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

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

FORM 10-K
(MARK ONE)

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

Commission File No. 1-6571

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

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

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

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

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

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

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

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

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

Documents Incorporated by Reference:

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

Table of Contents

Table of Contents

Table of Contents

PART I

Item 1. Business.

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

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

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

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

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

The Company was incorporated in New Jersey in 1970.

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

Product Sales

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

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

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

Table of Contents

Pharmaceutical

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

Oncology

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

Vaccines

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

Hospital Acute Care

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

Immunology

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

Neuroscience

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

Virology

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

2

Table of Contents

Cardiovascular

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

Diabetes

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

Women's Health

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

Animal Health

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

Livestock Products

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

Companion Animal Products

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

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

Table of Contents

2018 Product Approvals

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

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

4

Table of Contents

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

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

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

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

Competition and the Health Care Environment

Competition

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

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

Table of Contents

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

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

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

Health Care Environment and Government Regulation

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

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

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

Table of Contents

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

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

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

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

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

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

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

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

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

7

Table of Contents

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

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

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

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

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

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

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

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

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

8

Table of Contents

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

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

Access to Medicines

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

Privacy and Data Protection

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

Distribution

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

Raw Materials

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

Table of Contents

Patents, Trademarks and Licenses

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

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

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

Table of Contents

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

N/A: Currently no marketing approval.

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

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

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

(2) Eligible for 6 months Pediatric Exclusivity.

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

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

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

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

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

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

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

Research and Development

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

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

12

Table of Contents

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

Research and Development Update

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

14

Table of Contents

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

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

years of age.

Table of Contents

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

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

Phase 2

Cancer

MK-3475 Keytruda

Advanced Solid Tumors

Cutaneous Squamous Cell Carcinoma

Prostate

MK-7902 Lenvima[1]

Biliary Tract

Non-Small-Cell Lung

V937 Cavatak

Melanoma

MK-7690

Colorectal[2]

MK-7339 Lynparza[1]

Advanced Solid Tumors

Cytomegalovirus Vaccine

V160

Diabetes Mellitus

MK-8521[3]

HIV-1 Infection

MK-8591

Pediatric Neurofibromatosis Type-1

MK-5618 (selumetinib)[1]

Respiratory Syncytial Virus

MK-1654

Schizophrenia

MK-8189

Phase 3 (Phase 3 Entry Date)

Cancer

MK-3475 Keytruda

Breast (October 2015)

Cervical (October 2018) (EU)

Colorectal (November 2015)

Esophageal (December 2015)

Gastric (May 2015) (EU)

Hepatocellular (May 2016) (EU)

Mesothelioma (May 2018)

Nasopharyngeal (April 2016)

Ovarian (December 2018)

Renal (October 2016) (EU)

Small-Cell Lung (May 2017) (EU)

MK-7902 Lenvima[1,2]

Endometrial (June 2018)

MK-7339 Lynparza[1]

Pancreatic (December 2014)

Prostate (April 2017)

Cough

MK-7264 (gefapixant) (March 2018)

Heart Failure

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

Pneumoconjugate Vaccine

V114 (June 2018)

Under Review

New Molecular Entities/Vaccines

Bacterial Infection

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

Ebola Vaccine

V920[4] (U.S.)

Certain Supplemental Filings

Cancer

MK-3475 Keytruda

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

MK-7339 Lynparza[1]

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

HABP/VABP[5]

MK-7625A Zerbaxa (U.S.)

Footnotes:

(1) Being developed in a collaboration.

(2) Being developed in combination with

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

Employees

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

Restructuring Activities

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

Table of Contents

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

Environmental Matters

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

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

Geographic Area Information

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

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

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

Available Information

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

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

Table of Contents

Item 1A. Risk Factors.

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

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

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

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

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

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

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

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

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

20

Table of Contents

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

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

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

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

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

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

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

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

21

Table of Contents

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

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

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

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

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

The Company faces intense competition from lower cost generic products.

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

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

The Company faces intense competition from competitors' products.

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

Table of Contents

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

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

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

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

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

The Company expects pricing pressures to continue in the future.

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

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

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

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

24

Table of Contents

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

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

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

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

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

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

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

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

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

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

25

Table of Contents

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

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

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

Pharmaceutical products can develop unexpected safety or efficacy concerns.

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

Social media platforms present risks and challenges.

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

Table of Contents

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

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

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

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

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

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

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

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

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

Item 3. Legal Proceedings.

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

Item 4. Mine Safety Disclosures.

Not Applicable.

Table of Contents

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

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

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

Table of Contents

PART II

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

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

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

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

Issuer Purchases of Equity Securities

Period	Total Number of Shares Purchased[1]	Average Price Paid Per Share	($ in millions) Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs[1]
October 1 — October 31	59,154,075	$70.56	$12,709[2]
November 1 — November 30	5,279,715	$74.64	$12,315
December 1 — December 31	4,788,526	$76.30	$11,949
Total	69,222,316	$71.27	$11,949

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

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

Table of Contents

Performance Graph

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

Comparison of Five-Year Cumulative Total Return*

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

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

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

*Compound Annual Growth Rate

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

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

Table of Contents

Item 6. Selected Financial Data.

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

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

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

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

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

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

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

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

favorable benefit of certain tax items.

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

Table of Contents

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

Description of Merck's Business

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

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

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

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

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

Overview

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

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

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

36

Table of Contents

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

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

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

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

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

Table of Contents

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

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

Pricing

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

Cyber-attack

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

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

Operating Results

Sales

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

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

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

38

Table of Contents

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

Pharmaceutical Segment

Oncology

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

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

Table of Contents

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

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

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

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

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

Also in December 2018, the EC approved Keytruda for the adjuvant treatment of adults with stage III melanoma and lymph node involvement who have undergone complete resection. Keytruda