad discussed above.

Merck's sales of Zostavax, a vaccine to help prevent shingles (herpes zoster) in adults 50 years of age and older, 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's sales of Zostavax grew 16% to \$758 million in 2013 compared with 2012 driven by higher demand in the United States and Canada, as well as by launches within the Asia Pacific region. Merck is continuing to launch Zostavax outside of the United States.

Merck's sales of Pneumovax 23, a vaccine to help prevent pneumococcal disease, 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 3% in 2014. Merck's sales of Pneumovax 23 increased 13% in 2013 to \$653 million compared with 2012 driven primarily by volume growth in the emerging markets, as well as volume and price increases in the United States.

Merck's sales of RotaTeq, a vaccine to help protect against rotavirus gastroenteritis in infants and children, increased 4% in 2014 to \$659 million compared with 2013 primarily reflecting higher sales in certain emerging markets. Merck's sales of RotaTeq grew 6% in 2013 to \$636 million compared with 2012 reflecting higher pricing in the United States and volume growth in Japan.

### Other Segments

The Company's other segments are the Animal Health and Alliances segments, which are not material for separate reporting. Prior to its disposition on October 1, 2014, the Company also had a Consumer Care segment.

### 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 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. In August 2013, Merck Animal Health voluntarily suspended sales of Zilmax, a feed supplement for beef cattle, in the United States and Canada.

In May 2014, Merck announced that the FDA approved Bravecto chewable tablets for dogs to treat fleas and ticks. Bravecto is the first and only treatment that has been shown to quickly and effectively kill fleas and multiple tick species for 12 weeks in a single dose. Bravecto also is effective for eight weeks against *Amblyomma americanum* ticks. In addition, Bravecto has been approved and launched in approximately 30 countries outside of the United States.

Global sales of Animal Health products were \$3.4 billion in 2013, a decline of 1% compared with 2012 including a 2% unfavorable effect from foreign exchange. The sales decline reflects lower sales of ruminant products, primarily Zilmax, partially offset by growth in companion animal and poultry products. The suspension of Zilmax unfavorably affected Animal Health sales by 4% in 2014 and by 2% in 2013.

### 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



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Affiliate Information” below). Revenue from AZLP, primarily relating to sales of Nexium and Prilosec, was \$463 million in 2014 through the termination date on June 30, 2014, \$920 million in 2013 and \$915 million in 2012.

**Consumer Care**

As noted above, on October 1, 2014, the Company divested its Consumer Care segment. Consumer Care products included over-the-counter, foot care and sun care products. Global sales of Consumer Care were \$1.5 billion in 2014, \$1.9 billion in 2013 and \$2.0 billion in 2012.

**Costs, Expenses and Other**

(\$ in millions)	2014	Change	2013	Change	2012
Materials and production	\$16,768	-1	% \$16,954	3	% \$16,446
Marketing and administrative	11,606	-3	% 11,911	-7	% 12,776
Research and development <sup>(1)</sup>	7,180	-4	% 7,503	-8	% 8,168
Restructuring costs	1,013	-41	% 1,709	*	664
Equity income from affiliates	(257 )	-36	% (404 )	-37	% (642 )
Other (income) expense, net	(11,356 )	*	815	-27	% 1,116
	\$24,954	-35	% \$38,488	—	% \$38,528

\* 100% or greater.

(1) Includes \$49 million, \$279 million and \$200 million of IPR&D impairment charges in 2014, 2013 and 2012, respectively.

**Materials and Production**

Materials and production costs were \$16.8 billion in 2014, \$17.0 billion in 2013 and \$16.4 billion in 2012. Costs include expenses for the amortization of intangible assets recorded in connection with mergers and acquisitions which totaled \$4.2 billion in 2014, \$4.7 billion in 2013 and \$4.9 billion in 2012. Costs in 2014 and 2013 include intangible asset impairment charges of \$1.1 billion and \$486 million, respectively, related to marketed products (see Note 7 to the consolidated financial statements). The Company may recognize additional non-cash impairment charges in the future related to product intangibles that were measured at fair value and capitalized in connection with mergers and 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 were costs associated with restructuring activities which amounted to \$482 million, \$446 million and \$188 million in 2014, 2013 and 2012, 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 60.3% in 2014 compared with 61.5% in 2013 and 65.2% in 2012. The amortization of intangible assets, as well as the restructuring and impairment charges noted above reduced gross margin by 13.6 percentage points in 2014, 12.8 percentage points in 2013 and 10.7 percentage points in 2012. Excluding these impacts, 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. The gross margin decline in 2013 as compared with 2012 was driven in part by the loss of Singulair sales as result of patent expiries in the United States in August 2012 and in major European markets in February 2013. In addition, generic competition in the United States coupled with changes in product mix and continued pricing pressures in mature markets also negatively affected gross margin in 2013 as compared with 2012.

**Marketing and Administrative**

Marketing and administrative expenses declined 3% in 2014 to \$11.6 billion driven primarily by lower selling costs and promotional spending, the divestiture of MCC and the favorable effect of foreign exchange, partially offset by an additional year of expense related to the health care reform fee as discussed below, as well as higher acquisition and divestiture-related costs. Marketing and administrative expenses decreased 7% in 2013 to \$11.9 billion largely due to lower promotional spending and selling costs resulting from restructuring activities, and also reflecting the favorable effect of foreign exchange. Expenses for 2014, 2013 and 2012 include restructuring costs of \$200 million, \$145 million and \$90 million, respectively, related primarily to accelerated depreciation for facilities to be closed or





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divested. Separation costs associated with sales force reductions have been incurred and are reflected in Restructuring costs as discussed below. Expenses also include \$234 million, \$94 million and \$272 million of acquisition and divestiture-related costs in 2014, 2013 and 2012, respectively, consisting of incremental, third-party integration costs related to the Merger, including costs related to legal entity and systems integration, as well as transaction and certain other costs related to business acquisitions and 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 \$7.2 billion in 2014, \$7.5 billion in 2013 and \$8.2 billion in 2012. 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 \$3.7 billion in 2014, \$4.2 billion in 2013 and \$4.5 billion in 2012. 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, certain costs from operating segments, including the Pharmaceutical and Animal Health segments, as well as the Consumer Care segment until its divestiture on October 1, 2014, which in the aggregate were \$2.8 billion, \$2.9 billion and \$3.4 billion for 2014, 2013 and 2012, respectively. Costs for 2014 include an \$85 million charge related to a collaboration with Bayer (see Note 4 to the consolidated financial statements). The declines in research and development costs were driven by cost savings resulting from restructuring activities, targeted reductions and lower clinical development spend as a result of portfolio prioritization. The decline in these research and development expenses in 2013 as compared with 2012 also reflects lower payments for licensing activity.

Research and development expenses also include acquired in-process research and development ("IPR&D") impairment charges of \$49 million, \$279 million and \$200 million in 2014, 2013 and 2012, 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 mergers and acquisitions and such charges could be material. Also, during 2014, the Company recorded a charge of \$316 million to increase the estimated fair value of a liability for contingent consideration related to research projects obtained in connection with the acquisition of a business in a prior year (see Note 5 to the consolidated financial statements). Research and development expenses in 2014, 2013 and 2012 reflect \$283 million, \$101 million and \$57 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 \$1.0 billion, \$1.7 billion and \$664 million in 2014, 2013 and 2012, respectively. Costs in 2014 and 2013 include \$594 million and \$898 million, respectively, of costs related to the 2013 Restructuring Program. The remaining costs in 2014 and nearly all of the remaining costs recorded in 2013 and the costs recorded in 2012 related to the Merger Restructuring Program. In 2014, 2013 and 2012, separation costs of \$674 million, \$1.4 billion and \$489 million, respectively, were incurred associated with actual headcount reductions, as well as estimated expenses under existing severance programs for headcount reductions that were probable and could be reasonably estimated. Positions eliminated under the 2013 Restructuring Program were approximately 4,555 in 2014 and 1,540 in 2013. Positions eliminated under the Merger Restructuring Program were approximately 1,530 in 2014, 4,475 in 2013 and 3,975 in 2012. 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.

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## Equity Income from Affiliates

Equity income from affiliates, which reflects the performance of the Company's joint ventures and other equity method affiliates, declined 36% in 2014 to \$257 million compared with 2013. The decline was driven primarily by the termination of the Company's relationship with AZLP. As discussed below, on June 30, 2014, AstraZeneca exercised its option to purchase Merck's interest in a subsidiary and, through it, Merck's interest in Nexium and Prilosec. Effective July 1, 2014, the Company no longer records equity income from AZLP. (See "Selected Joint Venture and Affiliate Information" below.) Equity income from affiliates declined 37% in 2013 to \$404 million compared with 2012 driven primarily by lower equity income from AZLP, partially offset by higher equity income from SPMSD.

## Other (Income) Expense, Net

Other (income) expense, net was \$11.4 billion of income in 2014 compared with \$815 million of expense in 2013 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 sale 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 Sirna (see Note 4 to the consolidated financial statements), as well as by lower exchange losses in 2014 due to a Venezuelan currency devaluation in 2013 (see Note 14 to the consolidated financial statements). Partially offsetting the favorability of these items was a \$628 million loss on extinguishment of debt in 2014 (see Note 9 to the consolidated financial statements) and a \$93 million goodwill impairment charge related to the Company's joint venture with Supera (see Note 4 to the consolidated financial statements).

Other (income) expense, net was \$815 million of expense in 2013 compared with \$1.1 billion of expense in 2012 reflecting a \$493 million net charge in 2012 relating to the settlement of certain shareholder litigation (the "ENHANCE Litigation"), partially offset by higher exchange losses in 2013 driven by \$140 million of exchange losses related to a Venezuelan currency devaluation, as well as higher interest expense in 2013 resulting in part from issuances of debt in September 2012 and May 2013.

## Segment Profits

(\$ in millions)	2014	2013	2012
Pharmaceutical segment profits	\$22,164	\$22,983	\$25,852
Other non-reportable segment profits	2,546	3,094	3,163
Other	(7,427)	(20,532)	(20,276)
Income before income taxes	\$17,283	\$5,545	\$8,739

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 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 in 2014 gains on divestitures (including MCC), the gain on AstraZeneca's option exercise, the loss on extinguishment of debt and an additional year of expense related to the health care reform fee, as well as the charge recorded in 2012 related to the settlement of the ENHANCE Litigation 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, divested products or businesses, and other supply sales.

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. Pharmaceutical segment profits declined 11% in 2013 compared with 2012 driven primarily by the effects of the loss of market exclusivity for certain products, particularly Singulair. The decline in other segment

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profits in 2014 as compared with 2013 was driven primarily by 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 30.9% in 2014, 18.5% in 2013 and 27.9% in 2012 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 2014 reflects the impact of the gain on the divestiture of MCC being taxed at combined U.S. federal and state tax rates. 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 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 effective tax rate for 2012 also reflects the favorable impacts of a tax settlement with the Canada Revenue Agency (the "CRA"), the realization of foreign tax credits and the impact of a favorable ruling on a state tax matter. In addition, the 2012 effective tax rate reflects the unfavorable impact of the net charge recorded in connection with the settlement of the ENHANCE Litigation for which no tax benefit was recorded and does not reflect any impacts for the R&D tax credit, which expired on December 31, 2011. As a result of legislation passed in 2013 that extended the R&D tax credit, both the 2012 and 2013 R&D tax credits were recognized in 2013 as noted above.

**Net Income Attributable to Noncontrolling Interests**

Net income attributable to noncontrolling interests was \$14 million in 2014, \$113 million in 2013 and \$131 million in 2012. The decline in 2014 reflects the termination of the Company's relationship with AZLP (see Note 8 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 that are attributable to noncontrolling interests.

**Net Income and Earnings per Common Share**

Net income attributable to Merck & Co., Inc. was \$11.9 billion in 2014, \$4.4 billion in 2013 and \$6.2 billion in 2012. EPS was \$4.07 in 2014, \$1.47 in 2013 and \$2.00 in 2012. The increases in net income and EPS in 2014 as compared with 2013 were due primarily to the gain on the divestiture of MCC, a gain recognized on AstraZeneca's option exercise, gains on other divestitures, lower operating expenses, higher favorability from discrete tax items, revenue recognized from the sale of the U.S. marketing rights to Saphris, partially offset by lower sales, a loss on extinguishment of debt, higher intangible asset impairment charges, and an additional year of expense for the health care reform fee. The declines in net income and EPS in 2013 as compared with 2012 were due primarily to lower sales reflecting the loss of market exclusivity for certain products, particularly Singulair, as well as higher restructuring costs, intangible asset impairment charges and exchange losses, partially offset by the favorable impact of certain tax items and lower operating expenses.

**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

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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)	2014	2013	2012
Pretax income as reported under GAAP	\$17,283	\$5,545	\$8,739
Increase (decrease) for excluded items:			
Acquisition and divestiture-related costs	5,946	5,549	5,344
Restructuring costs	1,978	2,401	999
Other items:			
Gain on divestiture of Merck Consumer Care	(11,209	) —	—
Gain on AstraZeneca option exercise	(741	) —	—
Gain on the divestiture of certain ophthalmic products	(480	) —	—
Loss on extinguishment of debt	628	—	—
Additional year of expense for health care reform fee	193	—	—
Net charge related to settlement of ENHANCE Litigation	—	—	493
Other	(9	) (13	) —
	13,589	13,482	15,575
Taxes on income as reported under GAAP	5,349	1,028	2,440
Estimated tax (provision) benefit on excluded items <sup>(1)</sup>	(2,345	) 1,573	1,261
Tax benefits related to sale of Sirna Therapeutics, Inc. subsidiary	300	—	—
Net tax benefits from settlements of federal income tax issues	—	325	—
	3,304	2,926	3,701
Non-GAAP net income	10,285	10,556	11,874
Less: Net income attributable to noncontrolling interests as reported under GAAP	14	113	131
Acquisition and divestiture-related costs attributable to non-controlling interests	56	—	—
	70	113	131
Non-GAAP net income attributable to Merck & Co., Inc.	\$10,215	\$10,443	\$11,743
EPS assuming dilution as reported under GAAP	\$4.07	\$1.47	\$2.00
EPS difference <sup>(2)</sup>	(0.58	) 2.02	1.82
Non-GAAP EPS assuming dilution	\$3.49	\$3.49	\$3.82

<sup>(1)</sup> Amount for 2014 includes a net benefit of \$517 million recorded in connection with AstraZeneca's option exercise.

Represents the difference between calculated GAAP EPS and calculated non-GAAP EPS, which may be different

<sup>(2)</sup> 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 mergers, acquisitions and divestitures. These amounts include the amortization of intangible assets, intangible asset impairment charges and expense or income related to changes in the fair value measurement of contingent consideration. Also excluded are incremental, third-party integration costs associated with the Merger, such as costs related to legal entity and systems integration, as well as transaction and certain other costs associated with business acquisitions and divestitures. These costs should not be considered non-recurring; however, management excludes these amounts from





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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. Certain other items are comprised of a gain on the divestiture of MCC, a gain recognized in conjunction with AstraZeneca's option exercise, including a related net tax benefit on the transaction, a gain on the divestiture of certain ophthalmic products in several international markets, a loss on extinguishment of debt, an additional year of expense related to the health care reform fee, a tax benefit from the sale of Sirna and tax benefits from the settlements of certain federal income tax issues, as well as the net charge recorded in connection with the settlement of the ENHANCE Litigation.

### Research and Development

A chart reflecting the Company's current research pipeline as of February 20, 2015 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 anti-PD-1 (programmed death receptor-1) therapy under review by the EMA for the treatment of advanced melanoma. In September 2014, the FDA approved 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. Keytruda is the first anti-PD-1 therapy approved in the United States.

The Keytruda clinical development program also includes studies in more than 30 cancer types including: bladder, colorectal, gastric, head and neck, melanoma, non-small-cell lung, renal, triple negative breast and hematological malignancies. In addition, the Company has announced a number of collaborations with other pharmaceutical companies to evaluate novel combination regimens with Keytruda. In October 2014, Keytruda was granted Breakthrough Therapy Designation by the FDA for the treatment of patients with Epidermal Growth Factor Receptor mutation-negative, and Anaplastic Lymphoma Kinase rearrangement-negative non-small-cell lung cancer whose disease has progressed on or following platinum-based chemotherapy. The Company anticipates submitting an sBLA to the FDA in mid-2015 for Keytruda.

MK-8616, Bridion, is an investigational agent for the reversal of neuromuscular blockade induced by rocuronium or vecuronium (neuromuscular blocking agents). Neuromuscular blockade is used in anesthesiology to induce muscle relaxation during surgery. In September 2013, Merck announced that it had received a CRL from the FDA for the resubmission of the NDA for Bridion. To address the CRL, the Company conducted a new hypersensitivity study and, in October 2014, resubmitted the NDA to the FDA. The Company anticipates an FDA advisory committee



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meeting will be held on March 18, 2015 to review Bridion. If approved, the Company expects to launch Bridion in the United States later in 2015. Bridion is approved and has been launched in many countries outside of the United States. V419, DTaP5-IPV-Hib-HepB, is an investigational pediatric hexavalent vaccine that the Company is developing in partnership with Sanofi Pasteur under review by the FDA and the EMA. If approved, V419 would be the first pediatric combination vaccine in the United States 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. If approved, V419 will be co-promoted in the United States via a partnership with Sanofi Pasteur and marketed via the SPMSD joint venture in Europe.

MK-3102, omarigliptin, is an investigational once-weekly DPP-4 inhibitor in development for the treatment of type 2 diabetes. In November 2014, Merck announced that the Company has submitted a new drug application for omarigliptin to the Japanese Pharmaceuticals and Medical Devices Agency. Omarigliptin is in Phase 3 clinical development in the United States.

MK-1986, Sivextro, a once-daily oxazolidinone antibiotic developed for both intravenous and oral administration for the treatment of ABSSI caused by certain Gram-positive organisms, is under review by the EMA. In January 2015, Merck announced that the Committee for Medicinal Products for Human Use (the "CHMP") of the EMA has adopted a positive opinion recommending approval of Sivextro for the treatment of ABSSSI in adults. Merck acquired Sivextro as a part of its purchase of Cubist. If the EC affirms the CHMP opinion, it will grant a centralized marketing authorization with unified labeling that is valid in the 28 countries that are members of the EU, as well as European Economic Area members, Iceland, Liechtenstein and Norway. Sivextro is approved in the United States and is indicated for the treatment of adults with ABSSSI caused by designated susceptible Gram-positive organisms. The Company is conducting a Phase 3 clinical trial to assess the safety and efficacy of Sivextro in adult patients with ventilated nosocomial pneumonia, including ventilator-associated bacterial pneumonia ("VABP") and ventilated hospital-acquired bacterial pneumonia ("ventilated HABP"). In 2013, the FDA designated Sivextro as a Qualified Infectious Disease Product ("QIDP") for its now approved indication in ABSSSI, as well as for its potential indication in ventilated nosocomial pneumonia, including VABP and ventilated HABP, in each of the I.V. and oral dosage forms.

MK-7625A, Zerbaxa, a combination product for the treatment of certain serious bacterial infections in adults, is under review by the EMA. Merck acquired Zerbaxa as a part of its purchase of Cubist. In December 2014, Zerbaxa was approved by the FDA 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. The Company is conducting a Phase 3 clinical trial to assess the safety and efficacy of Zerbaxa in adult patients with ventilated nosocomial pneumonia, including VABP and ventilated HABP. The FDA designated Zerbaxa as a QIDP for its now approved indications as well as for its potential indication in ventilated nosocomial pneumonia, including VABP and ventilated HABP.

V503, Gardasil 9, the Company's nine-valent HPV vaccine that helps protect against certain HPV-related diseases, is under review by the EMA. V503 incorporates antigens against five additional cancer-causing HPV types as compared with Gardasil. Gardasil 9 was approved by the FDA in December 2014.

MK-8962, corifollitropin alfa injection, is an investigational fertility treatment under review by the FDA 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 is reviewing its options with respect to this drug candidate in response to the CRL. Corifollitropin alfa injection is marketed as Elonva in certain markets outside of the United States.

In addition to the candidates under regulatory review, the Company has several drug candidates in Phase 3 development. The Company anticipates filing an NDA or a BLA, as applicable, with the FDA with respect to certain of these candidates in 2015.

MK-5172A, a once daily, fixed-dose, combination, chronic HCV treatment regimen consisting of MK-5172, grazoprevir, an investigational HCV NS3/4A protease inhibitor, and MK-8742, elbasvir, an investigational HCV NS5A replication complex inhibitor, began Phase 3 clinical trials in June 2014. MK-5172A is being investigated in a broad clinical program that includes studies in patients with multiple HCV genotypes who are treatment-naïve, treatment failures, or who fit into other important HCV subpopulations such as patients with cirrhosis and those

co-infected with HIV. The Company expects to file an NDA with the FDA in the first half of 2015 for MK-5172A. On January 30, 2015,

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the Company received notification from the FDA of its intent to rescind Breakthrough Therapy Designation status for this combination treatment regimen, citing the availability of other recently approved treatments for Genotype 1 patients. The Company is discussing this matter with the FDA and does not expect that it will impact its ability to file an NDA for this combination regimen or the timing of that filing.

The Company has started the Phase 2 C-CREST studies to study combination regimens of grazoprevir and MK-3682 (formerly IDX21437) with either elbasvir or MK-8408 for the treatment of HCV infection. The Company expects to begin Phase 3 studies in 2015.

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, in support of regulatory submissions. Merck plans to submit an NDA to the FDA for odanacatib in 2015. Merck also plans to submit applications to the EMA and the Ministry of Health, Labour, and Welfare in Japan.

MK-8237 is an investigational allergy immunotherapy tablet for house dust mite allergy. In 2014, the FDA approved Grastek, a Timothy grass pollen allergen extract sublingual immunotherapy tablet, and Ragwitek, a short ragweed pollen allergen extract sublingual immunotherapy tablet. Both Grastek and Ragwitek, as well as the ongoing program for MK-8237, are part of a North America partnership between Merck and ALK-Abello.

MK-8931 is Merck's novel investigational oral  $\beta$ -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 amnesic mild cognitive impairment due to Alzheimer's disease, also known as prodromal Alzheimer's disease. MK-8931 is also being studied in another Phase 3 trial versus placebo in patients with mild-to-moderate Alzheimer's disease (EPOCH).

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 large, event-driven cardiovascular clinical outcomes trial, REVEAL (Randomized EVALuation of the Effects of Anacetrapib Through Lipid-modification), involving patients with preexisting vascular disease that is predicted to be completed in 2017.

MK-3415A, actoxumab/bezlotoxumab, an investigational candidate for the prevention of Clostridium difficile infection recurrence, is a combination of two monoclonal antibodies used to treat patients with a single infusion.

MK-4261, surotomycin, is an investigational oral antibiotic in development for the treatment of Clostridium difficile associated diarrhea. Merck acquired surotomycin as part of its purchase of Cubist. The FDA has designated surotomycin as a QIDP.

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.



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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.

MK-1293 is an insulin glargine candidate for the treatment of patients with type 1 and type 2 diabetes. In February 2014, the Company announced that it had expanded its collaboration with Samsung Bioepis to develop, manufacture and commercialize MK-1293. Under the terms of the agreement, the companies will collaborate on clinical development, regulatory filings and manufacturing. If approved, Merck will commercialize this candidate.

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.

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. 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.

In May 2014, Merck and Endocyte, Inc. (“Endocyte”) (the Company’s collaboration partner) announced the withdrawal of the conditional MAA from the EMA for vintafolide for the treatment of adult patients with folate receptor-positive, platinum-resistant ovarian cancer, in combination with pegylated liposomal doxorubicin (“PLD”). The companies’ decision was based on review of interim data from the PROCEED trial. The PROCEED trial has been terminated based on the Data Safety Monitoring Board’s (the “DSMB”) recommendation that the study be stopped because vintafolide in combination with PLD versus PLD alone did not meet the pre-specified criteria for progression-free survival to allow continuation of the study. The DSMB did not identify any safety concerns for the patients enrolled in the PROCEED trial. In June 2014, Merck returned worldwide rights for vintafolide in all indications to Endocyte. 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. Further, Merck has moved to diversify its portfolio through a collaboration on the development of biosimilars, which have the potential to harness the market opportunity presented by biological medicine patent expiries by delivering high quality biosimilars to enhance access for patients worldwide. 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 is evaluating certain late-stage clinical development and platform technology assets to determine their out-licensing or sale potential.

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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 mergers and 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, 2014, the balance of IPR&D was \$4.3 billion. A majority of this amount relates to the clinical development program for MK-3682, which the Company acquired in 2014 with the acquisition of Idenix as discussed below. Some of the other more significant projects in late-stage development include the Company's BACE inhibitor and Bridion discussed above.

During 2014, 2013 and 2012, approximately \$654 million, \$346 million and \$78 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 2014, the Company recorded \$49 million of IPR&D impairment charges within Research and development expenses 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. During 2012, the Company recorded \$200 million of IPR&D impairment charges primarily for pipeline programs that had previously been deprioritized and were subsequently deemed to have no alternative use during 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, 2014, the estimated costs to complete projects acquired in connection with mergers and acquisitions in Phase 3 development for human health and the analogous stage of development for animal health were approximately \$1.1 billion.

### 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 significant transactions in 2014 are described below. Merck is actively monitoring the landscape for growth opportunities that meet the Company's strategic criteria.

In August 2014, Merck completed the acquisition of Idenix for approximately \$3.9 billion in cash (\$3.7 billion net of cash acquired). Idenix is a biopharmaceutical company engaged in the discovery and development of medicines for the treatment of human viral diseases, whose primary focus is on the development of next-generation oral antiviral therapeutics to treat 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. The



determination of fair value requires management to make significant estimates and assumptions. Merck recognized an intangible asset for IPR&D of \$3.2 billion related to MK-3682 (formerly IDX21437), net deferred tax

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liabilities of \$856 million and other net assets and liabilities of approximately \$20 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 \$1.4 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, through which fair value is estimated based upon 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 11.5%. 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 October 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 the first and only drug treatment approved for patients with chronic thromboembolic pulmonary hypertension ("CTEPH"). Adempas is currently 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 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 currently marketed product 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 currently in clinical development and 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 and reasonably estimable. 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 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. The determination of fair value requires management to make significant estimates and assumptions. 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 and liabilities of \$10 million. 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 upon 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 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

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utilizing a discount rate of 11.5%. 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.

Also, in December 2014, Merck and Cubist announced a definitive agreement under which Merck would acquire Cubist for a total purchase price of approximately \$9.5 billion. Cubist is 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. This transaction closed on January 21, 2015; accordingly, the results of operations of the acquired business will be included in the Company's results of operations beginning after that date.

In addition, in February 2015, Merck and NGM Biopharmaceuticals, Inc. ("NGM"), a privately-held biotechnology company, announced they have 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 will make an upfront payment to NGM of \$94 million and will purchase a 15% equity stake in NGM for \$106 million. Merck will commit 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. This agreement will become effective upon the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act.

#### 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, \$920 million and \$915 million in 2014, 2013 and 2012, respectively, primarily relating to sales of Nexium, as well as Prilosec. In addition, Merck earned certain Partnership returns which were recorded in Equity income from affiliates. Such returns included a priority return provided for in the Partnership Agreement, a preferential return representing Merck's share of undistributed AZLP GAAP earnings, and a variable return related to the Company's 1% limited partner interest. These returns aggregated \$192 million, \$352 million and \$621 million in 2014, 2013 and 2012, respectively.

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. The remaining exercise price of \$91 million primarily represents a multiple of ten times

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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)	2014	2013	2012
Gardasil	\$248	\$291	\$264
Influenza vaccines	159	162	161
Zostavax	103	68	—
Other viral vaccines	87	104	107
RotaTeq	65	55	47
Hepatitis vaccines	38	31	31
Other vaccines	430	453	474
	\$1,130	\$1,164	\$1,084

## Capital Expenditures

Capital expenditures were \$1.3 billion in 2014, \$1.5 billion in 2013 and \$2.0 billion in 2012. Expenditures in the United States were \$873 million in 2014, \$902 million in 2013 and \$1.3 billion in 2012.

Depreciation expense was \$2.5 billion in 2014, \$2.2 billion in 2013 and \$2.0 billion in 2012 of which \$2.0 billion, \$1.5 billion and \$1.3 billion, respectively, applied to locations in the United States. Total depreciation expense in 2014, 2013 and 2012 included accelerated depreciation of \$900 million, \$577 million and \$235 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)	2014	2013	2012
Working capital	\$14,407	\$17,817	\$16,509
Total debt to total liabilities and equity	21.8	% 23.7	% 19.4
Cash provided by operations to total debt	0.4:1	0.5:1	0.5:1

Cash provided by operating activities was \$7.9 billion in 2014, \$11.7 billion in 2013 and \$10.0 billion in 2012. 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 previously disclosed settlement of the ENHANCE Litigation. Cash provided by operating activities in 2012 reflects higher contributions to its defined benefit plans as compared with 2014 and 2013. Cash provided by operating activities in 2012 also includes a payment of \$960 million related to the resolution of certain litigation related to Vioxx. 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



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dividends paid to shareholders. Global economic conditions and ongoing sovereign debt issues, among other factors, have adversely affected foreign receivables in certain European countries (see Note 5 to the consolidated financial statements).

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, primarily related to the transactions with Aspen and Santen (see Notes 3 and 4 to the consolidated financial statements), as well as cash received in connection with AstraZeneca's option exercise (see Note 8 to the consolidated financial statements), partially offset by higher purchases of and lower proceeds from the sale of securities and other investments, cash used for the acquisition of Idenix (see Note 4 to the consolidated financial statements) and a cash payment made upon formation of the collaboration with Bayer (see Note 4 to the consolidated financial statements). Cash used in investing activities was \$3.1 billion in 2013 compared with \$6.8 billion in 2012 primarily reflecting higher proceeds from the sales of securities and other investments and lower capital expenditures, partially offset by higher purchases of securities and other investments.

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. Cash used in financing activities was \$6.0 billion in 2013 compared with \$3.3 billion in 2012. The higher use of cash in financing activities was driven primarily by higher purchases of treasury stock, as well as higher payments on debt and a decrease in short-term borrowings, partially offset by higher proceeds from the issuance of debt.

At December 31, 2014, the total of worldwide cash and investments was \$29.2 billion, including \$15.7 billion of cash, cash equivalents and short-term investments, and \$13.5 billion of long-term investments. Generally 80%-90% of these 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, 2014 are as follows:

Payments Due by Period

(\$ in millions)	Total	2015	2016—2017	2018—2019	Thereafter
Purchase obligations <sup>(1)</sup>	\$2,865	\$543	\$932	\$539	\$851
Loans payable and current portion of long-term debt	2,701	2,701	—	—	—
Long-term debt <sup>(2)</sup>	18,535	—	2,380	4,273	11,882
Interest related to debt obligations <sup>(2)</sup>	7,209	489	915	854	4,951
Unrecognized tax benefits <sup>(3)</sup>	1,331	1,331	—	—	—
Operating leases	644	232	214	101	97
	\$33,285	\$5,296	\$4,441	\$5,767	\$17,781

(1) Includes future bulk supply purchases the Company has committed to in connection with certain divestitures, including the disposition of its API manufacturing business in 2013 discussed above.

(2) Amounts do not reflect debt and interest payments related to the Company's February 2015 debt issuance discussed below.

As of December 31, 2014, the Company's Consolidated Balance Sheet reflects liabilities for unrecognized tax benefits, interest and penalties of \$4.2 billion, including \$1.3 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 2015 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

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development obligations are potential future funding commitments of up to approximately \$70 million for investments in research venture capital funds. Loans payable and current portion of long-term debt reflects \$143 million of long-dated notes that are subject to repayment at the option of the holders. Required funding obligations for 2015 relating to the Company's pension and other postretirement benefit plans are not expected to be material. However, the Company currently anticipates contributing approximately \$40 million to its U.S. pension plans, \$150 million to its international pension plans and \$65 million to its other postretirement benefit plans during 2015.

In August 2014, the Company terminated its existing credit facility and entered into a new \$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 October 2014, the Company issued euro-denominated senior unsecured notes consisting of €1.0 billion principal amount of 1.125% notes due 2021, €1.0 billion principal amount of 1.875% notes due 2026 and €500 million principal amount of 2.5% notes due 2034. Interest on the notes is payable annually. The notes of each series are redeemable in whole or in part at any time at the Company's option at varying redemption prices. 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 addition, in November 2014, Merck redeemed its \$1.0 billion 4.00% notes due 2015 and its \$1.0 billion 6.00% notes due 2017. 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 substantial portion of the net proceeds of the offering to repay commercial paper issued to substantially finance the Company's acquisition of Cubist. Any remaining net proceeds will be used for general corporate purposes, including without limitation repurchases of the Company's common stock, and the repayment of outstanding commercial paper borrowings and upcoming debt maturities.

In December 2014, the Company entered into a bridge loan agreement with certain banks pursuant to which the Company had the ability to borrow up to \$8.0 billion for the purpose of obtaining short-term financing for the acquisition of Cubist. The Company did not borrow any funds under the bridge loan and, after issuing \$8.0 billion of senior unsecured notes as discussed above, terminated the bridge loan on February 20, 2015.

In December 2012, the Company filed a securities registration statement with the U.S. Securities and Exchange Commission (the "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's long-term credit ratings assigned by Moody's Investors Service and Standard & Poor's are A1 with a stable outlook and AA with a stable outlook, respectively. These ratings continue to allow access to the capital markets and flexibility in obtaining funds on competitive terms. 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. Despite this strong financial profile, certain contingent events, if realized, which are discussed in Note 10 to the consolidated financial statements, could have a material adverse impact on the Company's liquidity and capital resources. 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 2014, the Board of Directors declared a quarterly dividend of \$0.45 per share on the Company's common stock payable in January 2015.



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On May 1, 2013, the Company announced that its board of directors authorized additional purchases of up to \$15 billion of Merck's common stock for its treasury. Purchases may be made in open-market transactions, block transactions, on or off an exchange, or in privately negotiated transactions. The Company purchased \$7.7 billion of its common stock (134 million shares) for its treasury during 2014. The Company has approximately \$2.7 billion remaining under the May share repurchase program. The Company purchased \$6.5 billion and \$2.6 billion of its common stock during 2013 and 2012, 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 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 premium 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 \$660 million and \$547 million at December 31, 2014 and 2013, respectively, from a uniform 10% weakening of the U.S. dollar. The market value was determined using a foreign

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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 foreign currency denominated net monetary assets of foreign subsidiaries where the U.S. dollar is the 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, 2014 and 2013, Income before taxes would have declined by approximately \$25 million in 2014 and \$109 million in 2013. Because the Company was in a net long 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.

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. 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 March 2013, the Venezuelan government announced the creation of a new foreign exchange mechanism called the "Complimentary System of Foreign Currency Acquirement" (known as SICAD1) that operates similar to an auction system and allows entities in specific sectors to bid for U.S. dollars to be used for payments related to international investments and certain intangibles. In March 2014, the Venezuelan government launched another foreign exchange mechanism (known as SICAD2) and indicated that all industry sectors would be able to access SICAD2 and its use would not be restricted as to purpose. Both the SICAD1 and SICAD2 average rates are published by the Central Bank of Venezuela and at December 31, 2014, the average exchange rates inferred were 12.0 VEF per U.S. dollar and 49.99 VEF per U.S. dollar, respectively. Neither SICAD1 nor SICAD2 eliminated or changed the official rate of 6.30 VEF per U.S. dollar. At December 31, 2014, the Company had approximately \$670 million (U.S. dollar equivalent at the 6.30 official rate) of net monetary assets in its Venezuelan entities, of which the large majority was cash. In 2014, the Company received approximately \$190 million from Venezuela for transactions that were settled at the official rate of 6.30 VEF per U.S. dollar, and has approximately \$600 million pending approval for future settlement at the official rate. In February 2015, the Venezuelan government announced that SICAD2 has been replaced with the Sistema Marginal de Divisas (known as SIMADI). The SIMADI market is intended to operate based on the principles of supply and demand with buyers and sellers exchanging offers to transact. According to the Venezuelan Central Bank

the average exchange rate on the first day of trading on February 12, 2015 was 170.0 VEF per U.S. Dollar. The SICAD1 mechanism remains unchanged. Recent announcements by the Venezuelan government have indicated that essential goods, including food and medicine, will remain at the official rate of 6.30 VEF per U.S. dollar. The Company has not used

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either SICAD mechanism to settle any transactions and does not anticipate using either the SICAD1 or SIMADI mechanisms to settle any transactions. Accordingly, the Company concluded it was appropriate to continue to use the official rate of 6.30 VEF per U.S. dollar for remeasurement purposes. If circumstances change such that the Company concludes it would no longer be appropriate to use the official rate, or if a devaluation of the official rate occurs, it could result in a significant charge to the Company's future results of operations.

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, 2014, the Company was a party to 17 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	2014		
	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
3.875% notes due 2021	1,150	5	1,150
2.40% notes due 2022	1,000	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 are recorded in interest expense and offset by the fair value changes in the swap contracts.

During 2014, the Company terminated interest rate swap contracts that effectively converted the Company's 6.00% fixed-rate notes due in 2017 to floating-rate instruments. The interest rate swap contracts were designated hedges of the fair value changes in the notes attributable to changes in the benchmark LIBOR swap rate. As a result of the swap terminations, the Company received \$3 million in cash. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

In February 2015, in connection with the Company's February debt offering (see Note 9 to the consolidated financial statements), Merck entered into ten additional interest rate swap contracts with notional amounts of \$250 million each that effectively convert the Company's 1.85% notes due in 2020 and the Company's 2.35% notes due in 2022 to floating-rate instruments.

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

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Merck's investments and debt from a change in interest rates indicated that a one percentage point increase in interest rates at December 31, 2014 and 2013 would have positively affected the net aggregate market value of these instruments by \$1.0 billion and \$1.1 billion, respectively. A one percentage point decrease at December 31, 2014 and 2013 would have negatively affected the net aggregate market value by \$1.2 billion and \$1.3 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 mergers and acquisitions, including initial fair value determinations of assets and liabilities, primarily IPR&D and other intangible assets, 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.

### Mergers and 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 merger or 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 merger or acquisition. The fair values of intangible assets, including acquired IPR&D, are determined utilizing information available near the merger or 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 recorded in earnings. Changes in any of the inputs may result in a significantly different fair value adjustment.

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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 2014, 2013 or 2012.



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Summarized information about changes in the aggregate indirect customer discount accrual is as follows:

(\$ in millions)	2014	2013
Balance January 1	\$1,688	\$1,873
Current provision	6,560	5,451
Adjustments to prior years	(18	) (70
Payments	(6,076	) (5,566
Balance December 31	\$2,154	\$1,688

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 \$112 million and \$2.0 billion, respectively, at December 31, 2014 and were \$87 million and \$1.6 billion, respectively, at December 31, 2013.

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 1.7% in 2014, 1.5% in 2013 and 1.4% in 2012.

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, 2014 and 2013 were \$74 million and \$177 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

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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, 2014 and 2013 of approximately \$215 million and \$160 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

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

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

The Company believes that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on the Company. Expenditures for remediation and environmental liabilities were \$12 million in 2014, and are estimated at \$53 million in the aggregate for the years 2015 through 2019. In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled \$125 million and \$213 million at December 31, 2014 and 2013, 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 \$66 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 \$278 million in 2014, \$276 million in 2013 and \$335 million in 2012. At December 31, 2014, there was \$401 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.

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## Pensions and Other Postretirement Benefit Plans

Net periodic benefit cost for pension and other postretirement benefit plans totaled \$169 million in 2014, \$716 million in 2013 and \$509 million in 2012. 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 decrease in net periodic benefit cost for pension and other postretirement benefit plans in 2014 as compared with 2013 is largely attributable to a change in the discount rate.

The Company reassesses its benefit plan assumptions on a regular basis. For both the pension and other postretirement benefit plans, the discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due. At December 31, 2014, the discount rates for the Company's U.S. pension and other postretirement benefit plans ranged from 3.20% to 4.20% compared with a range of 3.60% to 5.20% at December 31, 2013.

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 2015, the Company's expected rate of return will range from 7.30% to 8.75%, the same range as in 2014 for its U.S. pension and other postretirement benefit plans.

In October 2014, the Society of Actuaries issued new retirement plan mortality assumptions that are used in measuring U.S. pension plan obligations. The Company has reflected an impact of these new assumptions in the measurement of its U.S. pension plan obligations at December 31, 2014.

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 \$23 million favorable (unfavorable) impact on its net periodic benefit cost. Required funding obligations for 2015 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.



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## 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 purchased 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 macro economic 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.

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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, 2014, foreign earnings of \$60.0 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 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. This guidance is effective for annual and interim periods beginning in 2017. Early adoption is not permitted. The Company is currently assessing the impact of adoption on its consolidated financial statements.



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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.”



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## Item 8. Financial Statements and Supplementary Data.

## (a) Financial Statements

The consolidated balance sheet of Merck & Co., Inc. and subsidiaries as of December 31, 2014 and 2013, 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, 2014, the notes to consolidated financial statements, and the report dated February 27, 2015 of PricewaterhouseCoopers LLP, independent registered public accounting firm, are as follows:

## Consolidated Statement of Income

Merck &amp; Co., Inc. and Subsidiaries

Years Ended December 31

(\$ in millions except per share amounts)

	2014	2013	2012
Sales	\$42,237	\$44,033	\$47,267
Costs, Expenses and Other			
Materials and production	16,768	16,954	16,446
Marketing and administrative	11,606	11,911	12,776
Research and development	7,180	7,503	8,168
Restructuring costs	1,013	1,709	664
Equity income from affiliates	(257 )	(404 )	(642 )
Other (income) expense, net	(11,356 )	815	1,116
	24,954	38,488	38,528
Income Before Taxes	17,283	5,545	8,739
Taxes on Income	5,349	1,028	2,440
Net Income	11,934	4,517	6,299
Less: Net Income Attributable to Noncontrolling Interests	14	113	131
Net Income Attributable to Merck & Co., Inc.	\$11,920	\$4,404	\$6,168
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	\$4.12	\$1.49	\$2.03
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	\$4.07	\$1.47	\$2.00

## Consolidated Statement of Comprehensive Income

Merck &amp; Co., Inc. and Subsidiaries

Years Ended December 31

(\$ in millions)

	2014	2013	2012
Net Income Attributable to Merck & Co., Inc.	\$11,920	\$4,404	\$6,168
Other Comprehensive Income (Loss) Net of Taxes:			
Net unrealized gain (loss) on derivatives, net of reclassifications	398	229	(101 )
Net unrealized gain (loss) on investments, net of reclassifications	57	(19 )	52
Benefit plan net (loss) gain and prior service (cost) credit, net of amortization	(2,077 )	2,758	(1,321 )
Cumulative translation adjustment	(504 )	(483 )	(180 )
	(2,126 )	2,485	(1,550 )
Comprehensive Income Attributable to Merck & Co., Inc.	\$9,794	\$6,889	\$4,618

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

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## Consolidated Balance Sheet

Merck &amp; Co., Inc. and Subsidiaries

December 31

(\$ in millions except per share amounts)

	2014	2013
Assets		
Current Assets		
Cash and cash equivalents	\$7,441	\$15,621
Short-term investments	8,278	1,865
Accounts receivable (net of allowance for doubtful accounts of \$153 in 2014 and \$146 in 2013) (excludes accounts receivable of \$80 in 2014 and \$275 in 2013 classified in Other assets - see Note 5)	6,626	7,184
Inventories (excludes inventories of \$1,664 in 2014 and \$1,704 in 2013 classified in Other assets - see Note 6)	5,571	6,226
Deferred income taxes and other current assets	5,257	4,789
Total current assets	33,173	35,685
Investments	13,515	9,770
Property, Plant and Equipment (at cost)		
Land	541	550
Buildings	13,101	13,627
Machinery, equipment and office furnishings	16,050	17,106
Construction in progress	1,448	1,811
	31,140	33,094
Less: accumulated depreciation	18,004	18,121
	13,136	14,973
Goodwill	12,992	12,301
Other Intangibles, Net	20,386	23,801
Other Assets	5,133	9,115
	\$98,335	\$105,645
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	\$2,704	\$4,521
Trade accounts payable	2,625	2,274
Accrued and other current liabilities	10,523	9,501
Income taxes payable	1,606	251
Dividends payable	1,308	1,321
Total current liabilities	18,766	17,868
Long-Term Debt	18,699	20,539
Deferred Income Taxes	4,266	6,776
Other Noncurrent Liabilities	7,813	8,136
Merck & Co., Inc. Stockholders' Equity		
Common stock, \$0.50 par value		
Authorized - 6,500,000,000 shares	1,788	1,788
Issued - 3,577,103,522 shares in 2014 and 2013		
Other paid-in capital	40,423	40,508
Retained earnings	46,021	39,257
Accumulated other comprehensive loss	(4,323)	(2,197)
	83,909	79,356
Less treasury stock, at cost:	35,262	29,591

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738,963,326 shares in 2014 and 649,576,808 shares in 2013

Total Merck & Co., Inc. stockholders' equity	48,647	49,765
Noncontrolling Interests	144	2,561
Total equity	48,791	52,326
	\$98,335	\$105,645

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

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

	Common Stock	Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock	Non- controlling Interests	Total
Balance January 1, 2012	\$1,788	\$40,663	\$38,990	\$ (3,132 )	\$(23,792)	\$ 2,426	\$56,943
Net income attributable to Merck & Co., Inc.	—	—	6,168	—	—	—	6,168
Other comprehensive loss, net of tax	—	—	—	(1,550 )	—	—	(1,550 )
Cash dividends declared on common stock (\$1.69 per share)	—	—	(5,173 )	—	—	—	(5,173 )
Treasury stock shares purchased	—	—	—	—	(2,591 )	—	(2,591 )
Net income attributable to noncontrolling interests	—	—	—	—	—	131	131
Distributions attributable to noncontrolling interests	—	—	—	—	—	(120 )	(120 )
Share-based compensation plans and other	—	(17 )	—	—	1,666	6	1,655
Balance December 31, 2012	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 )
Supera joint venture formation	—	116	—	—	—	112	228
Treasury stock shares purchased	—	—	—	—	(6,516 )	—	(6,516 )
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 )
	—	(85 )	—	—	2,032	46	1,993

Share-based compensation plans and  
other

Balance December 31, 2014	\$1,788	\$40,423	\$46,021	\$ (4,323 )	\$(35,262)	\$ 144	\$48,791
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The accompanying notes are an integral part of this consolidated financial statement.

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

	2014	2013	2012
Cash Flows from Operating Activities			
Net income	\$11,934	\$4,517	\$6,299
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	6,691	6,988	6,978
Intangible asset impairment charges	1,222	765	200
Gain on divestiture of Merck Consumer Care	(11,209)	—	—
Gain on AstraZeneca option exercise	(741)	—	—
Loss on extinguishment of debt	628	—	—
Equity income from affiliates	(257)	(404)	(642)
Dividends and distributions from equity method affiliates	185	237	291
Deferred income taxes	(2,600)	(330)	669
Share-based compensation	278	276	335
Other	(95)	399	28
Net changes in assets and liabilities:			
Accounts receivable	(554)	436	349
Inventories	79	(365)	(482)
Trade accounts payable	593	522	(302)
Accrued and other current liabilities	1,635	(397)	(717)
Income taxes payable	(21)	(1,421)	(34)
Noncurrent liabilities	190	(132)	(1,747)
Other	(98)	563	(1,203)
Net Cash Provided by Operating Activities	7,860	11,654	10,022
Cash Flows from Investing Activities			
Capital expenditures	(1,317)	(1,548)	(1,954)
Purchases of securities and other investments	(24,944)	(17,991)	(12,841)
Proceeds from sales of securities and other investments	15,114	16,298	7,783
Divestiture of Consumer Care business, net of cash divested	13,951	—	—
Dispositions of other businesses, net of cash divested	1,169	46	—
Proceeds from AstraZeneca option exercise	419	—	—
Acquisition of Idenix Pharmaceuticals, Inc., net of cash acquired	(3,700)	—	—
Acquisitions of other businesses, net of cash acquired	(181)	(246)	—
Acquisition of Bayer AG collaboration rights	(1,000)	—	—
Cash inflows from net investment hedges	195	350	39
Other	(80)	(57)	168
Net Cash Used in Investing Activities	(374)	(3,148)	(6,805)
Cash Flows from Financing Activities			
Net change in short-term borrowings	(460)	(159)	624
Payments on debt	(6,617)	(1,775)	(22)
Proceeds from issuance of debt	3,146	6,467	2,562
Purchases of treasury stock	(7,703)	(6,516)	(2,591)
Dividends paid to stockholders	(5,170)	(5,157)	(5,116)
Other dividends paid	(77)	(120)	(120)
Proceeds from exercise of stock options	1,560	1,210	1,310
Other	208	60	86

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Net Cash Used in Financing Activities	(15,113 )	(5,990 )	(3,267 )
Effect of Exchange Rate Changes on Cash and Cash Equivalents	(553 )	(346 )	(30 )
Net (Decrease) Increase in Cash and Cash Equivalents	(8,180 )	2,170	(80 )
Cash and Cash Equivalents at Beginning of Year	15,621	13,451	13,531
Cash and Cash Equivalents at End of Year	\$7,441	\$15,621	\$13,451

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

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## Notes to Consolidated Financial Statements

## Merck &amp; 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 three operating segments, which are the Pharmaceutical, Animal Health and Alliances segments, and one reportable segment, which is the Pharmaceutical 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. 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.

## 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.

**Mergers and 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 merger or 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 merger or 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”)





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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 \$112 million and \$2.0 billion, respectively, at December 31, 2014 and \$87 million and \$1.6 billion, respectively, at December 31, 2013.

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 10 to 50 years for Buildings, and from 3 to 15 years for Machinery, equipment and office furnishings. Depreciation expense was \$2.5 billion in 2014, \$2.2 billion in 2013 and \$2.0 billion in 2012.



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**Advertising and Promotion Costs** — Advertising and promotion costs are expensed as incurred. The Company recorded advertising and promotion expenses of \$2.3 billion, \$2.5 billion and \$2.8 billion in 2014, 2013 and 2012, 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 \$505 million and \$548 million, net of accumulated amortization at December 31, 2014 and 2013, 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 purchased. 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 3 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 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



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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 in 2014 include a charge to increase the fair value of a liability 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 mergers and acquisitions, including initial fair value determinations of assets and liabilities, primarily IPR&D and other intangible assets, as well as subsequent fair value measurements. Additionally, estimates are used in determining such items as provisions for sales discounts and returns, depreciable and amortizable lives, recoverability of inventories, including those produced in preparation for product launches, amounts recorded for contingencies, environmental liabilities and other reserves, pension and other postretirement benefit plan assumptions, share-based compensation assumptions, restructuring costs, impairments of long-lived assets (including intangible assets and goodwill) and investments, and taxes on income. Because of the uncertainty inherent in such estimates, actual results may differ from these estimates.

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

**Recently Issued Accounting Standards** — In May 2014, the Financial Accounting Standards Board 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. This guidance is effective for annual and interim periods beginning in 2017. Early adoption is not permitted. The Company is currently assessing the impact of adoption on its consolidated financial statements.



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## 3. Restructuring

## 2013 Restructuring Program

In 2013, the Company announced a global restructuring program (the “2013 Restructuring Program”) as part of a global initiative to sharpen its commercial and research and development focus. As part of the program, the Company expects to reduce its total workforce by approximately 8,500 positions. These workforce reductions will primarily come from the elimination of positions in sales, administrative and headquarters organizations, as well as research and development. The Company will also reduce its global real estate footprint and continue to improve the efficiency of its manufacturing and supply network. The Company will continue to hire employees in strategic growth areas of the business as necessary.

The Company recorded total pretax costs of \$1.2 billion in both 2014 and 2013 related to this restructuring program. Since inception of the 2013 Restructuring Program through December 31, 2014, Merck has recorded total pretax accumulated costs of approximately \$2.5 billion and eliminated approximately 6,095 positions comprised of employee separations, as well as the elimination of contractors and vacant positions. The actions under the 2013 Restructuring Program are expected to be substantially completed by the end of 2015 with the cumulative pretax costs estimated to be approximately \$3.0 billion. The Company estimates that approximately two-thirds of the cumulative pretax costs will result in 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.

## Merger Restructuring Program

In 2010, subsequent to the Merck and Schering-Plough Corporation (“Schering-Plough”) merger (the “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 reflect the elimination of positions in sales, administrative and headquarters organizations, as well as from the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities.

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 conjunction with the sale, the parties entered into a strategic long-term supply agreement whereby Aspen will supply API to the Company and approximately 960 employees who support the API business were transferred from Merck to Aspen. Also 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. The notes receivable consist of a \$261 million note with a present value of \$138 million due in 2023 and a \$67.5 million note with a present value of \$60 million that is payable over five years beginning on December 31, 2014. 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; therefore, at December 31, 2013, this amount was recorded as a receivable within Deferred income taxes and other current assets on the Consolidated Balance Sheet. In conjunction with this transaction, the Company transferred inventory of \$420 million, property, plant and equipment of \$220 million and cash of \$125 million to Aspen, reduced goodwill by \$45 million, other intangible assets by \$45 million and other assets by \$23 million and recorded \$90 million of transaction-related liabilities. This transaction resulted in a loss of \$65 million that was recorded within Restructuring costs in 2013.



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The Company recorded total pretax costs of \$730 million in 2014, \$1.1 billion in 2013 and \$951 million in 2012 related to this restructuring program. Since inception of the Merger Restructuring Program through December 31, 2014, Merck has recorded total pretax accumulated costs of approximately \$7.9 billion and eliminated approximately 28,410 positions comprised of employee separations, as well as the elimination of contractors and vacant positions. Approximately 3,440 position eliminations remain pending under this program as of December 31, 2014, which include the remaining actions under the 2008 Restructuring Program that are being reported as part of the Merger Restructuring Program as discussed below. The non-manufacturing related restructuring actions under the Merger Restructuring Program were substantially completed by the end of 2013. The remaining actions under this program primarily relate to ongoing manufacturing facility rationalizations, which are expected to be substantially completed by 2016. The Company expects the estimated total cumulative pretax costs for this program to be approximately \$8.5 billion. 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.

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 and \$48 million were recorded in 2013 and 2012, respectively, related to the 2008 Restructuring Program. Effective July 1, 2013, any remaining activities under the 2008 Restructuring Program are being accounted for as part of the Merger Restructuring Program. For segment reporting, restructuring charges are unallocated expenses.

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

Year Ended December 31, 2014	Separation Costs	Accelerated Depreciation	Other	Total
<b>2013 Restructuring Program</b>				
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
<b>Merger Restructuring Program</b>				
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
<b>Year Ended December 31, 2013</b>				
<b>2013 Restructuring Program</b>				
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
<b>Merger Restructuring Program</b>				
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
<b>2008 Restructuring Program</b>				
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
<b>Year Ended December 31, 2012</b>				
<b>Merger Restructuring Program</b>				
Materials and production	\$—	\$92	\$70	\$162
Marketing and administrative	—	75	6	81
Research and development	—	53	4	57
Restructuring costs	497	—	154	651
	497	220	234	951
<b>2008 Restructuring Program</b>				
Materials and production	—	7	19	26
Marketing and administrative	—	8	1	9
Restructuring costs	(8	) —	21	13
	(8	) 15	41	48
	\$489	\$235	\$275	\$999

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 4,555 in 2014 and 1,540 in 2013. Positions eliminated under the Merger Restructuring Program were approximately 1,530 in 2014, 4,475 in 2013 and 3,975 in 2012. 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

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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 2014, 2013 and 2012 includes \$240 million, \$259 million and \$155 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) gains resulting from sales of facilities and related assets of \$(133) million in 2014, \$(64) million in 2013 (primarily reflecting the loss on the transaction with Aspen discussed above) and \$28 million in 2012.

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
<b>2013 Restructuring Program</b>				
Restructuring reserves January 1, 2013	\$—	\$—	\$—	\$—
Expenses	866	334	41	1,241
(Payments) receipts, net	(121)	) —	9	(112)
Non-cash activity	—	(334)	) (27)	(361)
Restructuring reserves December 31, 2013	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 <sup>(1)</sup>	\$495	\$—	\$14	\$509
<b>Merger Restructuring Program</b>				
Restructuring reserves January 1, 2013	\$699	\$—	\$19	\$718
Expenses	481	241	384	1,106
(Payments) receipts, net	(517)	) —	(258)	(775)
Non-cash activity	62	(241)	) (133)	(312)
Restructuring reserves December 31, 2013	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 <sup>(1)</sup>	\$536	\$—	\$6	\$542

The cash outlays associated with the 2013 Restructuring Program are expected to be substantially completed by the end of 2015. The non-manufacturing cash outlays associated with the Merger Restructuring Program were substantially completed by the end of 2013; the remaining cash outlays are expected to be substantially completed by the end of 2016.

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

The Company continues its strategy of establishing external alliances to complement its substantial 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.

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In December 2014, Merck and Cubist Pharmaceuticals, Inc. (“Cubist”) announced a definitive agreement under which Merck would acquire Cubist for a total purchase price of approximately \$9.5 billion. Cubist is 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. This transaction closed on January 21, 2015; accordingly, the results of operations of the acquired business will be included in the Company’s results of operations beginning after that date.

Also 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. The determination of fair value requires management to make significant estimates and assumptions. 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 and liabilities of \$10 million. 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 upon 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 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%. 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 will be 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 the first and only drug treatment approved for patients with chronic thromboembolic pulmonary hypertension (“CTEPH”). Adempas is currently 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 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 currently marketed product 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

currently in clinical development and 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

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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 and reasonably estimable. 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 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 is a biopharmaceutical company engaged in the discovery and development of medicines for the treatment of human viral diseases, whose primary focus is 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. The determination of fair value requires management to make significant estimates and assumptions. Merck recognized an intangible asset for IPR&D of \$3.2 billion related to MK-3682 (formerly IDX21437), net deferred tax liabilities of \$856 million and other net assets and liabilities of approximately \$20 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 \$1.4 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, through which fair value is estimated based upon 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 11.5%. 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 ophthalmic products included in the agreement are Cosopt (dorzolamide hydrochloride-timolol maleate ophthalmic solution), Cosopt PF (dorzolamide hydrochloride-timolol maleate ophthalmic solution) 2%/0.5%, Trusopt (dorzolamide hydrochloride ophthalmic solution) sterile ophthalmic solution 2%, Trusopt PF (dorzolamide hydrochloride ophthalmic solution) preservative-free, Timoptic (timolol maleate ophthalmic solution), Timoptic PF (timolol maleate preservative free ophthalmic solution in unit dose dispenser), Timoptic XE (timolol maleate ophthalmic gel forming solution), Saflutan (tafluprost) and Taptiqom (tafluprost-timolol maleate ophthalmic solution, in development). The agreement provides that Santen make upfront payments 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. Upon closing of the transaction in most markets on July 1, 2014, the Company received \$515 million of upfront payments from Santen, net of certain adjustments, and an additional \$50 million upon closing of the remaining markets on October 1, 2014. Merck 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. Under the terms of the agreement, Merck received 85% of the Alnylam shares in the first quarter of 2014 (valued at \$172 million at the time of closing) and the remaining 15% of the shares in the second quarter

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of 2014 (valued at \$22 million at the time the shares were received). Merck recorded gains of \$204 million in 2014 related to this transaction that are included in Other (income) expense, net. 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 (asenapine), 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 has agreed to supply product to Forest (subsequently acquired by Actavis plc) until patent expiry.

In September 2013, Merck and AstraZeneca announced a worldwide out-licensing agreement for Merck's oral small molecule inhibitor of WEE1 kinase (MK-1775) being evaluated in clinical studies in combination with standard-of-care therapies for the treatment of patients with certain types of ovarian cancer. Under the terms of the agreement, AstraZeneca paid Merck a \$50 million upfront fee, which the Company recorded as revenue. In addition, Merck will be eligible to receive future payments tied to development and regulatory milestones, plus sales-related payments and tiered royalties. AstraZeneca will be responsible for all future clinical development, manufacturing and marketing.

In April 2013, Merck and Pfizer Inc. ("Pfizer") announced a worldwide (except Japan) collaboration agreement for the development and commercialization of Pfizer's ertugliflozin, an investigational oral sodium glucose cotransporter ("SGLT2") inhibitor being evaluated for the treatment of type 2 diabetes. The Company has initiated Phase 3 clinical trials for ertugliflozin with Pfizer. Under the terms of the agreement, Merck and Pfizer will collaborate on the clinical development and commercialization of ertugliflozin and ertugliflozin-containing fixed-dose combinations with metformin and with Januvia (sitagliptin) tablets. Merck will continue to retain the rights to its existing portfolio of sitagliptin-containing products. Through the end of 2013, Merck recorded research and development expenses of \$125 million for upfront and milestone payments made to Pfizer. Pfizer will be eligible for additional payments associated with the achievement of pre-specified future clinical, regulatory and commercial milestones. The companies will share potential revenues and certain costs 60% to Merck and 40% to Pfizer. Each party will have certain manufacturing and supply obligations. The Company and Pfizer each have the right to terminate the agreement due to a material, uncured breach by, or insolvency of, the other party, or in the event of a safety issue. Pfizer has the right to terminate the agreement upon 12 months notice at any time following the first anniversary of the first commercial sale of a collaboration product, but must assign all rights to ertugliflozin to Merck. Upon termination of the agreement, depending upon the circumstances, the parties have varying rights and obligations with respect to the continued development and commercialization of ertugliflozin and certain payment obligations.

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. During 2014, as a result of changes in cash flow assumptions for certain compounds, the Company recorded \$31 million of asset impairment charges related to IPR&D recorded in the Supera transaction. The changes in cash flow assumptions for these compounds, as well as for certain currently marketed products, also resulted in the write-off of the goodwill balance related to the joint venture with Supera, which was \$93 million at existing exchange rates. The Company had previously recorded \$15 million of impairment charges in the fourth quarter of 2013 related to the IPR&D recorded in the Supera transaction as a result of changes in cash flow assumptions for certain compounds.

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

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for license rights to develop and commercialize Simponi, a fully human monoclonal antibody. The Company has exclusive marketing rights to both products throughout Europe, Russia and Turkey. In December 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. On October 6, 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 (the "EU") following the receipt of pricing and reimbursement approval within the EU. Remicade lost market exclusivity in major European markets in February 2015. All profits derived from Merck's exclusive distribution of the two products 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 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 premium 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

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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 foreign currency denominated net monetary assets of foreign subsidiaries where the U.S. dollar is the 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 \$294 million in 2014 and pretax losses of \$84 million in 2013 and \$31 million in 2012 from the euro-denominated notes.



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## 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, 2014, the Company was a party to 17 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	2014		
	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
3.875% notes due 2021	1,150	5	1,150
2.40% notes due 2022	1,000	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 are recorded in interest expense and offset by the fair value changes in the swap contracts.

During 2014, the Company terminated interest rate swap contracts that effectively converted the Company’s 6.00% fixed-rate notes due in 2017 to floating-rate instruments. The interest rate swap contracts were designated hedges of the fair value changes in the notes attributable to changes in the benchmark LIBOR swap rate. As a result of the swap terminations, the Company received \$3 million in cash. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

In February 2015, in connection with the Company’s February debt offering (see Note 9), Merck entered into ten additional interest rate swap contracts with notional amounts of \$250 million each that effectively convert the Company’s 1.85% notes due in 2020 and the Company’s 2.35% notes due in 2022 to floating-rate instruments.



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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:

	Balance Sheet Caption	2014		U.S. Dollar Notional	2013		U.S. Dollar Notional
		Fair Value of Derivative Asset	Liability		Fair Value of Derivative Asset	Liability	
<b>Derivatives Designated as Hedging Instruments</b>							
Interest rate swap contracts (non-current)	Other assets	\$19	\$—	\$1,950	\$13	\$—	\$1,550
Interest rate swap contracts (non-current)	Other noncurrent liabilities	—	15	2,000	—	25	2,000
Foreign exchange contracts (current)	Deferred income taxes and other current assets	772	—	5,513	493	—	4,427
Foreign exchange contracts (non-current)	Other assets	691	—	6,253	515	—	6,676
Foreign exchange contracts (current)	Accrued and other current liabilities	—	—	—	—	19	1,659
		\$1,482	\$15	\$15,716	\$1,021	\$44	\$16,312
<b>Derivatives Not Designated as Hedging Instruments</b>							
Foreign exchange contracts (current)	Deferred income taxes and other current assets	\$365	\$—	\$6,966	\$69	\$—	\$5,705
Foreign exchange contracts (current)	Accrued and other current liabilities	—	88	3,386	—	140	7,892
		\$365	\$88	\$10,352	\$69	\$140	\$13,597
		\$1,847	\$103	\$26,068	\$1,090	\$184	\$29,909

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:

	2014		2013	
	Asset	Liability	Asset	Liability
Gross amounts recognized in the consolidated balance sheet	\$1,847	\$103	\$1,090	\$184
Gross amount subject to offset in master netting arrangements not offset in the consolidated balance sheet	(97 )	(97 )	(147 )	(147 )
Cash collateral (received) posted	(1,410 )	—	(652 )	—
Net amounts	\$340	\$6	\$291	\$37

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

Years Ended December 31	2014	2013	2012
Derivatives designated in a fair value hedging relationship			
Interest rate swap contracts			
Amount of (gain) loss recognized in Other (income) expense, net on derivatives <sup>(1)</sup>	\$(17 )	\$12	\$—
Amount of loss (gain) recognized in Other (income) expense, net on hedged item <sup>(1)</sup>	14	(14 )	—
Derivatives designated in foreign currency cash flow hedging relationships			
Foreign exchange contracts			
Amount of (gain) loss reclassified from AOCI to Sales	(143 )	45	50
Amount of (gain) loss recognized in OCI on derivatives	(775 )	(306 )	204
Derivatives designated in foreign currency net investment hedging relationships			
Foreign exchange contracts			
Amount of gain recognized in Other (income) expense, net on derivatives <sup>(2)</sup>	(6 )	(10 )	(20 )
Amount of gain recognized in OCI on derivatives	(192 )	(363 )	(208 )
Derivatives not designated in a hedging relationship			
Foreign exchange contracts			
Amount of (gain) loss recognized in Other (income) expense, net on derivatives <sup>(3)</sup>	(516 )	183	382
Amount of loss recognized in Sales	15	8	30

<sup>(1)</sup> There was \$3 million and \$2 million of ineffectiveness on the hedge during 2014 and 2013, respectively.

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

<sup>(3)</sup> These derivative contracts mitigate changes in the value of remeasured foreign currency denominated monetary assets and liabilities attributable to changes in foreign currency exchange rates.

At December 31, 2014, the Company estimates \$457 million of pretax net unrealized gains on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from AOCI to Sales. The amount ultimately reclassified to Sales may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.

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## Investments in Debt and Equity Securities

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

	2014				2013			
	Fair Value	Amortized Cost	Gross Gains	Unrealized Losses	Fair Value	Amortized Cost	Gross Gains	Unrealized Losses
Corporate notes and bonds	\$10,107	\$10,102	\$22	\$(17 )	\$7,054	\$7,037	\$32	\$(15 )
Commercial paper	6,970	6,970	—	—	1,206	1,206	—	—
U.S. government and agency securities	1,774	1,775	1	(2 )	1,236	1,239	1	(4 )
Asset-backed securities	1,460	1,462	1	(3 )	1,300	1,303	1	(4 )
Mortgage-backed securities	602	604	2	(4 )	476	479	2	(5 )
Foreign government bonds	385	385	—	—	125	126	—	(1 )
Equity securities	730	557	173	—	471	397	74	—
	\$22,028	\$21,855	\$199	\$(26 )	\$11,868	\$11,787	\$110	\$(29 )

Available-for-sale debt securities included in Short-term investments totaled \$8.3 billion at December 31, 2014. Of the remaining debt securities, \$12.0 billion mature within five years. At December 31, 2014 and 2013, there were no debt securities pledged as collateral.

## Fair Value Measurements

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

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

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

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

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

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

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

	Fair Value Measurements Using				Fair Value Measurements Using			
	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
	2014				2013			
Assets								
Investments								
Corporate notes and bonds	\$—	\$ 10,107	\$ —	\$ 10,107	\$—	\$ 7,054	\$ —	\$ 7,054
Commercial paper	—	6,970	—	6,970	—	1,206	—	1,206
U.S. government and agency securities	—	1,774	—	1,774	—	1,236	—	1,236
Asset-backed securities <sup>(1)</sup>	—	1,460	—	1,460	—	1,300	—	1,300
Mortgage-backed securities <sup>(1)</sup>	—	602	—	602	—	476	—	476
Foreign government bonds	—	385	—	385	—	125	—	125
Equity securities	495	—	—	495	238	—	—	238
	495	21,298	—	21,793	238	11,397	—	11,635
Other assets								
Securities held for employee compensation	181	54	—	235	186	47	—	233
Derivative assets <sup>(2)</sup>								
Purchased currency options	—	1,252	—	1,252	—	868	—	868
Forward exchange contracts	—	576	—	576	—	209	—	209
Interest rate swaps	—	19	—	19	—	13	—	13
	—	1,847	—	1,847	—	1,090	—	1,090
Total assets	\$ 676	\$ 23,199	\$ —	\$ 23,875	\$ 424	\$ 12,534	\$ —	\$ 12,958
Liabilities								
Other liabilities								
Contingent consideration	\$—	\$ —	\$ 428	\$ 428	\$—	\$ —	\$ 69	\$ 69
Derivative liabilities <sup>(2)</sup>								
Forward exchange contracts	—	46	—	46	—	134	—	134
Written currency options	—	42	—	42	—	25	—	25
Interest rate swaps	—	15	—	15	—	25	—	25
	—	103	—	103	—	184	—	184
Total liabilities	\$—	\$ 103	\$ 428	\$ 531	\$—	\$ 184	\$ 69	\$ 253

- 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.
- (1)
  - (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 2014. As of December 31, 2014, Cash and cash equivalents of \$7.4 billion included \$6.1 billion of cash equivalents (considered Level 2 in the fair value hierarchy).

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## Contingent Consideration

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

	2014	2013
Fair value January 1	\$69	\$49
Changes in fair value (recorded in Research and development expenses)	316	8
Additions	43	12
Fair value December 31	\$428	\$69

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, 2014, was \$22.5 billion compared with a carrying value of \$21.4 billion and at December 31, 2013, was \$25.5 billion compared with a carrying value of \$25.1 billion. Fair value was estimated using recent observable market prices and would be considered Level 2 in the fair value hierarchy.

## Concentrations of Credit Risk

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

The majority of the Company's accounts receivable arise from product sales in the United States 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. The Company continues to monitor the credit and economic conditions within Greece, Italy, Spain and Portugal, among other members of the EU. These economic conditions, as well as inherent variability of timing of cash receipts, have resulted in, and may continue to result in, an increase in the average length of time that it takes to collect accounts receivable outstanding. As such, time value of money discounts have been recorded for those customers for which collection of accounts receivable is expected to be in excess of one year. At December 31, 2014 and 2013, Other assets included \$80 million and \$275 million, respectively, of accounts receivable not expected to be collected within one year. 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.

As of December 31, 2014, the Company's accounts receivable in Greece, Italy, Spain and Portugal totaled approximately \$600 million. Of this amount, hospital and public sector receivables were approximately \$330 million in the aggregate, of which approximately 14%, 27%, 46% and 13% related to Greece, Italy, Spain and Portugal, respectively. As of December 31, 2014, the Company's total net accounts receivable outstanding for more than one year were approximately \$100 million, of which approximately 31% related to accounts receivable in Greece, Italy, Spain and Portugal, mostly comprised of hospital and public sector receivables.



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During 2014, the Company completed non-recourse factorings in Spain of approximately \$100 million and in Italy of approximately \$100 million of hospital and public sector receivables. During 2013, the Company completed non-recourse factorings of approximately \$210 million of hospital and public sector receivables in Spain. During 2012, the Company collected approximately \$500 million of accounts receivable in connection with the Spanish government's debt stabilization/stimulus plan. In addition, the Company completed non-recourse factorings of approximately \$230 million in 2012 of hospital and public sector accounts receivable in Italy.

Additionally, the Company continues to expand in the emerging markets. Payment terms in these markets tend to be longer, resulting in an increase in accounts receivable balances in certain of these markets.

The Company's customers with the largest accounts receivable balances are: AmerisourceBergen Corporation, Cardinal Health, Inc., McKesson Corporation, AAH Pharmaceuticals Ltd (U.K.) and Zuellig Pharma Ltd. (Asia Pacific), which represented, in aggregate, approximately 30% of total accounts receivable at December 31, 2014. 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, 2014 and 2013, the Company had received cash collateral of \$1.4 billion and \$652 million, respectively, from various counterparties and the obligation to return such collateral is recorded in Accrued and other current liabilities. The Company had not advanced any cash collateral to counterparties as of December 31, 2014 or 2013.

## 6. Inventories

Inventories at December 31 consisted of:

	2014	2013
Finished goods	\$1,588	\$1,738
Raw materials and work in process	5,141	5,894
Supplies	197	225
Total (approximates current cost)	6,926	7,857
Increase to LIFO costs	309	73
	\$7,235	\$7,930
Recognized as:		
Inventories	\$5,571	\$6,226
Other assets	1,664	1,704

Inventories valued under the LIFO method comprised approximately \$2.6 billion and \$2.3 billion of inventories at December 31, 2014 and 2013, respectively. Amounts recognized as Other assets are comprised almost entirely of raw materials and work in process inventories. At December 31, 2014 and 2013, these amounts included \$1.6 billion and \$1.5 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included \$74 million and \$177 million at December 31, 2014 and 2013, respectively, of inventories produced in preparation for product launches.



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## 7. Goodwill and Other Intangibles

The following table summarizes goodwill activity by segment:

	Pharmaceutical	All Other	Total	
Balance January 1, 2013	\$10,086	\$2,048	\$12,134	
Acquisitions	103	188	291	
Divestitures	(45	) —	(45	)
Other <sup>(1)</sup>	(79	) —	(79	)
Balance December 31, 2013	10,065	2,236	12,301	
Acquisitions	1,369	38	1,407	
Divestitures	(200	) (362	) (562	)
Impairments	(93	) —	(93	)
Other <sup>(1)</sup>	(33	) (28	) (61	)
Balance December 31, 2014 <sup>(2)</sup>	\$11,108	\$1,884	\$12,992	

<sup>(1)</sup> Other includes cumulative translation adjustments on goodwill balances and certain other adjustments.

<sup>(2)</sup> Accumulated goodwill impairment losses at December 31, 2014 were \$93 million.

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 (see Note 4).

The Company performed its most recent annual impairment test as of October 1, 2014 and concluded that goodwill was not impaired.

The additions to Pharmaceutical segment goodwill in 2013 resulted from the formation of the Supera joint venture (see Note 4) and the reductions resulted from the divestiture of the Company's API manufacturing business and related branded products (see Note 3).

In July 2013, the Company acquired the remaining shares of Physicians Interactive, a provider of on-line and mobile clinical resources and solutions for health care professionals in which Merck had an existing 24% ownership interest, for \$97 million. In November 2013, Merck acquired Health Management Resources Corporation, a leader in medical weight management, for \$87 million. These transactions collectively resulted in the addition of approximately \$175 million of goodwill during 2013 included in other segments. Pro forma financial information has not been included for these transactions because the historical financial results are not significant when compared with the Company's financial results.

Other intangibles at December 31 consisted of:

	2014			2013		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Products and product rights	\$38,714	\$23,830	\$14,884	\$41,691	\$21,216	\$20,475
In-process research and development	4,345	—	4,345	1,856	—	1,856
Tradenames	198	71	127	1,632	310	1,322
Other	1,527	497	1,030	958	810	148
	\$44,784	\$24,398	\$20,386	\$46,137	\$22,336	\$23,801

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. Some of the Company's more significant acquired intangibles related to marketed products (included in product and product rights above) at December 31, 2014 include Zetia, \$3.6 billion; Vytorin, \$2.1 billion; Nasonex,



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\$719 million; NuvaRing, \$684 million; and Implanon/Nexplanon \$703 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 \$858 million at December 31, 2014 reflected in other in the table above. Also, during 2014, \$2.2 billion of other intangible assets were divested in connection with the sale of MCC (see Note 4). During 2014 and 2013, the Company recorded impairment charges related to marketed products of \$1.1 billion and \$486 million, respectively, within Material and production costs. 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. During 2014, sales of these products were adversely affected by loss of market share or patient treatment delays in markets anticipating the availability of new 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 amount 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. During 2014, the Company recorded IPR&D of \$3.2 billion related to the acquisition of Idenix (see Note 4). 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 2014, 2013 and 2012, \$654 million, \$346 million and \$78 million, respectively, of IPR&D was reclassified to products and product rights upon receipt of marketing approval in a major market.

During 2014, the Company recorded \$49 million of IPR&D impairment charges within Research and development expenses 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. During 2012, the Company recorded \$200 million of IPR&D impairment charges primarily for pipeline programs that had previously been deprioritized and were subsequently deemed to have no alternative use during 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 \$4.2 billion in 2014, \$4.8 billion in 2013 and \$5.0 billion in 2012. The estimated aggregate amortization expense for each of the

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next five years is as follows: 2015, \$3.9 billion; 2016, \$3.2 billion; 2017, \$2.9 billion; 2018, \$1.4 billion; 2019, \$638 million.

#### 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 and was comprised of the following:

Years Ended December 31	2014	2013	2012
AstraZeneca LP <sup>(1)</sup>	\$192	\$352	\$621
Other <sup>(2)</sup>	65	52	21
	\$257	\$404	\$642

<sup>(1)</sup> As noted below, as of July 1, 2014, the Company no longer records equity income from AZLP.

<sup>(2)</sup> Includes results from Sanofi Pasteur MSD.

#### 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, \$920 million and \$915 million in 2014, 2013 and 2012, respectively, primarily relating to sales of Nexium, as well as Prilosec. In addition, Merck earned certain Partnership returns, which were recorded in Equity income from affiliates, as reflected in the table above. Such returns included a priority return provided for in the Partnership Agreement, a preferential return representing Merck's share of undistributed AZLP GAAP earnings, and a variable return related to the Company's 1% limited partner interest.

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 2014, \$140 million of the deferred revenue was recognized in Other (income) expense, net. 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.

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Summarized financial information for AZLP is as follows:

Years Ended December 31	2014 <sup>(1)</sup>	2013	2012
Sales	\$2,205	\$4,611	\$4,694
Materials and production costs	1,044	2,222	2,177
Other expense, net	604	1,175	1,312
Income before taxes <sup>(2)</sup>	557	1,214	1,205
December 31			2013
Current assets			\$4,832
Noncurrent assets			182
Current liabilities			3,958

<sup>(1)</sup> Includes results through the June 30, 2014 termination date.

<sup>(2)</sup> 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 \$1.1 billion for 2014, \$1.2 billion for 2013 and \$1.1 billion for 2012.

Investments in affiliates accounted for using the equity method, including the above joint ventures, totaled \$337 million at December 31, 2014 and \$1.6 billion at December 31, 2013. These amounts are reported in Other assets. Amounts due from the above joint ventures included in Deferred income taxes and other current assets were \$45 million at December 31, 2014 and \$277 million at December 31, 2013.

Summarized information for those affiliates (excluding AZLP disclosed separately above) is as follows:

Years Ended December 31	2014	2013	2012
Sales	\$1,370	\$1,326	\$1,295
Materials and production costs	577	581	573
Other expense, net	641	691	705
Income before taxes	152	54	17
December 31		2014	2013
Current assets		\$1,819	\$1,486
Noncurrent assets		208	149
Current liabilities		469	456
Noncurrent liabilities		129	154

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

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 holder. Loans payable at December 31, 2013 included \$2.1 billion of notes due in 2014, \$1.6 billion of commercial paper, \$402 million of short-term foreign borrowings and \$370 million of long-dated notes that are subject to repayment at the option of the holders. The weighted-average interest rate of the commercial paper borrowings was 0.15% and 0.09% at December 31, 2014 and 2013, respectively.

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Long-term debt at December 31 consisted of:

	2014	2013
2.80% notes due 2023	\$1,749	\$1,749
5.00% notes due 2019	1,291	1,293
4.15% notes due 2043	1,246	1,246
1.125% euro-denominated notes due 2021	1,218	—
1.875% euro-denominated notes due 2026	1,210	—
3.875% notes due 2021	1,150	1,148
2.40% notes due 2022	1,000	1,000
Floating-rate borrowing due 2018	1,000	1,000
1.10% notes due 2018	999	998
0.70% notes due 2016	998	997
1.30% notes due 2018	984	975
2.25% notes due 2016	858	866
6.50% notes due 2033	812	1,306
2.50% euro-denominated notes due 2034	603	—
6.55% notes due 2037	597	1,143
Floating-rate borrowing due 2016	500	500
3.60% notes due 2042	493	492
5.85% notes due 2039	418	749
5.75% notes due 2036	371	498
5.95% debentures due 2028	356	498
6.40% debentures due 2028	326	499
6.30% debentures due 2026	152	249
6.00% notes due 2017	—	1,095
4.00% notes due 2015	—	1,029
4.75% notes due 2015	—	1,023
Other	368	186
	\$18,699	\$20,539

Other (as presented in the table above) included \$309 million and \$119 million at December 31, 2014 and 2013, respectively, of borrowings at variable rates averaging 0.0% for 2014 and 2013. Other also included foreign borrowings of \$53 million and \$64 million at December 31, 2014 and 2013, respectively, at varying rates up to 6.25% and 4.50%, respectively.