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)

ý	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		
o	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 ý No o
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 o No ý
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 ý No o
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 ý No o
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. o
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting

company" in Rule 12b-2 of the Exchange Act. (Check One):

Large accelerated filer ý Accelerated filer o Non-accelerated filer o Smaller reporting company o
(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 o No ý

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[1]	1,547	1,894	1,952
Other Revenues[2]	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.

(2) 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

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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.)[1]
Integrilin[2]	2015 (use/formulation)
Emend	2015
Follistim AQ	2015
Invanz	2016 (compound)/2017 (composition)
Cubicin[3]	2016 (composition)
Zostavax	2016 (use)
Dulera	2017 (formulation)/2020 (combination)
Zetia[4]/Vytorin	2017
Asmanex	2018 (formulation)
Nasonex[5]	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

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

(2) 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 ß-amyloid precursor protein site-cleaving enzyme ("BACE") inhibitor for the treatment of Alzheimer's disease being studied in a Phase 3 trial (APECS) designed to evaluate the safety and efficacy of MK-8931 versus placebo in patients with amnestic mild cognitive impairment due to Alzheimer's disease, also known as prodromal Alzheimer's disease. MK-8931 is also being studied in another Phase 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
Alzheimer's Disease
MK-7622
Asthma
MK-1029
Bacterial Infection
MK-7655 (relebactam)
Cancer
MK-2206
MK-8628
Contraception, Medicated IUS
MK-8342
Contraception, Next Generation Ring
MK-8342B
Ebola Vaccine
V920
Gastric Cancer
MK-3475 Keytruda
Heart Failure
MK-1242 (vericiguat)[1]
Hepatitis C
MK-3682/MK-8742 (elbasvir)/ MK-5172 (grazoprevir)
MK-3682/MK-8408/MK-5172 (grazoprevir)
Pneumoconjugate Vaccine
V114

Phase 3 (Phase 3 entry date)
Allergy
MK-8237, House Dust Mite (March 2014)[1,2]
Alzheimer's Disease
MK-8931 (December 2013)
Atherosclerosis
MK-0859 (anacetrapib) (May 2008)
Bladder Cancer
MK-3475 Keytruda (October 2014)
Clostridium difficile Infection
MK-3415A (actoxumab/bezlotoxumab) (November 2011)
MK-4261 (surotomycin) (July 2012)
CMV Prophylaxis in Transplant Patients
MK-8228 (letermovir) (June 2014)
Diabetes Mellitus
MK-3102 (omarigliptin) (September 2012)
MK-8835 (ertugliflozin) (November 2013)[1]
MK-1293 (February 2014)[1]
Head and Neck Cancer
MK-3475 Keytruda (November 2014)
Hepatitis C
MK-5172A (grazoprevir/elbasvir) (June 2014)
Herpes Zoster
V212 (inactivated VZV vaccine) (December 2010)
HIV
MK-1439 (doravirine) (December 2014)
Non-Small-Cell Lung Cancer

Under Review
Acute Bacterial Skin & Skin Structure Infections (ABSSSI)
MK-1986 Sivextro (EU)
Complicated Intra-Abdominal Infections (cIAI) & Complicated Urinary Tract Infections (cUTI)
MK-7625A Zerbaxa (EU)
Diabetes Mellitus
MK-3102 (omarigliptin) (Japan)
Fertility
MK-8962 (corifollitropin alfa injection) (U.S.)[3]
HPV-Related Cancers
V503 Gardasil 9 (EU)
Melanoma
MK-3475 Keytruda (EU)
Neuromuscular Blockade Reversal
MK-8616 Bridion (U.S.)[4]
Pediatric Hexavalent Combination Vaccine
V419 (U.S./EU)[5]

Footnotes:
[1] Being developed in a collaboration.
[2] North American rights only.
[3] 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.
[4] In September 2013, Merck received a CRL from the FDA for the resubmission

MK-3475 Keytruda (September 2014)	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.
Opioid-Induced Constipation	
MK-2402 (bevenopran) (October 2012)	
Osteoporosis	
MK-0822 (odanacatib) (September 2007)	(5) 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. The Company will make available, free of charge at the "Investors" portion of its website, its Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after such reports are electronically filed with, or furnished to, the U.S. Securities and Exchange Commission (the "SEC").

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

Item 1A. Risk Factors.

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

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

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

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

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

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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	